



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 412 and 413

[CMS-1752-FC3]

RIN 0938-AU44

### Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; Changes to Medicare Graduate Medical Education Payments for Teaching Hospitals; Changes to Organ Acquisition Payment Policies

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule with comment period.

**SUMMARY:** This final rule with comment period finalizes certain provisions of the fiscal year 2022 IPPS/LTCH PPS proposed rule. These provisions implement policies based on legislative changes relative to Medicare graduate medical education (GME) for teaching hospitals provided by sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA), 2021; and changes, clarifications, and codifications for Medicare organ acquisition payment policies relative to organ procurement organizations (OPOs), transplant hospitals, and donor community hospitals. In addition, this final rule with comment period solicits comments on certain GME issues to inform potential future rulemaking

**DATES:** *Effective date:* This final rule with comment period is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

*Comment date:* To be assured consideration, comments on the graduate medical education provisions discussed in sections II.B.3.b.(5), II.B.3.d.(2). and II.B.5.e. of this final rule with comment period must be received at one of the addresses provided below, by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** In commenting, please refer to file code CMS-1752-FC3.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-1752-FC3,  
P.O. Box 8013,  
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-1752-FC3,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

## **FOR FURTHER INFORMATION, CONTACT:**

Donald Thompson, (410) 786-4487, and Michele Hudson, (410) 786-4487, Graduate Medical Education Issues.

Katie Lucas, (410) 786-7723, Amanda Michael, (410) 786-5834, and Kellie Shannon (410) 786-0416, Organ Acquisition Payment Issues.

## **SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

### **I. Executive Summary and Background**

#### A. Executive Summary

##### 1. Purpose and Legal Authority

Under various statutory authorities, we either discuss continued program implementation or are making changes to the Medicare IPPS, other related payment methodologies and programs and other policies and provisions included in this rule. The purpose of and the statutory authority(ies) for these changes include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A

(Hospital Insurance) based on prospectively set rates, including indirect medical education (IME) payments under section 1886(d)(5)(B) of the Act.

- The Consolidated Appropriations Act of 2021 relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs. Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.

- Organ acquisition costs are reimbursed to transplant hospitals and kidney acquisition costs are reimbursed to organ procurement organizations under reasonable cost principles under section 1861(v) of the Act. Under 42 USC 273(b), organ procurement organizations must have an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the cost to procure kidneys.

## 2. Summary of the Provisions

The following is a summary of the provisions in this final rule with comment period.

### a. Implementation of Sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA) of 2021

We are finalizing provisions to implement sections 126, 127, and 131 of the CAA. Section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) of the Act requiring the distribution of additional residency positions to qualifying hospitals. Section 127 of the CAA amended section 1886(h)(4)(H)(iv) of the Act to specify that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural track) in a rural area, the hospital, and each such hospital located in a rural area that participates in such a training, is allowed to receive an adjustment to its full-time equivalent (FTE) resident limit. Section 131 of the CAA amended section 1886(h)(2)(F) of the Act to provide an opportunity to hospitals with such extremely low or \$0

per resident amounts (PRAs) that meet certain criteria to reset and establish new PRAs if the hospital trains resident(s) in a cost reporting period beginning on or after enactment (December 27, 2020) and before the date that is 5 years after enactment (December 26, 2025). Section 131 of the CAA also amended section 1886(h)(4)(H)(i) of the Act to provide an opportunity for hospitals that meet certain criteria and that have very small FTE resident caps to replace those caps if the Secretary determines the hospital begins training residents in a new program beginning on or after enactment (December 27, 2020) and before 5 years after enactment (December 26, 2025).

In addition, this final rule with comment period solicits comments on certain issues to inform potential future rulemaking. Specifically, for the implementation of section 126 of the CAA regarding distribution of residency slots, we seek comment on using a measure of health care provided outside of a Health Professional Shortage Area (HPSA) to HPSA residents (as discussed in section II.B.3.b.(5) of the preamble of this final rule with comment period). For purposes of prioritizing hospitals awarded residency positions under section 126, we seek comment on feasible alternatives to HPSA scores as a proxy for health disparities (as discussed in section II.B.3.d.(2) of the preamble of this final rule). In addition, for the implementation of section 131, we seek comment on the review process to determine eligibility for per resident amount or full-time equivalent cap resets in situations where a hospital disagrees with the information on the cost report, in particular from cost reports that are no longer within the 3-year reopening period (as discussed in section II.B.5.e. of the preamble of this final rule).

We refer readers to section II.B.2. of this final rule with comment period for a summary of the provisions of sections 126, 127, and 131 of the CAA that we are implementing in this final rule with comment period.

#### b. Changes to Organ Acquisition Payment Policy

We proposed changes pertaining to Medicare's share of organ acquisition costs transplanted into Medicare beneficiaries. We also proposed changes to longstanding Medicare

organ acquisition payment policies and changes pertaining to charges for services provided to cadaveric organ donors by donor community hospitals. After considering the numerous public comments received, at this time, we are not finalizing our proposal with respect to the organ counting policy for Medicare's organ acquisition payment purposes and the research organ counting policy. We are finalizing other longstanding Medicare organ acquisition payment policies with some modifications. We are also finalizing rules with respect to Medicare-certified non-transplant hospitals and transplant hospitals' charges for hospital services provided to cadaveric donors, effective for cost reporting periods beginning on or after the effective date of this final rule with comment period.

### 3. Summary of Costs, Savings, Benefits, and Transfers

The following table provides a summary of the costs, savings, benefits associated with the provisions described in section

I.A.2. of this final rule.

<b>Provision Description</b>	<b>Description of Costs, Transfers, Savings, and Benefits</b>
Implementation of Sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA) of 2021	Section 1886(h) of the Act, as amended by sections 126, 127, and 131 of the CAA, provides for the distribution of additional residency positions (section 126), promotes a rural hospital GME funding opportunity (section 127), and requires resetting PRAs and FTE resident caps for certain hospitals after hosting medical resident rotators for short durations (section 131). We refer readers to section II.B. of this final rule with comment period for a summary of the provisions of sections 126, 127 and 131 that we are implementing in this final rule. We estimate that our implementation of section 126 of the CAA will result in an estimated cost of approximately \$1.830 billion from FY 2023 through FY 2031. We estimate that our implementation of section 127 of the CAA will result in an estimated cost of approximately \$0.130 billion from FY 2024 through FY 2031. We estimate our implementation of section 131 of the CAA will result in an estimated cost of approximately \$1.380 billion from FY 2022 through FY 2031.
Changes to Organ Acquisition Payment Policy	We refer readers to sections II.C.2.a. through g. and i through m. and II.C.3. of this final rule with comment period for a summary of organ acquisition payment policies we are implementing in this final rule. These final policies are not expected to have an impact on expenditures. However, the provisions in sections II.C.2.b.,e. and l. of this final rule with comment period to the extent that any of these provisions may have an impact on expenditures, that impact is not estimable without the availability of the appropriate cost information to calculate such impact.

## B. Background

### 1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these “subsection (d) hospitals.” Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M. The existing regulations governing the IME adjustment are located in §412.105.

### 2. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital’s number of residents in that period and the hospital’s costs per



resident in a base year. The existing regulations governing direct GME payments to the various types of hospitals are located in 42 CFR part 413.

### 3. Issuance of Proposed Rulemaking

In the FY 2022 IPPS/LTCH PPS proposed rule appearing in the May 10, 2021 **Federal Register** (86 FR 25070), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2022 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2022.

The following is a general summary of the changes that we proposed to make related to the provisions addressed in this final rule with comment period.

In section V. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we discussed proposed changes to certain provisions of the regulations in 42 CFR parts 412 and 413, including proposals to implement provisions of the Consolidated Appropriations Act relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs.

Section X. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule included proposed changes pertaining to Medicare's share of organ acquisition costs for organs transplanted into Medicare beneficiaries and the charges for services provided to cadaveric organ donors by donor community hospitals and transplants hospitals.

In Appendix A of the FY 2022 IPPS/LTCH PPS proposed rule, we set forth an analysis of the impact the proposed changes for the provisions listed would have on affected acute care hospitals, IPPS-excluded hospitals and other entities.

We received approximately 28,000 timely pieces of correspondence in response to the FY 2022 IPPS/LTCH PPS proposed rule. Approximately 570 items of the proposed rule's correspondence are addressed in this final rule with comment period.

We also note that the FY 2022 IPPS/LTCH PPS final rule appeared in the August 13, 2021 **Federal Register** (86 FR 44774) and that final rule included the vast majority of the provisions of the proposed rule. This final rule with comment period finalizes the graduate medical education and certain organ acquisition payment policy provisions of the FY 2022 IPPS/LTCH PPS proposed rule. As noted in section II.A. of this final rule with comment period, we are not addressing the proposed revisions to the regulations relating to the treatment of section 1115 waiver days for purposes of the disproportionate share hospital (DSH) adjustment in this final rule with comment period. We expect to revisit the issue of section 1115 waiver days in future rulemaking, and we encourage stakeholders to review any future proposal on this issue and to submit their comments at that time. As noted in section II.C. of this final rule with comment period, we are not addressing the proposed revisions to the Medicare organ counting policy in this final rule with comment period. We may revisit the Medicare organ counting policy in future rulemaking, and we encourage stakeholders to review any future proposal on this issue and to submit their comments at that time.

## II. Provisions of the Final Rule with Comment Period

### A. Medicare Disproportionate Share Hospital (DSH) Payments: Counting Days Associated with Section 1115 Demonstration Projects in the Medicaid Fraction (§ 412.106)

In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed revisions to the regulation relating to the treatment of section 1115 waiver days for purposes of the DSH adjustment (86 FR 25457 through 25459). In the FY 2022 IPPS/LTCH PPS final rule, we stated that due to the number and nature of the comments that we received on our proposal, we intended to address the public comments in a separate document (86 FR 45249). We thank the commenters for their input on the proposal, but after further consideration of the issue, we have determined not to move forward with the current proposal. We expect to revisit the issue of section 1115 waiver days in future rulemaking, and we encourage

stakeholders to review any future proposal on this issue and to submit their comments at that time.

B. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99-272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for determining a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105-33), established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

Section 422 of Pub. L. 108-173, the Medicare Modernization Act (MMA), provided for the redistribution of unused residency positions effective for portions of cost reporting periods beginning on or after July 1, 2005. The policy implementing section 422 of the MMA was included in the August 11, 2004 FY 2005 IPPS final rule (69 FR 49112 through 49169).

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident limit for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances.

Section 5503(a)(4) of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the redistribution of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section

5503(b) of the Affordable Care Act amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions in the same manner to the IME FTE resident caps. The policy implementing section 5503 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPSS/ASC final rule with comment period (75 FR 72147 through 72212) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53424 through 53434). Section 5506(a) of the Affordable Care Act amended section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The policy implementing section 5506 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPSS/ASC final rule with comment period (75 FR 72212 through 72238), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53448), and the FY 2015 IPPS/LTCH final rule (79 FR 50122 through 50140).

## 2. Provisions of the Consolidated Appropriations Act, 2021

The Consolidated Appropriations Act, 2021 (CAA), division CC, contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals. Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in fiscal year 2023, with priority given to hospitals in 4 statutorily-specified categories. Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track (RTT), and the 3-year rolling average set out at section 1886(h)(4)(G)(i) of the Act used to calculate payments for these hospitals. Section 131 of the CAA makes statutory changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. We provided detailed proposals for implementing these three CAA provisions in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR

25502 through 25523). In this section of this final rule with comment period, we discuss our proposals, respond to public comments received, and provide our final policies.

### 3. Distribution of Additional Residency Positions Under the Provisions of Section 126 of Division CC of the Consolidated Appropriations Act, 2021 (CAA)

#### a. Overview

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25503 through 25504), section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) of the Act requiring the distribution of additional residency positions to qualifying hospitals. Section 1886(h)(9)(A) of the Act requires that for FY 2023, and for each succeeding fiscal year until the aggregate number of full-time equivalent (FTE) residency positions distributed is equal to 1,000, the Secretary shall initiate separate rounds of applications from hospitals for these additional residency positions. The Secretary is required, subject to certain provisions in the law, to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by the number of positions that may be approved by the Secretary for that hospital. The Secretary is required to notify hospitals of the number of positions distributed to them by January 31 of the fiscal year of the increase, and the increase is effective beginning July 1 of that fiscal year. Section 1886(h)(9)(A) of the Act also limits the aggregate number of such positions made available in a single fiscal year across all hospitals to no more than 200.

In determining the qualifying hospitals for which an increase is provided, section 1886(h)(9)(B) of the Act requires the Secretary to take into account the “demonstrated likelihood” of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(9)(B) of the Act also requires a minimum distribution for certain categories of hospitals. Specifically, the Secretary is required to distribute at least 10 percent of the aggregate number of total residency positions available to each of four categories of

hospitals. Stated briefly, and discussed in greater detail later in this final rule with comment period, the categories are as follows: (1) hospitals located in rural areas or that are treated as being located in a rural area (pursuant to sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act); (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in states with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs). Section 1886(h)(9)(F)(ii) of the Act defines a qualifying hospital as a hospital in one of these four categories.

Section 1886(h)(9)(C) of the Act places certain limitations on the distribution of the residency positions. First, a hospital may not receive more than 25 additional FTE residency positions in total. Second, no increase in the otherwise applicable resident limit of a hospital may be made unless the hospital agrees to increase the total number of FTE residency positions under the approved medical residency training program of the hospital by the number of positions made available to that hospital.

#### b. Determinations Required for the Distribution of Residency Positions

##### (1) Determination that a Hospital has a “Demonstrated Likelihood” of Filling the Positions

Section 1886(h)(9)(B)(i) of the Act directs the Secretary to take into account the “demonstrated likelihood” of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(9)(A)(iii)(II) of the Act requires that the increase would be effective beginning July 1 of the fiscal year of the increase. For FY 2023, this means the additional positions would be effective July 1, 2023.

In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed that the application deadline for the additional positions available for a fiscal year would be January 31 of the prior fiscal year. However, as discussed later in this final rule with comment period, we are finalizing a

deadline of March 31, such that the application deadline for the additional positions available for a fiscal year will be March 31 of the prior fiscal year. Accordingly, for FY 2023, all references in section II.B.3. of this final rule with comment period to the application deadline are references to the application deadline of March 31, 2022.

We proposed that a hospital would show a “demonstrated likelihood” of filling the additional positions (sometimes equivalently referred to as slots) for which it applies by demonstrating that it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program.

In order to demonstrate that it does not have sufficient room under its current FTE resident cap(s), we proposed that a hospital would be required to submit copies of its most recently submitted Worksheets E, Part A and E-4 from the Medicare cost report (CMS-Form-2552-10) as part of its application for an increase to its FTE resident cap.

We proposed that a hospital would demonstrate and attest to a planned new program or expansion of an existing program by meeting at least one of the following two criteria:

- *“Demonstrated Likelihood” Criterion 1 (New Residency Program)*. The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs as part of a new residency program that it intends to establish on or after the date the increase would be effective (that is, a new program that begins training residents at any point within the hospital’s first 5 training years beginning on or after the date the increase would be effective).

Under “Demonstrated Likelihood” Criterion 1, we proposed that the hospital would be required to meet at least one of the following conditions as part of its application:

- Application for approval of the new residency program has been submitted to the ACGME or the American Board of Medical Specialties (ABMS) by the application deadline for that year.



The hospital has submitted an institutional review document or program information form concerning the new residency program in an application for approval of the new program by the application deadline for that year.

The hospital has received written correspondence by the application deadline for that year from the ACGME or ABMS acknowledging receipt of the application for the new residency program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

• *“Demonstrated Likelihood” Criterion 2 (Expansion of an Existing Residency Program)*. The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital’s first 5 training years beginning on or after the date the increase would be effective. Under “Demonstrated Likelihood” Criterion 2, we proposed that the hospital would be required to meet at least one of the following conditions as part of its application:

The hospital has approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

The hospital has submitted by the application deadline an institutional review document or program information form for the expansion of the existing residency training program.

Under “Demonstrated Likelihood” Criterion 2, we proposed that the hospital would be applying for an increase in its FTE resident cap in order to expand an existing residency program. We proposed that this would mean that as of the application deadline the hospital was either already training residents in this program, or, if the program existed at another hospital as of that date, the residents would begin to rotate at the applying hospital on or after the effective date of the increase.

We note that section 1886(h)(9)(C)(ii) of the Act requires that if a hospital is awarded positions, that hospital must increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on the newly awarded positions under section 126 of CAA. We therefore proposed that a hospital must, as part of its application, attest to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on any newly awarded positions.

We present a summary of the public comments and our responses to our proposals related to the determination that a hospital has a "demonstrated likelihood" of filling the positions awarded under section 126 of the CAA.

Comment: Several commenters expressed support for our proposed "Demonstrated Likelihood" criteria.

Response: We thank the commenters for their support.

Comment: A commenter supported our proposal to award additional residency positions only for newly-created positions, rather than for existing positions that a hospital may already be funding in excess of its statutory FTE caps. Conversely, another commenter expressed concern that hospitals training residents over their caps are neglected by our proposed "Demonstrated Likelihood" criteria. This commenter questioned why such hospitals were not being prioritized in the distribution of additional residency positions, given the commenter's belief that there is almost certain likelihood that additional residency positions awarded to these hospitals would be immediately filled and utilized.

Response: Section 1886(h)(9)(C)(ii) of the Act, as added by section 126 of the CAA, prohibits an increase in the otherwise applicable resident limit of a hospital unless the hospital agrees to increase its total number of FTE residency positions. Our proposed "Demonstrated Likelihood" criteria thus reflect the requirements set forth in the statute, which preclude the use of additional residency positions to fund existing positions. In response to the comment that hospitals that do not have sufficient room under their current FTE resident cap(s) (that is,

hospitals that are training at or above their Medicare GME cap(s) and do not have any remaining Medicare funding for positions to train additional FTE residents) should be prioritized in the distribution of additional residency positions, we note, as discussed in this section, that HPSA scores, while not a perfect measure, provide the best prioritization approach available at this time. In addition, and as discussed later in this section, in order to be eligible for prioritization based on HPSA scores, hospitals must first qualify under one or more of Category One, Category Two, Category Three, or Category Four. Category Two consists of hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit. Therefore, hospitals that do not have sufficient room under their current FTE resident caps, may qualify to be prioritized for the distribution of additional residency positions based on our prioritization of applications from hospitals based on HPSA score final policy, discussed further in this section.

Comment: A commenter suggested that hospitals should be able to meet the “demonstrated likelihood” requirement by showing that the number of residency positions currently filled for one or more programs at the hospital is less than the number of residents for which those programs have been accredited by the ACGME. Another commenter made a similar point by requesting that the number of residency positions distributed to a hospital take into account the hospital’s ability to use those residency positions immediately through existing programs. Another commenter stated that the reason a hospital has unfilled accredited residency positions may be that the hospital would be unable to train the full complement of residents without exceeding its FTE caps; the commenter added that such hospitals would not actually need to establish a new residency program or expand an existing program in order to quickly put any additional residency positions awarded to them to use.

Response: We agree that a hospital should be able to meet the “demonstrated likelihood” requirement by showing that it has unfilled, previously accredited positions in its residency program, and that it is now seeking to fill those positions, as long as the hospital does not have

sufficient room under its FTE resident cap(s) for the planned expansion. Therefore, we are modifying “Demonstrated Likelihood” Criterion 2 (Expansion of an Existing Residency Program) to include the scenario where a hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

Comment: Several commenters recommended that rural hospitals should only be awarded additional residency positions for the purpose of expanding existing programs, since such hospitals can already receive a cap adjustment whenever they establish a new program.

Response: We believe rural hospitals should be given the option of receiving a permanent cap increase for a new program either under section 126 of the CAA, or under the existing 5-year cap-building process (42 CFR 413.70(e)). A rural hospital making this decision should carefully consider which option is more appropriate to its specific scenario.

Comment: A commenter expressed concern that many small rural hospitals would be unlikely to meet the proposed requirements for residency positions under “Demonstrated Likelihood” Criterion 2 (Expansion of an Existing Residency Program), since such hospitals often restrict the size of their programs for reasons other than funding, for example, because of teaching capacity or recruiting challenges. The commenter stated that only large rural hospitals with established programs would be likely to meet the proposed requirements under “Demonstrated Likelihood” Criterion 2.

Response: We appreciate the concerns raised by the commenter about unique challenges that may be faced by small rural hospitals. However, the statute requires us to take into account the “demonstrated likelihood” of a hospital filling the positions. Expansion of an existing program is a valid way for a hospital to demonstrate the likelihood of filling the positions. We note that since we are adopting a criterion that 50 percent of the program’s training take place in the HPSA and not at the applicant hospital as proposed (which is discussed in section II.B.3.d. of this final rule with comment period), a rural hospital may be able to more easily partner with

other participating training sites to meet the 50 percent criterion and be able to apply (and meet the requirements for “demonstrated likelihood”) for the amount of FTEs that will be training at its (the rural) hospital.

Comment: Several commenters requested that we update our proposed “Demonstrated Likelihood” criteria to be consistent with the terminology currently used by the ACGME and the ABMS. Specifically, commenters noted that the ACGME “accredits” new residency programs, whereas we used the term “approval” in our proposed criteria. In addition, the ACGME no longer employs the terms “institutional review document” or “program information form.” Rather, if an existing ACGME-accredited program seeks to expand, the program director would submit a request to the relevant specialty Review Committee for a permanent complement increase. Finally, commenters noted that ACGME accreditation deadlines occur multiple times per year, whereas in our proposal we referred to requirements that must be satisfied “by the application deadline for that year”.

Response: We thank commenters for bringing the terminology issues to our attention and are revising the language accordingly as summarized below. However, we believe that the commenters have misinterpreted our references to the “application deadline” as references to the ACGME accreditation deadlines. In the context of our proposed “Demonstrated Likelihood” criteria, the “application deadline” refers to the deadline for submitting applications to CMS for additional residency positions under section 126 of the CAA, not the deadline for submitting program materials to the ACGME or the ABMS, as the commenters stated. We are therefore also clarifying that the phrase “application deadline” used in this context refers to the deadline for submitting applications under section 126 of the CAA for a given fiscal year. (As noted previously, in this final rule with comment period we are revising this deadline to March 31 of the prior fiscal year.)

In summary, after consideration of the public comments received, we are finalizing our proposed policy regarding the determination that a hospital has demonstrated a likelihood of

filling the positions for “Demonstrated Likelihood” Criterion 1 (New Residency Program) with modifications. Under the policy finalized in this final rule with comment period, as we proposed, a hospital will show a “demonstrated likelihood” of filling the additional positions (sometimes equivalently referred to as slots) for which it applies by demonstrating that it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program. To do so, as we proposed, we are finalizing a policy that a hospital will submit copies of its most recently submitted Worksheets E, Part A and E-4 from the Medicare cost report (CMS-Form-2552-10) as part of its application for an increase to its FTE resident cap, and will demonstrate and attest to a planned new program or expansion of an existing program by meeting at least one of two “Demonstrated Likelihood” criteria.

Specifically, we are finalizing the following for “Demonstrated Likelihood” Criterion 1:

- *“Demonstrated Likelihood” Criterion 1 (New Residency Program)*. The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs as part of a new residency program that it intends to establish on or after the date the increase would be effective (that is, a new program that begins training residents at any point within the hospital’s first 5 training years beginning on or after the date the increase would be effective). Under “Demonstrated Likelihood” Criterion 1, the hospital will be required to meet at least one of the following conditions as part of its application:

- Application for accreditation of the new residency program has been submitted to the ACGME (or application for approval of the new residency program has been submitted to the ABMS) by the application deadline.

- The hospital has received written correspondence from the ACGME (or ABMS) acknowledging receipt of the application for the new residency program, or other types of communication concerning the new program accreditation or approval process (such as notification of site visit) by the application deadline.

For “Demonstrated Likelihood” Criterion 2, we are finalizing the following:

- “*Demonstrated Likelihood*” Criterion 2 (*Expansion of an Existing Residency Program*). The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital’s first 5 training years beginning on or after the date the increase would be effective. Under “*Demonstrated Likelihood*” criterion 2, the hospital will be required to meet at least one of the following conditions as part of its application:

The hospital has received approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

The hospital has submitted a request by the application deadline for a permanent complement increase of the existing residency program.

The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

We are also finalizing, as we proposed, a policy that under “*Demonstrated Likelihood*” Criterion 2, the hospital is applying for an increase in its FTE resident cap because it is expanding an existing residency program. This means that as of the application deadline the hospital is either already training residents in this program, or, if the program exists at another hospital as of that date, the residents will begin to rotate at the applying hospital on or after the effective date of the increase. In addition, we note that section 1886(h)(9)(C)(ii) of the Act requires that if a hospital is awarded positions, that hospital must increase the number of its residency positions by the amount the hospital’s FTE resident caps will increase, based on the newly awarded positions under section 126 of CAA. Therefore, we will require that a hospital must, as part of its application, attest to increase the number of its residency positions by the amount the hospital’s FTE resident caps are increased based on any newly awarded positions in accordance with the provisions of section 1886(h)(9)(B)(i) of the Act.

(2) Determination of Hospitals that are Located in a Rural Area or are Treated as Being Located in a Rural Area (Category One)

Section 1886(h)(9)(B)(ii) of the Act requires the Secretary to distribute not less than 10 percent of resident positions available for distribution to each of four categories of hospitals. Under section 1886(h)(9)(B)(ii)(I) of the Act, the first of these categories consists of hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. We refer to this category as Category One.

Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing regulations at § 412.64(b)(1)(ii), an “urban area” means an MSA or a Metropolitan Division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by the Office of Management and Budget. Under existing § 412.64(b)(1)(ii)(C), a “rural area” means any area outside an urban area. Since FY 2005, we no longer use the term MSA, but instead use the term Core-Based Statistical Area (CBSA). Certain CBSAs are designated as urban, while those not designated as urban are considered rural. For purposes of section 1886(h)(9)(B)(ii) of the Act, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25504), we proposed that a hospital with its main campus located in an area outside of an urban CBSA would be considered a rural hospital. We note that this definition of “rural area” is consistent with our policy concerning designation of rural areas for wage index purposes.

Similar to our historical wage index policy of cross walking counties to CBSAs, CMS proposed to use the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, or successor files containing similar information, from the most recent FY IPPS final rule (or correction notice if applicable) to determine if a hospital is a rural hospital. (This file is available on the CMS website in approximately August of the year prior to



the year of the application deadline. Under the file's current format, blank cells in Columns D and E indicate an area outside of a CBSA.)

Under section 1886(d)(8)(E) of the Act, a subsection (d) hospital (that is, generally, an IPPS hospital) that is physically located in an urban area is treated as being located in a rural area for purposes of payment under the IPPS if it meets criteria specified in section 1886(d)(8)(E)(ii) of the Act, as implemented in the regulations at § 412.103. Under these regulations, a hospital may apply to CMS to be treated as located in a rural area for purposes of payment under the IPPS.

Given the fixed number of available residency positions, it is necessary to establish a deadline by which a hospital must be treated as being located in a rural area for purposes of Category One. We proposed to use Table 2, or a successor table containing similar information, posted with the most recent IPPS final rule (or correction notice if applicable) to determine whether a hospital is reclassified to rural under § 412.103. If a hospital is not listed as reclassified to rural on Table 2, but has been subsequently approved by the CMS Regional Office to be treated as being located in a rural area for purposes of payment under the IPPS as of the application deadline for additional positions for the fiscal year, we proposed that the hospital must submit its approval letter with its application in order to be treated as being located in a rural area for purposes of Category One.

In this section we present a summary of the public comments and our responses to our proposals related to the determination of hospitals that are located in a rural area or are treated as being located in a rural area (Category One).

Comment: Several commenters expressed support for our proposed definition of Category One hospitals.

Response: We thank the commenters for their support.

Comment: A commenter supported our proposed definition of a rural area, but suggested that we expand it to include certain locations within MSAs that are considered rural by the

Federal Office of Rural Health Policy. The same commenter recommended that we assign a lower priority to geographically urban hospitals that have been reclassified as rural for wage index purposes, stating that this reclassification is done for payment equity purposes and does not make such facilities rural in any meaningful sense.

Response: Our proposed definition of a rural area is consistent with how that term is employed in the context of the Medicare statute. In particular, it is consistent with section 1886(h)(9)(B)(ii)(I) of the Act, as added by section 126 of the CAA, which refers specifically to the definition of a rural area at section 1886(d)(2)(D) of the Act. Furthermore, as we stated in the FY 2022 IPPS/LTCH PPS proposed rule, our definition is consistent with our policy concerning designation of rural areas for other purposes, including the wage index. For these reasons, we are not amending our definition of rural for purposes of section 126 of the CAA.

With respect to the commenter's second point concerning rural reclassifications, we believe that the commenter may have misinterpreted our proposal. The commenter referred specifically to urban hospitals that have been reclassified as rural for wage index purposes. We believe that the commenter was referring to hospitals that have been reclassified as rural by the Medicare Geographic Classification Review Board (MGCRB). Under section 1886(d)(10) of the Act, as implemented at 42 CFR 412.230, the MGCRB may change the classification of a hospital for purposes of the wage index only. However, the legislation directs the Secretary to consider hospitals that are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act, which is a separate provision. Section 1886(d)(8)(E) of the Act, as implemented at § 412.103, is applicable beyond the calculation of the wage index. In particular, under § 412.103(a)(1), an urban hospital may apply to be reclassified as rural if it is located in a rural census tract of an MSA as determined by the Federal Office of Rural Health Policy. We believe that this is the same criterion that the commenter requested be consider in expanding our proposed definition of a rural area. Additionally, because section 1886(h)(9)(B)(ii)(I) of the Act references both hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of

the Act) and those that are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act, we read the statutory language as intending for both groups of hospitals to receive equal treatment.

With respect to hospitals that have reclassified as rural under § 412.103 (section 1886(d)(8)(E) of the Act), we note that consistent with our past application of rural reclassification to GME payment policies, these hospitals are considered rural for IME payment purposes and urban for direct GME payment purposes. However, we believe the inclusion of these hospitals under section 126 of the CAA is intended only to deem these hospitals as eligible recipients of the additional slots being distributed under section 126 of the CAA. We do not believe section 126 of the CAA limits urban hospitals that have reclassified as rural to only receiving IME FTE residency positions. As such, these hospitals are eligible for both direct GME and IME FTE residency positions under section 126 of the CAA.

Comment: Several commenters requested that we clarify whether rural referral centers are included in the definition of hospitals that are located in a rural area or are treated as being located in a rural area.

Response: Generally, in order to qualify for rural referral center (RRC) status under the criteria set forth at 42 CFR 412.96, a hospital must be rural, that is, either located in a rural area, or treated as being located in a rural area under section 1886(d)(8)(E) of the Act. Most RRCs would therefore qualify under Category One as defined previously in this final rule with comment period. However, we permit hospitals that previously qualified as an RRC but lost their status due to the Office of Management and Budget (OMB) redesignation of the county in which they are located from rural to urban to be reinstated as an RRC (August 1, 2000 IPPS final rule (65 FR 47054, 47089)). Currently, there are a relatively small number of hospitals with RRC status that are neither located in a rural area nor treated as being located in a rural area under section 1886(d)(8)(E) of the Act (approximately 11 percent). We are clarifying that such hospitals, despite their status as RRCs, would not qualify under Category One.

Comment: A commenter expressed concern that, as a result of our proposal to use the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, urban hospitals reclassified to rural may still be able to claim treatment as rural hospitals despite being located well within a CBSA. The same commenter also suggested what they characterized as a grammatical edit to our definition of rural for purposes of Category One. In the proposed rule, we proposed that a hospital with its main campus located in an area outside of an urban CBSA is a rural hospital. The commenter recommended that we revise this language to state that a hospital would be considered located in a rural area, or treated as such, if its main campus was located in an area outside of an urban CBSA and was classified as a rural hospital (that is, not reclassified as urban). The commenter added that this restriction would avoid allowing large urban rural referral centers to expand an existing program and take these residency positions from geographically rural hospitals, which would thwart what the commenter believes to be the legislative intent of the statute.

Response: We believe the commenter is referring to hospitals that are located in urban CBSAs and have been reclassified as rural under section 1886(d)(8)(E) of the Act, as implemented in the regulations at 42 CFR 412.103. As discussed previously, the statute explicitly refers to such reclassified hospitals among the categories of qualifying hospitals in section 1886(h)(9)(B)(ii)(I) of the Act. The preamble language cited by the commenter, and to which a grammatical edit was suggested, is only part of our proposed definition, which also includes hospitals reclassified as rural, as required by the statute. We further note that, as we proposed, such hospitals would not be identified using the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, but rather by consulting Table 2, or a successor table containing similar information, posted with the most recent IPPS/LTCH PPS final rule (or correction notice if applicable). If a hospital is not listed as reclassified to rural on Table 2, but has been subsequently approved by the CMS Regional Office to be treated as being located in a rural area for purposes of payment under the IPPS as of the

application deadline for additional positions for the fiscal year, the hospital must submit its approval letter with its application in order to be treated as being located in a rural area for purposes of Category One.

It also appears that the commenter may have conflated two distinct categories of hospitals, namely, urban hospitals reclassified as rural under § 412.103, and RRCs, which are governed by the regulations at § 412.96. While an urban hospital reclassified as rural may elect to apply for RRC status if it meets the criteria set forth at § 412.96, such assignment is not automatic, and many RRCs are in fact geographically rural. Thus, as explained previously, many, but not all, RRCs may qualify as rural hospitals for purposes of section 126 of the CAA, depending on whether they otherwise satisfy the criteria for Category One.

Comment: A commenter, located in an urban area within a largely rural state, requested that CMS reconsider our proposed definition of hospitals located in rural areas or treated as being located in rural areas. Another commenter, stated that despite being located in a rural area and serving a mostly rural population, they would not qualify under Category One since the zip code of the hospital itself is not located in a HPSA.

Response: In response to the first commenter, we refer to the language of section 1886(h)(9)(B)(ii)(I) of the Act concerning rural hospitals, and note that a hospital located in an urban area cannot qualify under this category (Category One) unless it has reclassified as rural in accordance with the regulations at 42 CFR 412.103. We believe that the second commenter has conflated our proposals regarding two distinct statutory categories, namely, Category One (rural hospitals) and Category Four (hospitals that serve HPSAs). In response, we are clarifying that a hospital located in a rural area, or that is treated as being located in a rural area, qualifies under Category One whether or not it is physically located in a HPSA.

Comment: A commenter requested that the states of Hawaii and Alaska, in addition to the U.S. territories of Guam, American Samoa, Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands, be recognized as rural for any federal definition. The

commenter stated that these areas face significant health care challenges as they are non-contiguous and distant from the rest of the United States, and that their health care systems are isolated and vulnerable.

Response: Designating the states of Hawaii and Alaska, in addition to the U.S. territories of Guam, American Samoa, Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands, as rural for any federal definition is beyond the scope of this rulemaking. We note that hospitals in these states and territories that are located in a rural area or are treated as being located in a rural area, as applicable, are eligible to apply for residency positions under section 126.

Comment: A commenter stated that we should revise our proposed definition of Category One to include the requirement that the majority of residents' training should take place in a rural area. The commenter argued that, if the goal is to train more physicians to remain and serve in communities of need, then the greatest priority should be given to hospitals and systems that themselves are located in rural areas, and in fact serve rural communities. According to the commenter, this should include caveats that the training itself take place in a "rural MSA," and residency positions should not be awarded to an organization that has a facility located in a rural MSA if that facility would not be the primary place of training.

Response: We agree with the commenter that the training and retention of physicians in rural and underserved areas is an important goal. However, the law requires that hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act are qualifying hospitals. Prioritization of applications is a separate issue from the definition of Category One (and is discussed in section II.B.3.d. of this final rule with comment period).

After review of the public comments received, we are finalizing our proposal regarding the determination of hospitals that are located in a rural area or are treated as being located in a rural area (Category One) as proposed, without modification.

(3) Determination of Hospitals for which the Reference Resident Level of the Hospital is Greater than the Otherwise Applicable Resident Limit (Category Two)

Under section 1886(h)(9)(B)(ii)(II) of the Act, the second category consists of hospitals in which the reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii) of the Act) is greater than the otherwise applicable resident limit. We refer to this category as Category Two.

Under section 1886(h)(9)(F)(iii) of the Act, the term ‘reference resident level’ means, with respect to a hospital, the resident level for the most recent cost reporting period of the hospital ending on or before the date of enactment of section 1886(h)(9) of the Act, December 27, 2020, for which a cost report has been settled (or, if not, submitted (subject to audit)), as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25505).

Under section 1886(h)(9)(F)(iii) of the Act, the term ‘resident level’ has the meaning given such term in paragraph (7)(C)(i). That section defines “resident level” as with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

Under section 1886(h)(9)(F)(i) of the Act, the term ‘otherwise applicable resident limit’ means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to the changes made by this provision of CAA 2021, but taking into account section 1886(h)(7)(A), (7)(B), (8)(A), and (8)(B) of the Act. These paragraphs all address the distribution of positions and redistribution of unused positions.

In the CY 2011 OPSS final rule with comment period, we previously interpreted these terms when we implemented section 5503 of the Affordable Care Act. Under section 1886(h)(8)(H)(i) of the Act (as interpreted in the CY 2011 OPSS final rule (75 FR 46391)), the “reference resident level” generally refers to the number of unweighted allopathic and

osteopathic FTE residents who are training at a hospital in a given cost reporting period. That is, the “reference resident level” refers to a hospital’s allopathic and osteopathic FTE resident count for a specific period. The definition can vary based on what calculation is being performed to determine the correct allopathic and osteopathic FTE resident count (see, for example, 42 CFR 413.79(c)(1)(ii)). As noted previously, section 126 of the CAA, under new section 1886(h)(9)(F)(iii) of the Act defines the “reference resident level” as coming from the most recent cost reporting period of the hospital ending on or before the date of enactment of the CAA (that is, December 27, 2020).

Under new section 1886(h)(9)(F)(i) of the Act, the term “otherwise applicable resident limit” is defined as “the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraphs (7)(A), (7)(B), (8)(A), and (8)(B).” In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25505), we proposed to define this as the hospital’s 1996 cap during its reference year, adjusted for the following: new programs as defined at § 413.79(e); participation in a Medicare GME affiliation agreement as defined at §§ 413.75(b) and 413.79(f); participation in an Emergency Medicare GME affiliation agreement as defined at § 413.79(f); participation in a hospital merger; whether an urban hospital has a separately accredited rural training track program as defined at § 413.79(k); applicable decreases or increases under section 422 of the MMA, applicable decreases or increases under section 5503 of the Affordable Care Act, and applicable increases under section 5506 of the Affordable Care Act.

Regarding the term “resident level”, in the CY 2011 OPPS final rule (75 FR 46391) we indicated that we generally refer to a hospital’s number of unweighted allopathic and osteopathic FTE residents in a particular period as the hospital’s resident level, which we proposed to define consistently with the definition in section 126 of the CAA; that is, the “resident level” under section 1886(h)(7)(c)(i) of the Act, which is defined as the total number of full-time equivalent



residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

For the purposes of section 126 of the CAA we proposed that the definitions of the terms “otherwise applicable resident level,” “reference resident level,” and “resident level” should be as similar as possible to the definitions those terms have in the regulations at §413.79(c) as developed in the CY 2011 OPSS rulemaking.

The following is a summary of the public comments and our responses to our proposals related to the determination of hospitals for which the reference resident level of the hospital is greater than the otherwise applicable resident limit (Category Two).

Comment: Several commenters expressed support for our proposed definition of Category Two hospitals.

Response: We thank the commenters for their support.

Comment: A few commenters requested that we clarify that a hospital qualifies under Category Two if it is over its direct GME cap, its IME cap, or both. Some commenters added that such an interpretation would be consistent with our implementation of the distribution process under section 5503 of Pub. L. 111-148.

Response: We are clarifying that a hospital qualifies for direct GME residency positions under Category Two if it is over its direct GME cap; qualifies for IME residency positions under Category Two if it is over its IME cap; and qualifies for both direct GME and IME residency positions if it is over both its direct GME and IME caps. Furthermore, we are clarifying that a hospital may only apply for direct GME and/or IME residency positions if it does not have sufficient room to start a new program or expand an existing program under its existing direct GME and/or IME caps, respectively. For example, if a hospital has sufficient room under its IME cap to expand an existing program, but not under its direct GME cap, that hospital may only apply for direct GME residency positions, but not IME residency positions, to facilitate the planned expansion.

Comment: A commenter expressed concern that Category Two may bias financing decisions toward larger hospitals that are more likely to be able to support residency positions in excess of their caps due to the training of more self-sustaining subspecialty physicians.

Response: While we acknowledge the commenter's concern, we note that hospitals training residents in excess of their otherwise applicable resident limit or caps, are included among qualifying hospitals as defined by the statute, which also requires that we distribute at least 10 percent of the aggregate number of additional residency positions to hospitals that qualify under this category.

After review of the public comments received, we are finalizing our proposal regarding the determination of hospitals for which the reference resident level of the hospital is greater than the otherwise applicable resident limit (Category Two) as proposed, without modification.

(4) Determination of hospitals located in States with New Medical Schools, or Additional Locations and Branch Campuses (Category Three)

The third category specified in section 1886(h)(9)(B)(ii) of the Act, as added by section 126 of CAA, consists of hospitals located in States with new medical schools that received 'Candidate School' status from the Liaison Committee on Medical Education (LCME) or that received 'Pre-Accreditation' status from the American Osteopathic Association (AOA) Commission on Osteopathic College Accreditation (the COCA) on or after January 1, 2000, and that have achieved or continue to progress toward 'Full Accreditation' status (as such term is defined by the LCME) or toward 'Accreditation' status (as such term is defined by the COCA); or additional locations and branch campuses established on or after January 1, 2000, by medical schools with 'Full Accreditation' status (as such term is defined by LCME) or 'Accreditation' status (as such term is defined by the COCA). We note that the statutory language is specific with respect to these definitions. We refer to this category as Category Three.

Based on research and assistance received from LCME and the COCA, we understand that each accrediting body administers a multi-step process for applicant medical schools to

progress to fully accredited status within the first few years after they are established and begin training students. LCME grants candidate status to an applicant medical education program after it reviews and approves the medical school's data collection instrument and planning self-study; at this point, it determines that the school is ready for a survey visit, and the preliminary accreditation survey visit is scheduled. After that visit, LCME reviews the survey team's preliminary survey report and determines whether or not sufficient progress toward compliance with accreditation standards has been made and satisfactory plans for the medical education program have been developed.

If LCME grants preliminary accreditation status, the school may begin accepting applications for enrollment. During the second year of the school's charter class, a school with preliminary accreditation status may submit information and receive a survey site visit to determine whether it meets criteria for provisional accreditation status. Finally, LCME grants full accreditation status to schools with provisional accreditation status, typically in the fourth teaching year, after determining the school is in compliance with or has made significant progress toward attaining compliance with all full accreditation standards.

LCME defines a regional campus, comparable to "additional locations and branch campuses" in section 1886(h)(9)(B)(ii)(III)(bb) of the Act, as a site distinct from the main campus of the medical school where students spend at least 1 full year of the curriculum. Regional campuses of a medical education program receive accreditation status through the main campus of the program and are not separately accredited.

The COCA may grant pre-accreditation status to a proposed college of osteopathic medicine (COM) that has achieved candidate status and meets the standards of pre-accreditation status. The pre-accreditation process starts with the submission of a pre-accreditation self-study by a proposed COM; COCA staff then reviews the submission and conducts a site visit to examine the proposed COM's compliance with accreditation standards. Following the site visit, the COCA reviews the site visit report and other submitted information and grants pre-

accreditation status to a proposed COM that meets the pre-accreditation standards. Once a proposed COM receives pre-accreditation status, it may begin to recruit, accept applications from, and admit prospective students. We note that prior to 2017, the COCA used the term “provisional status” instead of “pre-accreditation status.”

The COCA may grant accreditation status to a COM that has achieved pre-accreditation status and meets the standards for accreditation. These accreditation statuses include accreditation with exceptional outcome, accreditation, accreditation with heightened monitoring, accreditation with warning, and accreditation with probation. Any accreditation status constitutes full accreditation, in contrast to pre-accreditation status or candidate status, which do not constitute full accreditation status.

The COCA defines a branch campus as a geographically separate location apart from the COM’s main campus that is: permanent in nature; offers courses in educational programming leading to a doctorate in osteopathic medicine; has its own faculty and administrative or supervisory organization; and maintains its own budgetary and hiring authority. A COM that establishes a branch location must apply for and receive separate approval from the COCA; the application process has four steps: a written application and branch campus self-study, a progress report, a revised branch campus self-study and site visit, and a final, pre-operational site visit.

The COCA defines an additional location as a location that is geographically separate from the main campus of a COM, but unlike a branch location, shares administration, faculty, curriculum, and budgetary authority with the main campus. Additional locations receive accreditation through the main campus of the COM following the review of documents and a survey site visit, after which a COM may enroll students in the additional location.

Based on information gathered from LCME and the COCA about new medical schools, additional locations and branch campuses, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25506), we proposed that hospitals located in the following 35 States and 1 territory, referred to as Category Three States, would be considered Category Three hospitals: Alabama,

Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin. We further stated that if a hospital is located in a state not listed here, but believes the state in which it is located should be on this list, the hospital could submit a formal comment on the proposed rule to make a change to this list, or could provide documentation with submission of its application to CMS that the state in which it is located has a medical school or additional location or branch campus of a medical school established on or after January 1, 2000. Pursuant to the statutory language, all hospitals in such states are eligible for consideration; the hospitals, themselves, do not need to meet the conditions of section 1886(h)(9)(B)(ii)(III)(aa) or (bb) of the Act in order to be considered.

Comment: Several commenters expressed support for our proposed definition of Category Three hospitals.

Response: We thank the commenters for their support.

In addition, we did not receive any comments requesting that a state be added to the list of Category Three states.

Therefore, after review of the public comments received, we are finalizing our proposal regarding the determination of hospitals located in states with new medical schools, or additional locations and branch campuses (Category Three) as proposed, without modification.

(5) Determination of Hospitals that Serve Areas Designated as Health Professional Shortage Areas under Section 332(a)(1)(A) of the Public Health Service Act (Category Four)

The fourth category specified in the law consists of hospitals that serve areas designated as health professional shortage areas under section 332(a)(1)(A) of the Public Health Service Act (PHSA), as determined by the Secretary. We refer to this category as Category Four.

The Health Resources and Services Administration (HRSA) designates certain areas as health professional shortage areas (HPSAs). Section 332(a)(1)(A) of the PHSA, states that a “health professional shortage area” is “an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage”. HRSA designates HPSAs for primary care, mental health, and dental health.

A geographic area may be designated as a HPSA under section 332(a)(1)(A) of the PHSA only on the basis of a shortage of services for the entire population within that area (a “geographic HPSA”). Subsequent clauses of 332(a)(1) refer to other types of HPSAs, to which we will return later in this final rule with comment period. The geographic area to which a geographic HPSA is assigned may be a single county, multiple counties, a county subdivision, census tract, or a group of census tracts.

As we noted in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25506), section 126 of the CAA does not explicitly address the question of how HPSAs for different medical specialties should factor into determining which hospitals serve areas designated as HPSAs. In our consideration of this question, we began by examining the use of HPSAs in the HPSA Physician Bonus Program authorized under section 1833(m) of the Act. This program is relevant because Congress established the program as an incentive to attract new physicians to medically underserved communities and to encourage physicians in those areas to remain there (69 FR 47517 through 47518).

The HPSA Physician Bonus Program was created by Section 4043 of the Omnibus Budget Reconciliation Act (OBRA) of 1987, which added section 1833(m) to the Act. It provides incentive payments to physicians who furnish services to an individual in an area that is designated as a HPSA. Originally, under section 1833(m) of the Act, a 5 percent payment was added, beginning January 1, 1989, to the amounts otherwise payable to physicians who furnish services to Medicare patients in designated HPSAs. Section 6102 of OBRA 1989 further

amended section 1833(m) of the Act to raise the amount of this incentive payment from 5 percent to 10 percent for services furnished after December 31, 1990. The OBRA 1989 amendment also expanded eligible service areas to include both rural and urban HPSAs.

We first examined the role of primary care geographic HPSAs in the HPSA Physician Bonus program. Physicians furnishing services in a primary care geographic HPSA are eligible to receive the bonus payments and the payments apply to all physicians who perform covered services within a primary care geographic HPSA, regardless of specialty. Similarly, section 126 of the CAA does not explicitly distinguish between physician specialties for purposes of allocating the additional residency positions. Therefore, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25507), we proposed that primary care geographic HPSAs would be considered in determining what hospitals qualify under Category Four and that hospitals that have main campuses or provider-based facilities in these HPSAs may apply for additional residency positions for any specialty. We also note CMS used primary care HPSAs for the allocation of residency positions for purposes of section 5503 of the Affordable Care Act (75 FR 72147).

We next considered the use under the HPSA Physician Bonus Program of areas that are solely mental health geographic HPSAs and not also primary care geographic HPSAs. We will refer to these areas as mental health only geographic HPSAs. The HPSA Physician Bonus Program provides incentive payments for services provided in mental health only geographic HPSAs, but only for services provided by psychiatry provider specialties. The distinction between primary care geographic HPSAs, in which all physician provider specialties, including psychiatry provider specialties, receive the incentive payments, and mental health only geographic HPSAs, in which only psychiatry provider specialties receive the incentive payments, is relevant to the question of how mental health only geographic HPSAs should factor into determining hospitals that serve areas designated as HPSAs for purposes of section 126 of the CAA. We believe that it is appropriate to incorporate this feature of the HPSA Physician Bonus

Program as well, and proposed to use mental health only geographic HPSAs for mental health providers accordingly in the determination of hospitals that serve areas designated as HPSAs. Thus, we proposed that hospitals that only have main campuses or provider-based facilities in mental health only geographic HPSAs could only apply for residency positions for psychiatry residency programs.

We next considered dental geographic HPSAs. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of allopathic and osteopathic residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during the same cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Given that dental residents are not included in this statutory cap and that section 126 of the CAA distributes additional residency positions in the context of the statutory cap, we did not propose that dental geographic HPSAs should factor into the determination of whether a hospital serves a HPSA for purposes of section 126 of the CAA.

In summary, we proposed to consider geographic HPSAs for primary care and mental health providers for purposes of determining hospitals that serve areas designated as HPSAs. We proposed that hospitals that only have campuses or provider-based facilities in mental health only geographic HPSAs could only apply for positions for psychiatry residency programs. We did not propose to consider dental HPSAs as dental FTE residents are not subject to a hospital's IME and direct GME caps.

We next considered what hospitals serving areas designated as primary care or mental health HPSAs means for purposes of Category Four. As with the question regarding the role of primary care, mental health, and dental HPSAs, section 126 of the CAA does not explicitly address this question.



As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25507), there are many possible interpretations of what hospitals that serve areas designated as primary care or mental health HPSAs means for purposes of Category Four. The most expansive interpretation might be that this refers to the universe of hospitals where each hospital provides care to at least one patient that resides in a HPSA without regard to the location of the main campus of the hospital or of its other patient care locations. This interpretation could be made less expansive by developing a relative or absolute threshold for the number of patients of the hospital that reside in HPSAs. It could also be made less expansive by considering whether the physical location of the main campus of the hospital and/or its other patient care locations are inside of or proximate to a HPSA.

In considering this issue, we prioritized objective factors that would maximize distribution of GME positions to residency programs serving underserved populations. (See section V.J.2.a.(4). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule for a further discussion of our proposals for prioritizing care to underserved populations.) To this end, we proposed that a hospital could qualify under Category Four if it had its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health only geographic HPSA. Additionally, as part of the qualification requirements under Category Four, in the residency program for which the hospital was applying, we proposed that at least 50 percent of the residents' training time over the duration of the program would have to occur at those locations in the HPSA. We stated in the proposed rule that we believed it was important to avoid the possibility that a hospital with provider-based facilities in multiple locations, some of which may not be located in a HPSA, uses an additional residency position mostly or entirely to serve populations that face no health service shortage.

We proposed that a Category Four hospital submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, that it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a

primary care or mental health only geographic HPSA, and in the program for which the hospital is applying, at least 50 percent of the residents' training time over the duration of the program occurs at those locations in the HPSA.

For example under our proposal, Hospital A applies under Category Four for a psychiatry residency program. Its main campus is located in a non-HPSA area and it has one provider-based facility located in a mental health only geographic HPSA. Hospital A must attest that residents training in the psychiatry residency program spend at least 50 percent of the duration of their training in the program at its provider-based facility located in the mental health only geographic HPSA.

As another example, Hospital B applies for a residency program. Its main campus is located in a primary care geographic HPSA and it has two provider-based facilities, one in the same geographic HPSA as the main campus and one in a non-HPSA area. Hospital B must attest that residents training in the program will spend at least 50 percent of the duration of their training in the program on the main campus or at the provider-based facility located in the geographic HPSA, combined (for example, 30 percent of the time on the main campus and 20 percent at the provider-based facility).

The following is a summary of the public comments and our responses to our proposals related to Category Four qualification requirements.

Comment: Many commenters objected to the proposed requirement that a hospital or provider-based facilities be located in a primary care or mental health only geographic HPSA to be eligible under Category Four. Several commenters expressed concern that our proposed definition of Category Four limits hospitals from eligibility and that as a result, only a small number of hospitals would qualify for residency positions awarded under section 126 of the CAA. Other commenters argued that this constraint does not take into account that many geographic HPSA residents rely on health services provided outside of their HPSA. A commenter noted this is particularly true of certain specialty care services, such as mental health

services, for which HPSA-residing patients are referred to academic medical centers located in urban areas. Several commenters suggested that it is for this reason that the statutory language describes hospitals that serve HPSAs rather than explicitly limiting eligibility under this category to hospitals physically located within the geographic boundaries of HPSAs.

Many commenters believe Category Four should be interpreted to more generally include hospitals that play a meaningful role in providing health services to residents of shortage areas. These commenters suggested we modify our proposal to include both hospitals located within HPSAs and those within a reasonable distance of one. Several commenters provided specific recommendations on what would be considered within a reasonable distance of a HPSA, such as within one mile, 10 miles, 20 miles, and 25 miles. In addition, a commenter requested that CMS revise our proposed definition of Category Four so that a hospital may be eligible for section 126 of the CAA residency positions on the basis of serving either a geographic or “population”

HPSA (the following link includes a brief description of HPSAs:

<https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation#hpsas>). Another commenter noted that some underserved communities do not qualify for geographic or population HPSAs because of their proximity to wealthier areas, but face provider shortages that deserve recognition under Category Four. Some commenters recommended that we define Category Four in terms of the measure of the hospital’s patient population that reside within geographic HPSAs, using either an absolute or proportionate threshold. A commenter requested flexibility in the data sources that hospitals may use to demonstrate they are serving or will at some point serve HPSA populations, including data from other government agencies and non-profit organizations.

Many commenters opposed the proposed requirement that to qualify under Category Four, at least 50 percent of residents’ training time in the program must occur in facilities located in the geographic HPSA. According to some commenters, this requirement would impede teaching hospitals’ ability to structure programs to best meet the needs of the patients and

communities they serve as well as to satisfy administrative obligations, including accreditation standards. Commenters also stated that the requirement that 50 percent or more of residents' time be spent in a HPSA, often in rural areas, would not be possible since supervising physicians and training schedules must be focused on population centers with patient and condition mixes that are necessary for training. A few commenters explained that the proposed 50 percent requirement, in addition to the proposed requirement that hospitals or their facilities be physically located in a HPSA to qualify under Category Four, is too restrictive to meet the policy goal of directing new residency positions to areas that provide services to underserved populations and does not meet congressional intent.

Several commenters, while supporting the proposed requirement that 50 percent of resident training time in programs take place in locations in the HPSA, requested that nonprovider settings where hospitals may count training time for IME and direct GME purposes be counted. Commenters stated that community settings, such as critical access hospitals, Federally Qualified Health Centers (FQHCs), and rural health clinics (RHCs), are important contributors to the provision of services in HPSAs and to residency training. Several commenters added that, in their view, it was Congress's intent that FTEs awarded under section 126 of the CAA train at nonprovider settings in addition to hospital main campuses and provider-based facilities.

Several commenters were opposed to the proposed 50 percent training time requirement because they believe it would impose a recordkeeping burden on hospitals that administer residency programs. A few commenters noted that normally, resident rotations are reported in the Intern and Resident Reporting System (IRIS) in aggregate, whereas the proposed 50 percent training time requirement would demand individual resident tracking and reporting. Commenters stated that to attest to meeting the requirement, teaching hospitals would need to develop a new system and process to document and track section 126 of the CAA funded residents that is separate from the system and process used to track residents funded by other sources.

A commenter requested clarification on whether the proposed requirement that residents spend 50 percent or more of their training time in a geographic HPSA in order for the hospital to be eligible under Category Four is based on all residents in aggregate or to individual residents.

Response: We appreciate commenters' feedback and concerns regarding the eligibility requirements under Category Four. After further consideration, as discussed in greater detail later in this section, we are modifying certain aspects of our proposal in response to public comments. These modifications are intended to provide additional flexibilities in meeting these requirements, while still targeting Category Four eligibility to hospitals that are most clearly serving HPSAs. We are persuaded by commenters' arguments and agree that training in settings other than hospital settings is consistent with our goal of maximizing distribution of GME positions to residency programs serving underserved populations, including serving those in community settings, and should be counted toward meeting Category Four eligibility requirements. Therefore, we are modifying our proposal. Any and all program training that occurs in a geographic HPSA at scheduled program training sites that are physically located in that HPSA and treat the HPSA's population, including nonprovider settings and Veterans Affairs facilities, will count towards meeting the 50 percent training requirement to qualify under Category Four. In addition, because we are revising our proposed definition of Category Four to allow all of these settings to be qualifying training sites, an applicant hospital (including any provider-based facilities) itself will not be required to be physically located in a geographic HPSA in order to be eligible under Category Four as proposed. Rather, as long as the hospital participates in training residents in a program where at least 50 percent of the training time occurs at scheduled training site(s) that are physically located in a geographic HPSA, that hospital is considered to be eligible under Category Four. We believe these changes will provide additional flexibility for teaching hospitals to design programs to effectively serve patients and communities and meet any administrative requirements while targeting Category Four eligibility to hospitals that are most clearly serving HPSAs.

Consider an example where Hospitals A, B, and C participate in training residents in an approved family medicine program. The program also has Training Site 1 as part of the rotation schedule (could be a nonprovider setting, a Veterans Affairs facility, or another community setting). Hospitals A and B are located in a primary care geographic HPSA as is Training Site 1. Hospital C is not located in the HPSA. Residents in the family medicine program spend 40 percent of their training time at Hospitals A and B, 40 percent of their training time at Hospital C, and 20 percent of their time training at Training Site 1. Since at least 50 percent of the program's total training time is spent training at facilities located in the primary care geographic HPSA, Hospitals A, B, and C all qualify under Category Four.

We appreciate commenters' suggestions to expand the proposed requirement for Category Four beyond a hospital's training sites that are physically located in HPSAs to include those within a certain distance of a HPSA. While we believe a distance or proximity threshold may warrant further consideration in the future for Category Four, we note the suggested distances by some commenters ranged anywhere between one mile to 25 miles. Based on these comments, a single uniform distance threshold may not always be appropriate in the context of section 126 of the CAA. For example, a single fixed mileage threshold may not equitably address tertiary care situations because hospitals providing equivalent tertiary care to residents of HPSAs may be located varying distances from those HPSAs. At this time, we believe the requirement that at least 50 percent of training time occurs at training sites that are physically located in a geographic HPSAs targets Category Four eligibility for hospitals that are most clearly serving HPSAs.

We also appreciate comments recommending that we consider the measure of a hospital's patient population that resides within a HPSA to determine whether a hospital serves a HPSA, as well as the suggestion of using different data sources to establish whether a hospital serves a HPSA. We believe there should be a consistent method used for hospitals to demonstrate that they meet the definition of Category Four. We note, simultaneously allowing the use of different

data sources to establish whether a hospital serves a HPSA would mean that we might compare applications supported by different data collection methods, different definitions, or different data altogether. As discussed earlier, at this time we believe requiring that at least 50 percent of the training time of the program the hospital participates in occurs at training site(s) that are physically located in a geographic HPSA targets Category Four eligibility to hospitals that are most clearly serving HPSAs. However, we continue to welcome further feedback on the dependence of geographic HPSA residents on health services provided outside of their HPSA and are seeking comment on appropriate summary measures of where HPSA residents seek medical care as a feasible alternative for potential use in future rulemaking.

With regard to commenters' concern that the proposed definition of Category Four would limit the pool of eligible applicants relative to more expansive definitions, we appreciate the feedback. However, we do not believe the goal of Category Four should be to create the most expansive eligibility pool possible. Targeting Category Four eligibility to hospitals that are clearly serving HPSAs (as discussed previously) is entirely consistent with this statutory eligibility criterion and our policy objectives for section 126 of the CAA regarding medically underserved communities. In addition, as stated previously, we are seeking comments on potential alternative feasible definitions of Category Four to inform future rulemaking.

With regard to the request to include population HPSAs in the definition of Category Four, we note that section 1886(h)(9)(B)(ii)(IV) of the Act specifies that Category Four consists of hospitals that serve areas designated as health professional shortage areas under section 332(a)(1)(A) of the PHSA, as determined by the Secretary. Paragraph (A) of section 332(a)(1) of the PHSA describes a geographic HPSA, as explained previously and in the proposed rule (86 FR 25506). A population HPSA is described by paragraph (B) of section 332(a)(1), as explained in section II.B.3.d. of this final rule with comment period and section V.J.2.a.(4).(a). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508). Therefore, we are

not revising the definition of Category Four to include population HPSAs as requested by the commenter.

In response to comments that including a training time requirement for qualification falls outside of the legislative intent of section 126 of the CAA, we disagree. The statute at 1886(h)(9)(B)(2)(IV) limits Category Four eligibility to hospitals that serve areas designated as HPSAs under section 332(a)(1)(A) of the PHSA, as determined by the Secretary. As discussed in the proposed rule and in line with the Administration's support for advancing health equity in underserved communities, targeting Category Four eligibility to hospitals serving HPSAs is consistent with this statutory eligibility criterion and our policy objectives. We also note, as stated previously, we are seeking comment on potential alternative definitions of Category Four to inform future rulemaking.

We disagree with the comments that a minimum rotation time requirement imposes a significant tracking or reporting requirement. We do not expect hospitals to establish entirely new training tracks or administrative structures to accommodate FTE slots awarded under section 126 of the CAA. Hospitals regularly develop rotation schedules to facilitate residents' training at participating sites and a program's participating site information is generally readily available on the ACGME website. As such, we are specifying that the percentage of training time that residents in the program spend in the HPSA for purposes of Category Four is required to be substantiated, utilizing resident rotation schedules (or similar documentation). Regarding IRIS, we do not expect the existing reporting requirements to change for hospitals that receive these residential slots. We note that the 50 percent requirement applies to the program in its entirety, not to individual residents. As such, hospitals would not need to track the training time of individual residents to ensure each individual resident spends 50 percent or more of their training time in a geographic HPSA, so long as the program in its entirety meets the requirement.

Comment: Several commenters objected to our approach to address the issue of how specialties factor into determining which hospitals serve areas designated as HPSAs.



Commenters stated that our use of the HPSA Physician Bonus Program as a model for addressing this question is flawed because hospitals do not respond to incentives and cannot relocate to new areas or establish new operations in the same manner as individual physicians and physician practices. Additionally, commenters stated that unlike the bonus payments in the HPSA Physician Bonus Program, the proposed size of the FTE awards will be insufficient to incentivize the establishment of new training programs in HPSAs.

Response: While we agree that the HPSA Physician Bonus Program and the Category Four eligibility of hospitals for additional GME residency positions target different types of entities, one being physicians and the other physician training programs, as we discussed in the proposed rule the policy objective underlying each is to strengthen the physician workforce in underserved areas. We therefore disagree with the comment that one is an unsuitable template upon which to build the other. However, as discussed in greater detail later in this section, we agree with commenters that the proposed 1.0 FTE per year limitation on FTE awards with no assurance of follow-on awards would be an insufficient incentive to encourage many hospitals to expand an existing or establish a new training program. As such, we are finalizing a policy to increase maximum award sizes to 5.0 FTEs per hospital per year, which we discuss in more detail in section II.B.3.c.(2). of this final rule with comment period.

Comment: Several commenters stated that hospital applications associated with mental health only geographic HPSAs should not be limited to psychiatry training programs. The commenters stated that provider shortages in mental health only geographic HPSAs are not limited to psychiatric services and the expansion of service availability in any specialty would help address community health care challenges.

A commenter objected to our inclusion of mental health only geographic HPSAs in the definition for Category Four. Instead, the commenter believed that eligibility under Category Four should only be met when a hospital's main campus or other facilities are in a primary care

geographic HPSA. The commenter also stated that the new resident slots should only be used to fund training for primary care residents.

Response: We appreciate the comments requesting that hospitals not be limited to psychiatry training programs for hospitals that apply under mental health only geographic HPSAs for Category Four. While we understand that such an expansion could help address health care challenges in underserved communities, we have no direct evidence of a shortage of other specialties in mental health only geographic HPSAs nor do we have a method at this time to uniformly measure a shortage of other, non-psychiatric specialty providers in mental health only geographic HPSAs. As we discussed in the proposed rule and previously, the HPSA Physician Bonus Program provides incentive payments for services provided in mental health only geographic HPSAs, but only for services provided by psychiatry provider specialties. We continue to believe that it is appropriate to use mental health only geographic HPSAs for mental health providers in the determination of hospitals that serve areas designated as HPSAs. Therefore, we disagree with the comment that we should exclude mental health only geographic HPSAs from the definition of Category Four and limit residency positions to primary care training programs. However, we also believe it is equally important to advance health equity in physical and mental health services in underserved areas. Therefore, we are therefore modifying our policy in this final rule with comment period to include psychiatric subspecialty residency programs in addition to psychiatric residency programs within the mental health only geographic HPSA category.

Therefore, in this final rule with comment period, specific to mental health only geographic HPSAs, we are finalizing the policy that if a hospital participates in training residents in a psychiatric or a psychiatric subspecialty program, where at least 50 percent of the program's training time occurs in a training site(s) in the HPSA, the hospital is eligible under Category Four.

Comment: Several commenters expressed support for our proposed definition of Category Four hospitals.

Response: We thank the commenters for their support.

In summary, after consideration of and in response to the public comments received, we are finalizing our proposed requirements for determining eligibility under Category Four with modification in this final rule with comment period. Under our final policy, an applicant hospital qualifies under Category Four if it participates in training residents in a program in which the residents rotate for at least 50 percent of their training time to a training site(s) physically located in a primary care or mental health only geographic HPSA. Specific to mental health only geographic HPSAs, the program must be a psychiatric or a psychiatric subspecialty program. In addition, under this final policy, as proposed, a Category Four hospital must submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, that it meets the 50 percent requirement. We did not receive any comments on our proposal not to consider dental HPSAs, as dental FTE residents are not subject to a hospital's IME and direct GME caps. We are finalizing that policy as proposed.

#### (6) Determination of Qualifying Hospitals

Section 1886(h)(9)(F)(ii) of the Act defines a qualifying hospital as a hospital described in any of the subclauses (I) through (IV) of subparagraph (B)(ii). As such, we proposed that a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories.

The following is a summary of the public comments and our responses to our proposals related to the determination of qualifying hospitals.

Comment: A commenter supported our proposal for determining which hospitals are considered qualifying hospitals. Specifically, hospitals that meet the definitions of Category One, Category Two, Category Three, or Category Four, or hospitals that meet the definitions of more than one of these categories, are eligible for section 126 of the CAA residency positions.

Response: We thank the commenter for their support.

Comment: A commenter stated that the Department of Veterans Affairs should be included in future planning and evaluation of a more refined distribution approach for future years.

Response: We thank the commenter for the feedback. We note that residency positions distributed under section 126 will not be distributed to Veterans Affairs hospitals. These hospitals are eligible for GME payments through the Veterans Access, Choice, and Accountability Act GME Expansion. However, we note that when considering the percentage of program training time that occurs in a HPSA for purposes of section 126, training time occurring at a Veterans Affairs facility physically located in a HPSA will be included in that percentage.

Comment: Several commenters recommended adding eligibility criteria that would allow hospitals not meeting any of the definitions of Categories One through Four to qualify for residency positions awarded under section 126 of the CAA. Commenters recommended including the following eligibility categories: small hospitals with fewer than 250 beds, hospitals with single residency programs, Indian health care providers, safety-net providers, and hospitals that host residency programs whose graduates later practice in either predominantly rural states or states with a large proportion of rural service areas designated as HPSAs.

Response: We appreciate the commenters' feedback and input on qualifying criteria. Section 1886(h)(9)(F)(ii) restricts eligibility to the four categories discussed previously. However, we agree with commenters that including hospitals with fewer than 250 beds in our final policy, may be useful in further prioritizing residency positions in certain instances. We refer commenters to the discussion in section II.B.3.d.(2). of this final rule with comment period, where we incorporate the suggested bed limit into our final policy. We also welcome further comment regarding whether the remaining priority hospitals or hospital characteristics identified by commenters should be addressed in other aspects of our policy in future years.

Comment: A commenter requested that we issue a list of hospitals that are likeliest to obtain additional residency positions under our finalized criteria. The commenter stated that advance signaling of which hospitals are likely to receive FTE awards will help them plan for contingent expansions of existing programs or establishment of new programs.

Response: We thank the commenter for the feedback. While we understand that significant planning resources are required to establish and expand training programs, we cannot anticipate changes to training program rotations between now and the start of the 2023 program year that will affect applications or predict which hospitals have determined that it is in their interest to expand their training programs with distributions under section 126 of the CAA and will apply. Therefore, we are unable to provide a list of hospitals that are likeliest to be awarded residency positions before awards are made. However, we intend to make available relevant information regarding the distribution of positions at the completion of the distribution process.

After consideration of comments received, we are finalizing our policy related to the determination of qualifying hospitals as proposed, without modification. Specifically, a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories.

#### c. Number of Residency Positions Made Available to Hospitals and Limitation on Individual Hospitals

##### (1) Number of Residency Positions Made Available to Hospitals

Section 1886(h)(9)(A)(ii)(II) limits the aggregate number of total new residency positions made available in a single fiscal year across all hospitals to no more than 200. In order to provide these additional residency positions to hospitals as quickly as possible, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), we proposed to make 200 residency positions available for FY 2023 and each subsequent year.

In this section, we present a summary of the public comments and our responses to our proposals related to the number of residency positions made available to hospitals.

*Comment:* A number of commenters supported our proposal to make 200 residency positions available for FY 2023 and each subsequent year. A commenter recommended that we distribute all 200 residency positions each year even if fewer than 200 facilities apply, by allowing additional FTEs to be assigned to hospitals that do not apply; the commenter stated that this would fulfill the intent of Congress that 200 residency positions are distributed in each of the years.

*Response:* We thank the commenters for their support. With respect to the suggestion that we distribute all 200 residency positions each year even if fewer than 200 facilities apply, section 1886(h)(9)(A)(i) of the Act, as added by section 126 of the CAA, makes it clear that, in order to receive additional FTEs, a hospital must submit a timely application. The law does not grant us the authority to distribute residency positions to hospitals that do not apply. We also note that section 1886(h)(9)(A)(ii)(II) of the Act states that the aggregate number of residency positions made available shall not exceed 200 for a fiscal year; it does not require that all 200 residency positions to be distributed each year if there are insufficient numbers of applicant hospitals. Although we do not expect that there will be an insufficient number of applicant hospitals we intend to track progress in meeting all statutory requirements and evaluate the need for potential modifications in future rulemaking.

Comment: A few commenters expressed support for the statutory limit on the aggregate number of residency positions. Conversely, a commenter stated that the distribution of 200 residency positions per year across potentially 50 states will likely have minimal impact, particularly after a 25-year wait given that caps were implemented based on the number of FTE residents hospitals trained in 1996.

Response: The limit on the aggregate number of residency positions made available each year is set by the statute at 200.

Comment: A commenter was concerned about the impact of the distribution of residency positions under section 126 of the CAA on Medicaid. The commenter stated that the immediate

impact on Medicaid in its state is unclear as it is uncertain how many of the new residency positions will be awarded to hospitals in its state. However, the commenter further noted that since hospitals awarded residency positions under section 126 will likely be incurring new medical education costs, Medicaid expenditures would increase.

Response: We are clarifying that residency positions under section 126 of the CAA are related to Medicare GME payments, not Medicaid. However, to the extent hospitals awarded residency positions under section 126 and the partial Medicare funding of new residency positions in that state might indirectly be associated with additional expenditures under that state's Medicaid program, any additional Medicaid expenditures that might occur are inestimable because it is unknown what hospitals in what states will apply and be awarded additional residency positions under section 126.

After consideration of comments received, we are finalizing our policy related to the number of residency positions made available to hospitals as proposed, without modification. Specifically, the aggregate number of total residency positions made available in a single fiscal year across all hospitals will be limited to no more than 200. Additionally, in order to provide these additional residency positions to hospitals as quickly as possible, we are making 200 residency positions available for FY 2023 and each subsequent year.

## (2) Limitation on Individual Hospitals

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), we expect the demand from hospitals for the aggregate number of total residency positions made available for each fiscal year to significantly exceed the 200 maximum. For example, there are currently over 300 teaching hospitals that have their main campus located in a primary care or mental health only geographic HPSA. In that same proposed rule, we stated that we expect the majority of these hospitals would apply for additional residency positions because they would qualify under our proposed Category Four. Even if we were to exclusively allocate the maximum 200 positions permitted under the statute each year to these hospitals, which are only a subset of

Category Four hospitals (and Category Four itself is only one of four categories), it would still be insufficient to award even 1.0 FTE to each hospital each year. Therefore, in order to make additional residency positions available to more hospitals each year, we proposed to limit the increase in the number of residency positions made available to each individual hospital to no more than 1.0 FTE each year. We note that the proposal was not 1.0 FTE for each program at a hospital each year, but rather 1.0 FTE for each hospital each year.

As noted earlier, section 1886(h)(9)(C)(i) of the Act places certain limitations on the distribution of the residency positions, one of which is that a hospital may not receive more than 25 additional FTE residency positions. Under our proposed 1.0 FTE limitation per hospital per year, no hospital would receive more than 25 additional FTE residency positions. Rather, under the proposed 1.0 FTE limitation, hospitals would receive a maximum of 5 additional FTE residency positions.

The following is a summary of the public comments and our responses to our proposals related to the limitation on individual hospitals.

Comment: A commenter supported our proposal to limit the size of awards to 1.0 FTE per hospital per year. This commenter stated that the more stringent limit was warranted since the demand for additional residency positions will far exceed the total number of residency positions available, and applying a 1.0 FTE limit would promote the distribution of additional residency positions across a wider range of qualifying hospitals. Furthermore, the commenter recommended that, in subsequent distribution cycles, we prioritize applications from hospitals that have not yet received residency positions, so that no hospital would be awarded a second residency position until all other qualifying hospitals have received their first award.

Response: We thank the commenter for their support, however, as we explain in this section, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per year. Regarding the recommendation that in subsequent distribution



cycles, we prioritize applications from hospitals that have not yet received residency positions, we will take this recommendation under consideration for potential future rulemaking.

Comment: A commenter requested CMS clarify whether or not the proposal would distribute 1.0 FTE for the duration of a program, which equates to 3-5 residency positions per FTE, without requiring hospitals to reapply each year; for example, a hospital applying for a 3-year Family Medicine program would receive 3 residency positions total, while a hospital applying for a 5-year General Surgery program would receive 5 residency positions. Similarly, another commenter stated that they support our proposed limit and requested that in addition to the proposal, the FTE be financed for the duration of their training rather than a separate FTE being awarded for each year of training, and that this consideration be taken into account in determining the aggregate limit of 1,000 FTEs.

Response: We believe that the commenters have misconstrued our proposal, and that they are interpreting the term “FTE” to refer to the funding necessary to support one resident in each program year of a residency training program for the length of the program. On the contrary, the term “FTE” refers to the funding necessary to support one resident during a single year of training; this is the sense in which we employed the term in our proposal as written in the FY 2022 IPPS/LTCH PPS proposed rule, as well as in previous rulemaking cycles. We did not propose to distribute additional residency positions in blocks of 3.0-5.0 FTEs in the manner requested by the commenters. However, as we explain later in this section, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per application year.

Comment: Many commenters strongly objected to our proposal to limit the size of awards to 1.0 FTE per hospital per year. Several commenters argued that the proposal is contrary to congressional intent, and that CMS was overstepping its authority by imposing a limit more stringent than what is specified in the law. Others stated that the proposed limit is inconsistent with the overall goal of increasing residency training levels, especially in rural areas, and that the

proposal could significantly lessen the potential impact of the new legislation. A commenter worried that the nationwide physician shortage may be further exacerbated by the proposal to limit the size of awards to 1.0 FTE per year, and stated that it may not be capable of producing trained physicians to keep up with the need, if the cost burden for the residency training programs is not further shared with Medicare.

Many commenters argued that an award of 1.0 FTE per hospital per year would be insufficient to establish a new residency program or meaningfully expand an existing program. With respect to new programs, commenters observed that the ACGME Program Requirements specify a minimum complement of two to four residents in each program year for most specialties. They argued that the minimum cohort size is intended to ensure an appropriate learning environment and to provide residents with a sufficient shared clinical and educational experience that promotes peer learning, teamwork, and coordination of care. Accordingly, some commenters feared that the proposed limit would threaten program continuity and disrupt the training of residents. Moreover, a commenter observed that many programs are dependent on other specialties for the education of residents, and that the proposed limit would hinder an institution's ability to support new or expanded residency programs as a result of their inability to simultaneously expand residencies in the specialties that support those programs.

Several commenters were concerned that the proposed limit would not be economically feasible for many institutions, particularly smaller hospitals. A commenter estimated that five additional residency positions over 5 years might be sufficient to support some new fellowship programs, but would likely be insufficient to support even half of the FTEs for most new residency programs. Another commenter stated that receiving financial support for only one year of training would be untenable for most smaller institutions, and that only large hospitals with multiple programs could absorb the full cost of expanding a program by one resident per program year. Such considerations led a commenter to conclude that under our proposal the costs

of starting or expanding a residency program would outweigh the benefits, while several others predicted that it would discourage small hospitals from submitting applications altogether.

Numerous commenters worried that the proposal would result in an onerous and unpredictable annual application process, which again would disproportionately burden smaller hospitals. They observed that hospitals would be forced to submit applications year after year with no guarantee of receiving awards in subsequent rounds and thus no guarantee of being able to fund a residency position for the full length of a program. As an example, a commenter envisioned the scenario of a hospital that receives 1.0 FTE to establish a new residency program and does not qualify for additional residency positions in subsequent years; assuming a program duration of 3 years and a cohort size of four residents, such a hospital might be responsible for self-funding 11.0 additional FTEs in order to run the new program. Another commenter worried that hospitals may be forced to relocate residents if they are unable to secure funding for future years.

Several commenters also maintained that the proposed limit would particularly disadvantage hospitals in rural and underserved areas. A commenter stated that many such hospitals have consistently operated over their caps, often to their severe financial detriment; these hospitals are especially in need of financial assistance, and the proposed limit establishes a detrimental ceiling on the level of support they would be able to receive. As a result, the commenter concluded, our proposal would be likely to favor hospitals located in densely-populated urban areas. Another commenter added that an award of 1.0 FTE per year would risk limiting residency positions to existing programs, and would therefore disadvantage small institutions that are seeking to become teaching hospitals.

Commenters suggested various alternatives to our proposed limit of 1.0 FTE per hospital per year, with several saying that we should adhere to the statutory maximum of 25.0 FTEs. Among the most common recommendations was that we should tie the size of the award to the duration of the program for which a hospital is applying: for example, a hospital applying for a

Family Medicine program would receive 3.0 FTEs total (1.0 FTE × 3 years of training), while a hospital applying for a General Surgery program would receive 5.0 FTEs (1.0 FTE × 5 years of training). Several commenters stated that this should be considered a minimum allocation, and expressed their preference for a maximum award of 15.0 FTEs total, which would allow a hospital to meaningfully expand one or more programs over 5 years. Other recommendations we received include: distributing at least 3.0 FTEs per hospital per year; at least 3.0 FTEs per year for new programs, and 1.0 FTE per year for existing programs; at least 5.0 FTEs per year, with a commenter again suggesting that the amount could be different for new and existing programs; awarding residency positions in groupings or blocks of 4.0 FTEs; awarding up to 10.0 FTEs per hospital per year; and allowing hospitals to apply for up to three programs and no more than 15.0 FTEs each year.

Several commenters recommended that, if we retain the limit of 1.0 FTE per hospital per year, then we should streamline the application process to make it less burdensome and unpredictable for hospitals. All of these commenters suggested that hospitals that receive an award in a given fiscal year should be guaranteed to receive awards in subsequent application cycles, up to a certain minimum amount, which might be based on the duration of the training program. Such hospitals might be permitted to apply for all of their residency positions up front, without being required to submit further applications, or they might have the option of resubmitting less detailed applications in future years. Some commenters noted that under this model the minimum award might not be guaranteed in instances where a hospital initially applies for a program in one of the later application cycles, for example for FY 2026, assuming that all 1,000 residency positions are distributed over the course of 5 fiscal years. A commenter stated that, at a minimum, CMS should provide more clarity on the number of residency positions awarded over time to reduce the need for annual applications and to allow hospitals to better plan for their GME programs.

Response: We disagree with commenters who asserted that our proposed limitation of 1.0 FTE per hospital per year is contrary to congressional intent. Section 1886(h)(9)(C)(i) of the Act specifies that a hospital may not receive more than 25 additional full-time equivalent residency positions under the provisions of section 126 of the CAA; it does not specify a minimum award size, and leaves the Secretary broad latitude in determining the number of residency positions that will be distributed to individual hospitals.

However, after reviewing comments received, in particular the comments which expressed concern that our proposed limitation would be insufficient to establish a new program or meaningfully expand an existing program, that it would be impractical for many institutions, and that it would result in an unpredictable and burdensome application process, we have reconsidered our proposal. Therefore, in this final rule with comment period, we are modifying our proposal to adjust the size of the award to the length of the program for which a hospital is applying. Specifically, the maximum award amount is contingent on the length of the program for which a hospital is applying, with up to 1.0 FTE being awarded per program year, not to exceed a program length of 5 years or 5.0 FTEs. For example, a hospital applying to train residents in a program in which the length of the program is 3 years may request up to 3.0 FTEs per fiscal year.

We understand that in many cases a limit of 5.0 FTEs per hospital per year may not be sufficient for a hospital to fully fund Medicare's portion of a new program or planned expansion of an existing program; however, we believe that the increased limitation will provide a meaningful level of financial support to hospitals that would otherwise have to rely solely on their own resources to develop their GME infrastructure. Based on the comments we received, we believe that a limitation of 5.0 FTEs per hospital per year will be a sufficient amount to fully fund at least one resident in each program year for most specialties.

We note that if a hospital is applying for a program which has more than one participating site, the hospital should only request the FTE amount (not to exceed 1.0 FTE per

program year) associated with the training time at its facilities (including any nonprovider settings consistent with 42 CFR 413.78).

Given the limited number of residency positions available and the number of hospitals expected to apply, our focus under this modification continues to be on hospitals that are applying to establish or expand a single residency program. Therefore, we are finalizing our proposal that a hospital may not submit more than one application in any fiscal year. We continue to expect that a hospital would choose to apply for a program that serves the HPSA with the highest score among its programs, but a hospital is not required to do so. Hospitals that receive awards in a given round of applications will be able to reapply in subsequent years, either for the same program or for a different program, but with no guarantee of receiving additional residency positions.

With respect to hospitals that are seeking to become teaching hospitals, we note that such hospitals are also eligible to establish a cap(s) under 42 CFR 413.79(e). We refer these hospitals to section II.B.5. of this final rule with comment period where we discuss the implementation of section 131 of the CAA, specifically the 1.0 FTE cost reporting threshold. We note that a hospital that trains residents for the first time in an existing program or a new program will have a per resident amount (PRA) established for direct GME payment purposes, consistent with the regulations at 42 CFR 413.77(e). Such a hospital will also have a cap(s) established if the program in which it trains residents is a new program. We refer these hospitals to the August 31, 2012 **Federal Register** (77 FR 53416 through 53424), where we discuss the 5-year cap building period for new teaching hospitals.

Comment: Several commenters recommended that the limit on the number of residency positions should be adjusted to reflect the demonstrated need of individual hospitals. For instance, a commenter believed that hospitals in areas of great medical need should be allowed to receive more than 1.0 FTE per year; another commenter argued that, since the need for residency positions and full-time employees is not uniform across HPSAs, hospitals should not be

subjected to a uniform cap on the size of their awards. A commenter stated that the limit should apply only to hospitals that do not qualify under any of the four statutory priority categories.

Response: We appreciate the commenters' concern for hospitals located in areas of high need, and believe these concerns are addressed by the statutory requirement which specifies that hospitals may qualify for additional residency positions by serving HPSAs, and that at least 10 percent of the aggregate number of residency positions should be distributed to hospitals in this category. In addition, as explained previously, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per fiscal year.

With respect to the suggestion that the limit should apply only to hospitals that do not qualify under any of the four statutory priority categories, we note that section 1886(h)(9)(A)(i) of the Act directs the Secretary to distribute additional residency positions to qualifying hospitals, while section 1886(h)(9)(F)(ii) of the Act defines the term "qualifying hospital" as a hospital that satisfies the criteria of at least one of the four categories of hospitals described in subclauses (I) through (IV) of subparagraph (B)(ii). In other words, a hospital that does not qualify under any of the statutory categories would not be eligible to apply for and receive additional residency positions under section 126 of the CAA.

Comment: A few commenters recommended that CMS should delay the implementation of the proposed limitation on individual hospitals and evaluate the results of the first round of applications to determine whether a limit below the statutory maximum is warranted.

Response: As explained previously, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per year. Under this modification to allow up to 5.0 FTEs, our focus continues to be a single program given the limited number of residency positions available and the number of hospitals we expect to apply. Therefore, we are finalizing our proposal that a hospital may not submit more than one application in any fiscal year. We continue to expect that a hospital would choose to apply for a program that serves the HPSA with the highest score among its programs, but a hospital is not required to do so. We

plan to evaluate the results of the first round of applications and to consider whether any changes to the limitation on individual hospitals should be adopted in future rulemaking.

Additionally, as noted in the proposed rule and earlier in this section, section 1886(h)(9)(C)(i) of the Act places certain limitations on the distribution of the residency positions, one of which is that a hospital may not receive more than 25 additional FTE residency positions. Under our final policy to allow hospitals to receive up to 5.0 FTEs per year, no hospital would receive more than 25 additional FTE residency positions.

Comment: In considering our proposed limit of 1.0 FTE per hospital per year, a commenter stated that our proposal to prorate residency positions in case the number of hospitals with the same HPSA score exceeds the number of remaining residency positions will diminish the value of awards and increase the likelihood that the costs of creating a new program or expanding one would outweigh the benefits. Several commenters recommended that in case of a tie, rather than prorating residency positions, we should prioritize hospitals that are training residents in excess of their statutory FTE caps.

Response: We thank the commenters for their suggestions. As explained previously, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per year. We refer the commenters to our discussion of our final policy to distribute residency positions, including our policy should there be a situation where the number of FTEs requested by hospitals with the same HPSA score, exceeds the number of remaining positions, in section II.B.3.d.(2). of this final rule with comment period.

In summary, we are modifying our proposal to account for the size of a hospital's award to the length of the program for which the hospital is applying, with a maximum award of 5.0 FTEs per hospital per year. We are also finalizing the portion of our proposal that a hospital may not submit more than one application in any fiscal year.

d. Prioritization of Applications from Hospitals for Residency Programs that Serve Underserved Populations



## (1) Use of Geographic HPSAs and Population HPSAs

The Executive Order on “Ensuring an Equitable Pandemic Response and Recovery” noted that the COVID-19 pandemic has exposed and exacerbated severe and pervasive health and social inequities in America (see <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/>.) As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), in order to help address these exposed health inequities longer term, we believe that it would be appropriate to prioritize the applications from hospitals that will use the additional residency positions under section 126 of the CAA in residency programs serving underserved populations.

This prioritization was already partially reflected in our proposed definition of Category Four, where we discussed maximizing the number of GME positions distributed to residency programs serving underserved populations in geographic HPSAs designated by HRSA under PHSA section 332(a)(1)(A). However, under PHSA section 332(a)(1)(B), HRSA also designates HPSAs on the basis of a shortage of services for a specific subset of the population (“population HPSAs”) rather than the entire population in an area as is the case in geographic HPSAs. These population subsets include, but are not limited to: low-income populations, Medicaid-eligible populations, Native American populations, homeless populations, and migrant farmworker populations. (For information on the location and types of population HPSAs see <https://data.hrsa.gov/tools/shortage-area/hpsa-find>).

In order to more fully address health inequities for underserved populations, we believe that it also would be appropriate to prioritize the applications from hospitals that serve the specific designated underserved population of a population HPSA.

We have already discussed our proposed definition in Category Four of hospitals that serve the populations of geographic HPSAs. Similar to that approach, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), we proposed that a hospital would be considered to serve a population HPSA if it has its main campus or a provider-based facility (under 42 CFR

413.65) physically located in a primary care or mental health population HPSA, and any such locations serve the designated underserved population of that HPSA. Additionally, we proposed that, as part of the qualification requirements under Category Four, in the residency program for which the hospital is applying, at least 50 percent of the residents' training time over the duration of the program must occur at those locations in the HPSA. As with geographic HPSAs, we believe it is important to avoid the possibility that a hospital with provider-based facilities in multiple locations, some of which may not be located in a population HPSA or serve the designated population of that HPSA, uses an additional residency position mostly or entirely to serve populations that face no health service shortage.

Also similar to our proposed use of geographic HPSAs, we proposed that hospitals that only have main campuses or provider-based facilities in mental health only population HPSAs may only apply for positions for psychiatry residency programs.

We proposed that a hospital submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, that it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health population HPSA, any such locations serve the designated underserved population of that HPSA, and in the program for which the hospital is applying, the criterion that at least 50 percent of the residents' training time over the duration of the program occurs at those locations in the HPSA. We note that there is a difference between the Category Four qualification "requirement" and the prioritization "criterion" that 50 percent of a program's training time occur at training sites physically located in a HPSA. Section 1886(h)(9)(B)(ii)(IV) of the Act specifies that not less than 10 percent of the residency positions distributed shall go to hospitals that serve areas designated as HPSAs under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary (that is, geographic HPSAs, as discussed previously). Since section 1886(h)(9)(B)(ii)(IV) of the Act (referred to as Category Four in this preamble discussion) requires that not less than 10 percent of residency positions under section

126 of the CAA be awarded to hospitals that serve geographic HPSAs, our Category Four policy includes a “requirement” that the applicant hospital participates in training residents in a program in which the residents rotate for at least 50 percent of their training time to a training site(s) physically located in a primary care or mental health only geographic HPSA, as previously discussed. Separately, hospitals that qualify under categories One through Four are then subject to the prioritization criteria, including the “criterion” that at least 50 percent of a program’s training time occur at facilities physically located in a geographic or population HPSA, as described in more detail later in this section. The HPSA training percentage under the prioritization “criterion,” while not required by statute, is consistent with the Administration’s policy to prioritize training programs that have a higher likelihood of training physicians that will practice in underserved communities with the greatest need.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 22508 through 25509), we explained that our proposed approach for population-based HPSAs means that we potentially would be awarding a residency position for the provision of care that is not exclusively provided to the designated underserved population for which the shortage exists. However, in the context of our proposal to use HPSA scores to prioritize applications by the severity of the shortages, our proposal to limit the number of additional residency positions awarded to 1.0 FTE per hospital each year, and our proposed criterion that at least 50 percent of the training time over the duration of the program occur at locations in the HPSA that serve the designated underserved population of that HPSA, we believe it is sufficient for the residents in a program to provide care to the designated underserved population of that HPSA, and it is not necessary for residents to provide care exclusively to that population.

We note that HRSA also designates certain facilities as HPSAs under PHSA section 332(a)(1)(C) and the regulations at 42 CFR part 5. The process for facility HPSA designation is dissimilar from that for geographic and population HPSAs. Further, a HPSA score for a facility does not reflect on the adequacy of the health care workforce outside that facility in a geographic

area, and so it is not comparable to geographic or population HPSAs. Therefore, we did not propose to use facility HPSA designations for the purposes of this rulemaking.

We also note that there are teaching hospitals that may not have facilities in areas designated as geographic or population HPSAs, but that under their Medicare provider agreement operate one or more facilities that serve areas for which there exists a shortage of providers. If this is the case, we recommend that a hospital interested in applying for FTE resident cap positions under this section contact its state or territorial Primary Care Office (PCO) to receive information on the HPSA designation process. HRSA maintains cooperative agreements with the 54 state and territorial PCOs, which conduct needs assessments and submit applications to HRSA to designate areas as HPSAs. We refer interested parties to 42 CFR part 5 and 57 FR 2473 for information on procedures for HPSA designation for primary care and mental health HPSAs, respectively.

In summary, we are finalizing without modification our proposal to prioritize applications from qualifying hospitals (that is, hospitals that qualify under categories One through Four, as previously described) for residency programs that serve underserved populations in geographic HPSAs or population HPSAs. In the next section we discuss our proposal and final policy for the use of HPSA scores for this purpose.

## (2) Use of HPSA Scores for Prioritization

HRSA assigns HPSA scores on a scale of 0 to 25 as a measure of the severity of a primary care or mental health provider shortage in a geographic area, with higher scores indicating a more severe health professional shortage. As we observed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25509), using HPSA scores to differentiate applications from hospitals that qualify under categories One through Four would allow us to optimize the use of the limited number of additional residency positions under section 126 of the CAA and best address health inequities by focusing those residency positions on underserved populations with the most need.

In the proposed rule we stated that, in preparing its application for an additional residency position for a program, a hospital should refer to HRSA’s HPSA Find Tool (<https://data.hrsa.gov/tools/shortage-area/hpsa-find>) to obtain the HPSA score of the HPSA served by the program and include this score in its application. A HPSA is served by a program if that program meets the requirements discussed earlier. Given our proposal to limit the additional positions awarded to individual hospitals to 1.0 FTE for any given year, we proposed that a hospital may not submit more than one application in any fiscal year. Given the limited number of residency positions available and the number of hospitals we expect to apply, we expect that a hospital would choose to apply for a program that serves the HPSA with the highest score among its programs, but a hospital is not required to do so.

We proposed to allocate 1.0 FTE to each hospital with the highest HPSA score, prorating only in the event that the number of hospitals with the highest score exceeds the number of residency positions available. If the number of hospitals with the highest score is less than the number of residency positions available, each hospital with the next highest score would receive 1.0 FTE, with proration again occurring only in the event that the number of hospitals with this score exceeds the number of positions remaining. We would continue in this manner, moving on to hospitals with the next highest score until all available positions are distributed. We noted that, under this proposal, hospitals applying for residency positions for programs that do not serve HPSAs would not be categorically excluded, but those applications would have the lowest priority.

In the proposed rule we included the following as an illustrative example, assume the following hospitals apply, Hospitals A through HV. Assume there are 200 additional residency positions available. Under our proposal, Hospitals A through ET would each get 1.0 FTE, while Hospitals EU through HV would each get a prorated FTE award of 0.625, as follows:

<b>HOSPITAL NAME</b>	<b>HPSA SCORE</b>	<b>FTEs AWARDED</b>	<b>FTEs DISTRIBUTED/REMAINING</b>
A-AX (50 hospitals)	25	1.0	50/150
AY-CV (50 hospitals)	24	1.0	50/100

CW-ET (50 hospitals)	21	1.0	50/50
EU-HV (80 hospitals)	19	0.625	50/0

In summary, we proposed that additional residency positions under section 126 of the CAA would be distributed to hospitals that qualify under categories One through Four based on the HPSA score of the HPSA served by the residency program for which each hospital is applying, with programs serving higher HPSA scores receiving higher prioritization. Hospitals applying for residency positions for programs that do not serve HPSAs would not be categorically excluded, but those applications would have the lowest priority.

In this section, we present a summary of the public comments and our responses to our proposals related to the prioritization of applications from hospitals for residency programs that serve underserved populations.

Comment: Some commenters expressed support for our proposal to use HPSA scores to prioritize applications from qualifying hospitals and the policy goal that underlies this approach, specifically that of addressing health disparities faced by underserved populations. Commenters supporting our proposal indicated that where residents train has an impact on where they practice. Some commenters stated that the proposed methodology is a fair approach to increasing access to care in rural and underserved areas. Some commenters indicated that the use of HPSA scores would help improve the distribution of physicians across the country.

Response: We thank the commenters for their support.

Comment: Some commenters agreed with CMS that a prioritization of applications by HPSA scores would likely result in the statutory minimum of at least 10 percent of total residency positions being awarded to each of the four categories in section 1886(h)(9)(B)(ii) of the Act. A commenter added that in the event minimum distributions to each category are not met, minor adjustments can be made to the methodology without substantially compromising the approach.

Other commenters disagreed and indicated that our proposed approach would not result in the minimum statutory distributions being met. For example, some of these commenters believed that our proposed prioritization approach might result in the minimum only being met for Category Four.

Response: We thank the commenters for their support. In response to the commenters that disagreed that our proposed approach would result in the minimum statutory distributions being met, we are finalizing our approach, as proposed, to collect information regarding qualification for all four categories in the application to allow us to track progress in meeting all statutory requirements, and evaluate the need to modify the distribution methodology in future rulemaking. However, we continue to believe that our proposed approach will most likely result in the statutory minimum 10 percent distributions being met for all four of the statutory categories by the end of the 5-year distribution process for the 1,000 FTE slots. Therefore, as described in more detail later in this section, we are finalizing our proposal that the residency positions will be distributed to qualifying applicant hospitals using a method that prioritizes allotments based on HPSA scores.

Comment: Many commenters objected to some or all of the aspects of the proposed criterion that at least 50 percent of a program's training time occur at applicant hospital locations inside a HPSA in order for CMS to use that HPSA's score to prioritize the section 126 of the CAA application for that program. Some of these commenters stated that nonprovider settings inside the HPSA that are not applicant hospital locations, such as FQHCs and RHCs, are important contributors to care in the HPSA and training time at these sites should count. Several of these commenters added that training time in nonprovider settings counts for other GME purposes.

Other commenters objected to the existence of a minimum training time criterion inside of a HPSA at all, regardless of what types of locations. These commenters argued that many HPSA residents rely on care provided outside of their HPSA. Some commenters noted this is

particularly true for certain specialty care for which HPSA-residing patients are referred to teaching hospitals located outside the HPSA. Some of these commenters suggested we modify our proposal to include training locations within a HPSA and those within a reasonable distance of one. Several commenters provided specific recommendations for a reasonable distance, such as within 1 mile, 10 miles, 20 miles, or 25 miles. A commenter requested that all Indian and Tribal facilities be considered for prioritization regardless of where they are located.

According to some commenters, a minimum training time inside the HPSA would impede teaching hospitals' ability to structure programs to best meet the needs of the patients and the communities they serve, as well as make it difficult to satisfy administrative obligations such as accreditation standards. For example, some commenters indicated it would be impossible for some programs to satisfy this criterion because locations in a HPSA provide insufficient training opportunities for some specialties, and we would force hospitals to operate programs in areas that are ill-suited to sustain training programs.

Some commenters were opposed to the minimum training time criterion because they believe it would impose a recordkeeping burden on hospitals. A few commenters noted that normally, resident rotations are reported in IRIS in aggregate, whereas the proposed 50 percent training time criterion would demand individual resident tracking and reporting. Commenters stated that to attest to meeting the criterion, teaching hospitals would need to develop a new system and process to document and track section 126 of the CAA funded residents that is separate from the system and process used to track residents funded by other sources.

A commenter requested clarification on whether the minimum training time criterion is based on all residents in a program in aggregate or to individual residents.

Response: We appreciate commenters' concerns regarding the proposed criterion that at least 50 percent of a program's training time occur at applicant hospital locations inside a HPSA in order for CMS to use that HPSA's score to prioritize the section 126 of the CAA application



for that program. After consideration of these comments, we are modifying certain aspects of this prioritization criterion.

After considering the comments received, we agree with commenters that training should not be limited to hospital settings physically located in the HPSA to the exclusion of other settings physically located in the HPSA. For a geographic HPSA, any and all program training based on resident rotation schedules (or similar documentation) that occurs in the HPSA at program training sites that are physically located in the HPSA and treat the HPSA's population, including nonprovider settings and Veterans Affairs facilities, will count towards meeting the 50 percent training criterion. For a population HPSA, any and all program training based on resident rotation schedules (or similar documentation) that occurs in the HPSA at program training sites that are physically located in the HPSA and treat the HPSA's designated population, including nonprovider settings and Veterans Affairs facilities, will count towards meeting the 50 percent training criterion.

We disagree with commenters who objected to the existence of a minimum training time criterion inside of a HPSA at all. We acknowledge that many HPSA residents receive care provided outside of their HPSA in areas where the physician shortages are less severe. However, with the limited FTE slots available under section 126 of the CAA we are choosing at this time to prioritize in a clear way the care provided inside of HPSAs in order to increase the likelihood of residents choosing to practice in areas with more severe shortages. We seek comment to inform potential future rulemaking on incorporating a measure of care provided outside of a HPSA to HPSA residents into the section 126 of the CAA methodology.

We have considered the comment suggesting that all Indian and Tribal facilities be considered for prioritization regardless of where they are located. Given the unique relationship between the Medicare program and Indian and Tribal facilities, and the health care disparities that exist for the Indian and Tribal populations served by these facilities, we believe it would be appropriate to also prioritize applications for programs where the residents rotate into these

facilities. Specifically, for purposes of prioritization we will allow the training time spent in Indian and Tribal facilities outside of a HPSA to count towards the minimum training time criterion for that HPSA, up to a maximum of 45 percentage points of the 50 percentage points required.

We disagree with the commenters who claimed that the minimum training time criterion inside the HPSA forces a hospital to restructure its residency programs or operate programs that include training opportunities in areas that cannot support them. Section 126 of the CAA is a voluntary program. Hospitals can choose to apply for additional residency positions or not. We developed a prioritization methodology because we anticipate that the number of FTE slots requested will exceed the number available. If that were not the case the minimum training time criterion would have no effect since even applications at the lowest priority level (that is, applications for programs that do not meet the minimum training time criterion for any HPSA) would receive the number of FTE slots requested assuming all other applicable requirements were met. We understand that some commenters disagree with a prioritization method based on HPSA scores, but that is different from the prioritization method forcing a hospital to restructure residency programs or operate them in areas that cannot support them.

As noted in responses to similar comments on Category Four, we also disagree with the comments that a minimum rotation time criterion imposes a significant tracking or reporting requirement. We are not requiring hospitals to establish entirely new administrative structures to accommodate section 126 of the CAA FTEs. Hospitals regularly develop rotation schedules to facilitate residents' training at participating sites and a program's participating site information is generally readily available on the ACGME website. As such, we are specifying that the percentage of time that residents in the program spend in the HPSA and in Indian and Tribal facilities (if applicable) for purposes of prioritization is required to be based on resident rotation schedules (or similar documentation).

Regarding IRIS, we do not expect the existing reporting requirements to change for hospitals that receive section 126 of the CAA FTEs. In response to the question regarding whether the minimum training time criterion applies to all residents in aggregate or to individual residents, the criterion applies to the program in its entirety, not to individual residents. As such, hospitals are not expected to track the training time of individual residents so long as the program in its entirety meets the criterion as demonstrated by the rotation schedule.

Comment: Many commenters expressed concern about the accuracy of HPSA scores and appropriateness of their use. Several commenters stated that HPSA scores are not the most precise measures of barriers to access to care or health care workforce shortages. A commenter provided a link to a letter they had written to HRSA on recommendations to improve their HPSA scoring methodology, including counting residents and physicians differently in the population to provider ratio, including an older-adult measure in the primary care HPSA score, and taking steps to smooth out the volatility of HPSA scores to improve predictability for providers in shortage areas<sup>1</sup>. Another commenter provided a link to an academic article that argued HPSAs alone are an insufficient means to guide policies intended to address complex and interrelated health challenges<sup>2</sup>. Some commenters stated that the provider to population ratio is an important component of HPSA scores while the travel time to care outside of a HPSA is not. Some commenters argued that HPSA scores do not provide information on the availability of non-physician clinicians, such as nurse practitioners and physician assistants, or on the availability of non-primary care specialties, such as general surgery. Thus, according to the commenters, the HPSA score reflects an incomplete picture of physician availability in an area. A commenter claimed that some states game their HPSA scores or submit faulty data that incidentally lifts their scores. A commenter referenced HRSA's June 2020 RFI that sought ideas on improving its

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<sup>1</sup> <https://www.aha.org/system/files/media/file/2020/09/aha-comments-submitted-response-hrsas-rfi-health-professional-shortage-area-hpsa-scorin-9-18-20.pdf>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7182224/>

HPSA scoring methodology as an acknowledgment that the current system does not accurately capture local access to care challenges.

Response: We continue to believe that HPSA scores, while not a perfect measure, provide the best prioritization approach available at this time. They are transparent, widely used, publicly available, regularly updated, and have verifiable inputs for measuring the severity of a service area's need for additional providers. Consistent with the Administration's policy objectives and the authority provided to the Secretary under section 126 of the CAA, we have prioritized training programs that have a higher likelihood of training physicians that will practice in underserved communities with the greatest need.

With regard to the comment that HPSAs do not take into account the availability of non-physician clinicians in shortage areas, we believe that since the residency positions distributed under section 126 of the CAA are not available to non-physician clinicians, our focus should be on measuring physician shortages. In response to the commenters who expressed concerns related to HPSA scores being based on primary care specialties and not non-primary care specialties, we acknowledge this concern but note that the statutory Physician Bonus program utilizes primary care HPSAs for non-primary care specialties and we believe provides a currently feasible and appropriate template here.

Regarding the comment that claimed some states game their HPSA scores or submit faulty data that incidentally lifts their scores, the commenter did not provide any information to substantiate this claim.

We encourage stakeholders to continue to work with HRSA to improve HPSAs as part of its Shortage Designation Modernization Project (SDMP), which has been ongoing since 2013. We are also seeking comment on feasible alternatives to HPSA scores as a proxy for health disparities to inform potential future rulemaking regarding prioritization.

Comment: A commenter supported the use of geographic HPSA scores to prioritize applications, but opposed the use of population HPSA scores. The commenter indicated that

population HPSA designations are sought by areas that do not meet the criteria for geographic HPSA designations and there are so many population HPSAs that their inclusion would undermine legislative intent to target the distribution of residency positions to areas with the greatest need.

Response: Although we agree with the commenter's assessment that the inclusion of population HPSA scores changes the prioritization of some applications, we disagree with the commenter that the inclusion of population HPSAs undermines targeting the distribution of FTE slots to areas of greatest need. The more targeted underserved populations in population HPSAs are as equally deserving as the broader populations in geographic HPSAs, and the HPSAs scores for both types of HPSAs reflect the severity of the need. We also note that in the case of a population HPSA, the requisite amount of training time for the residency program must occur at facilities that treat the underserved population of the population HPSA.

Comment: Several commenters argued that HPSAs are designed to inform about health professional shortages and do not reflect the capacity of hospitals to train residents.

Response: Our use of HPSA scores for prioritization is not intended to measure a hospital's capacity to train residents. We rely on a training program's ACGME accreditation and the "demonstrated likelihood" criterion for that information.

Comment: A commenter alleged that the example distribution table we provided in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25509) is invalid because the number of areas and specific HPSA scores represented in it do not reflect actual data. The commenter provided their own HPSA table that includes data from June 2020 and that indicates there are too few primary care geographic and population HPSAs with scores ranging from 21 to 25 to distribute all 1,000 residency positions to hospitals that serve those HPSAs if award sizes are capped at 1.0 FTE, so that the majority of the awards would be made to hospitals that serve HPSAs with scores below 21.

Response: The table provided in the preamble of the proposed rule was not designed to project the likely distribution of FTEs under section 126 of the CAA, but to illustrate how the prioritization methodology would be applied in practice based on hypothetical data. The minimum score for an application to receive sufficient prioritization to receive an award will not be known until all of the applications are received and evaluated for an application year.

Comment: A commenter stated that HPSAs can overlap and expressed concern that hospitals may have trouble locating their HPSA scores. The commenter cautioned that unless CMS posts a list of HPSA scores, hospitals will not be able to assess the impact on residency training and ultimately on patients' access to physicians. Another commenter stated that we should be more transparent about HPSA scores and clearer about how HPSA scores will be assigned to applicant hospitals. A commenter stated that they performed a study of the HPSA scoring methodology that found that rural and frontier areas with populations less than 5,000 people received lower scores. The commenter concluded that the HPSA scoring system discriminates against populations at that level or lower.

Response: A primary care HPSA, either a geographic or population one, cannot overlap with any other primary care HPSAs. Similarly, a mental health HPSA, either a geographic or population one, cannot overlap with any other mental health HPSAs. However, there are areas that are designated as both mental health and primary care HPSAs, and have different scores for each. Overlap between primary care and mental health HPSAs may be either complete or partial.

Hospitals can find information about the HPSA or HPSAs associated with their training program locations using the HRSA search tool at: <https://data.hrsa.gov/tools/shortage-area/by-address>. When a hospital finds that its residency training program meets the requirement to be prioritized by more than one HPSA, it may choose which HPSA to use on its application. A hospital cannot choose more than one HPSA to prioritize its application. CMS does not assign a HPSA to prioritize an application.

The HPSA scoring methodology is a relative measure that is applied uniformly and equitably regardless of the size of the underlying population. Hospitals that would like to learn more about how HRSA developed the HPSA scoring methodology through notice and comment rulemaking and how it calculates the HPSA scores can find out more by contacting HRSA or visiting this web page: <https://www.hhs.gov/guidance/document/hpsa-and-muap-hpsa-scoring-criteria>.

Comment: Several commenters requested that CMS clarify whether there is any difference in prioritization between primary care or mental health only geographic HPSAs and population HPSAs.

Response: There is no difference in prioritization with respect to the HPSA score of a primary care geographic HPSA, a mental health only HPSA, or a population HPSA. For example, a HPSA score of 21 is treated the same in the prioritization regardless of whether it is associated with a primary care geographic HPSAs, a mental health only HPSA, or a population HPSA.

Comment: Some commenters recommended other methods of prioritizing applications to distribute FTE slots to areas that are in most need. A commenter recommended prioritizing applications by a composite of HPSA scores and Medically Underserved Area (MUA) scores. Another commenter suggested that for the 60 percent of residency positions not required to be allocated to hospitals that meet the statutory eligibility categories, priority should be given to hospitals that are located in MUAs, or service areas or populations designated as medically underserved by state health entities. A commenter urged CMS to prioritize applications for addiction medicine in mental health only HPSAs. Other commenters requested that any program for any physician specialty be allowed to use the score from a mental health only HPSA, with preference given to applications for psychiatry training programs. A commenter stated that CMS should use the Medicare disproportionate share hospital (DSH) patient percentage of the applicant hospital to prioritize applications. Some commenters indicated that CMS should

prioritize applications from small hospitals with less than 250 beds, and hospitals with only one residency program.

Response: We thank the commenters for their feedback. As indicated earlier, we continue to believe that HPSA scores, while not a perfect measure, provide the best prioritization approach available at this time. They are transparent, widely used, publicly available, regularly updated, uniformly calculated, and have verifiable inputs for measuring the severity of a service area's need for additional physicians. Different methodologies that would be used by individual states to designate areas or populations as underserved do not possess all of these characteristics.

We also do not believe that MUAs are as appropriate as HPSAs for purposes of section 126 of the CAA. HPSAs were designed for the National Health Service Corps to distribute clinicians to where they are needed most, they form the statutory basis for the Medicare Physician Bonus Program, and geographic HPSAs are explicitly referenced in section 126 of the CAA. In contrast, MUAs were designed to help establish health maintenance organizations and community health centers<sup>3</sup>, play no role in the Medicare Physician Bonus Program, and are not referenced in section 126 of the CAA.

We disagree that any residency training program regardless of specialty should be allowed to use the score from a mental health only HPSA for prioritization. These areas are only designated as shortage areas for mental health services and such a wide use would be broadly inconsistent with the Medicare Physician Bonus Program. Therefore, we are allowing only programs for Psychiatry and subspecialties of Psychiatry to use the score from a mental health only HPSA. We note that the subspecialties of Psychiatry include addiction psychiatry and multispecialty addiction medicine.

We disagree with the commenter who stated that CMS should use the Medicare DSH patient percentage of the applicant hospital to prioritize applications. We believe that using the

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<sup>3</sup> <https://bhwh.hrsa.gov/workforce-shortage-areas/shortage-designation#mups>



DSH patient percentage is a less targeted way to increase the likelihood of residents choosing to practice in areas with more severe shortages.

We disagree with commenters who indicated that CMS should prioritize applications from small hospitals with less than 250 beds and generally smaller hospitals with only one residency program to the extent that the commenters meant irrespective of the HPSA scores associated with these applications. However, we do believe there is merit in considering smaller hospital size as a tiebreaker when prioritizing applications with equal HPSA scores in order to further reduce the impact of proration. Of the two suggestions by commenters, bed count is one of the most transparent and currently used measures of hospital size (42 CFR § 412.105(b)). Therefore, if there are insufficient FTE slots remaining to distribute to applications with equal HPSA scores, we will first distribute FTE slots to applications from hospitals with less than 250 beds. If there are insufficient FTE slots to distribute to applications from hospitals with less than 250 beds, only then would we prorate among those applications. If there are sufficient slots to distribute to applications from hospitals with less than 250 beds, we would prorate the remaining slots among the applications from hospitals with 250 beds or more.

Comment: Several commenters who otherwise supported the HPSA scoring methodology recommended the incorporation of an “impact factor” that measures the proportion of residents that ultimately go on to practice in HPSAs. The use of this additional factor, according to commenters, would help ensure that section 126 of the CAA distributions support physician pipelines that produce lasting benefits for underserved areas. A commenter noted that one research-focused non-profit already documents the flow of residents to eventual practice locations for family medicine programs. Commenters also stated that the use of such an impact factor is aligned with the President’s Executive Order on “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” which calls on federal agencies to recognize and address policies and programs that serve as barriers to equal opportunity. Another commenter expressed a similar view, that hospitals should be given priority

if their training programs have records of sending residents on to practice in provider shortage areas.

Response: We thank the commenters for their feedback and agree that a measure of the extent to which residents later practice in underserved areas may be beneficial. In order to inform potential future rulemaking, we welcome further comment on how to best estimate the impact factor using appropriately comprehensive and transparent data sources across physician specialties, and how to weigh an impact factor in the prioritization.

Comment: A commenter expressed their opinion that if Congress passes new legislation increasing the number of available GME training residency positions, then the distribution process will need to be changed.

Response: Because we consider this comment to be outside the scope of the section 126 proposals, we are not directly responding to this comment in this final rule with comment period. However, we appreciate the commenter's concern and expect that any future changes following new legislation would be made through notice and comment rulemaking.

In summary, after considering the comments received, we are finalizing the following prioritization policy. Applications from hospitals for a fiscal year are grouped by the HPSA score of the application, with each grouping consisting of those hospitals with the same HPSA score. Applications are prioritized by descending HPSA score. Within each grouping, applications with equal priority (i.e. those with the same HPSA score) are next grouped by whether the application is from a hospital with a bed size of less than 250 beds, or 250 beds or more. Applications from hospitals with less than 250 beds are prioritized within each grouping. The number of beds in the hospital is determined in accordance with § 412.105(b).

If there are insufficient slots available to be distributed to all applications with both the same HPSA score and the same bed size grouping, the remaining available slots are prorated among those applications.

e. Alternative Considered for Prioritization

As an alternative to our proposed prioritization approach, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25509 through 25510), we considered a simpler prioritization approach for FY 2023 that would allow additional time to work with stakeholders to develop a more refined approach for future years. Under this alternative approach, CMS would distribute 200 additional residency positions for FY 2023 among hospitals that qualify in Category One, Category Two, Category Three, and/or Category Four, with higher priority given to applications from hospitals that qualify in more categories. That is, hospitals that qualify under all four categories would receive top priority, hospitals that qualify under any three of the four categories would receive the next highest priority, then any two of the four categories, and finally hospitals that qualify under only one category. Under this alternative proposal considered, in the proposed rule, we stated that we would distribute 1.0 FTE to each hospital that qualified under all four categories, prorating only in the event that the number of hospitals that qualified under all four categories exceeds 200. If the number of hospitals that qualified under all four categories is less than 200, each hospital that qualified under three out of four categories would receive 1.0 FTE, with proration again occurring only in the event that the number of hospitals that qualified under three out of four categories exceeds the number of positions remaining. We would continue in this manner, moving on to hospitals that qualified under two out of four and one out of four categories until all 200 positions are distributed.

We sought comment on this alternative prioritization approach considered to allow for additional time to work with stakeholders to develop a more refined approach for future years.

Comment: Many commenters supported the proposed alternative prioritization approach. Commenters stated it would be less burdensome, more straightforward, and better reflect Congressional intent. Some commenters indicated this was similar to part of the approach used for Section 5503 of the Affordable Care Act. Several commenters indicated that CMS should only use the alternative method for FY 2023 and should work with stakeholders to develop a better approach for future years. Some commenters indicated that because the four eligibility

categories are treated equally in the statute, hospitals that qualify under each one should be equally positioned to receive FTE slots. Several commenters stated that our proposed prioritization method based on HPSA scores would disadvantage many hospitals that qualify only under Category One, Category Two, and/or Category Three, and therefore would be contrary to Congressional intent. Some commenters indicated that for applications from hospitals that qualify under the same number of statutory categories under the alternative method, we secondarily prioritize those applications from hospitals training 10 FTEs or more above their caps, with those most above their cap receiving slots first.

Response: We thank the commenters for their feedback on the prioritization method described in the “Alternatives Considered” portion of the proposed rule.

We acknowledge that our proposed method based on HPSA scores prioritizes applications for programs where the residents spend significant time in a geographic or population HPSA. This is intentional. It is appropriate and entirely consistent with the statute for CMS to establish a sufficiently focused prioritization methodology so that our policy objectives for section 126 of the CAA regarding reducing health care disparities for medically underserved communities are most likely to be achieved. We disagree with commenters who believe our proposed prioritization method based on HPSA scores is not likely to achieve those goals. The locations of residents’ training affects where they practice, as noted by other commenters. We acknowledge some similarity between aspects of the alternative approach and part of the approach taken in the implementation of section 5503 of the Affordable Care Act, but believe our approach based on HPSA scores is a more targeted improvement over section 5503’s approach. We also note that as discussed earlier, the vast majority of commenters strenuously opposed our proposed 1.0 FTE limit per hospital and in response to those comments we are increasing that limit in this final rule with comment period.

We considered the comments that we should secondarily prioritize those applications from hospitals training 10 FTEs or more above their caps, with those most above their cap

receiving slots first. We disagree with these comments because this secondary prioritization method would be less effective at increasing the likelihood of residents choosing to practice in areas with more severe shortages compared to using the method we are adopting for prioritization based on HPSA scores.

Comment: Some commenters opposed the use of the alternative method and indicated it would exclude hospitals in states that do not have new medical schools or additional locations and branch campuses from top priority, disadvantaging many rural states. Commenters stated that some of those states have made efforts to address physician workforce shortages by increasing medical school class sizes rather than establishing new medical schools. Some commenters stated that new allopathic medical schools train fewer family physicians than older medical schools so the alternative method disadvantages primary care.

Response: We agree with commenters that the alternative method would exclude hospitals in states that do not have new medical schools or additional locations and branch campuses from top priority (that is, qualifying under all four categories) because those hospitals cannot qualify under Category Three. In addition, as several commenters pointed out, and as discussed earlier, section 126 of the CAA addresses a nationwide provider shortage and ensures minimum allotments to certain categories of hospitals; prioritization for all 1,000 residency positions distributed under this section to hospitals that meet all four statutory eligibility categories could lead to the possibility that hospitals located in the following 20 areas (15 states, one district and four territories) would be awarded zero positions: Alaska, American Samoa, Guam, Hawaii, Iowa, Maine, Maryland, Minnesota, Montana, Nebraska, New Hampshire, North Dakota, Northern Mariana Islands, Oregon, Rhode Island, South Dakota, U.S. Virgin Islands, Vermont, Washington D.C., and Wyoming. We believe that prioritization according to the severity of the provider shortage is the more equitable approach to distribution. Therefore, after consideration of the comments received, and the reasons discussed, we are not finalizing the alternative methodology for FY 2023.

f. Distributing At Least 10 Percent of Positions to Each of the Four Categories

Section 1886(h)(9)(B)(ii) of the Act requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to each of the following categories of hospitals discussed earlier: Category One, Category Two, Category Three, and Category Four.

In the proposed rule (86 FR 25510), we stated that because it is possible for a hospital to be eligible for distribution of additional residency positions via more than one of the four categories, Category One, Two, Three or Four, there is a strong likelihood that by prioritizing applications by HPSA score the result will be that 10 percent or more of the additional residency positions will be distributed to hospitals in each of the four categories. In the proposed rule (86 FR 25510), we proposed to collect information regarding qualification for all four categories in applications to allow us to track progress in meeting all statutory requirements, and evaluate the need to modify the distribution methodology in future rulemaking.

We received no comments on this proposal. Therefore, we are also finalizing our plan as proposed to collect information regarding qualification for all four categories to allow us to track progress in meeting all statutory requirements, and evaluate the need to modify the distribution methodology in future rulemaking.

g. Hospital Attestation to National CLAS Standards

In order to ensure that the residents are educated and trained in culturally and linguistically appropriate policies and practices, we proposed that all applicant hospitals would be required to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) to ensure the section 126 of the CAA additional residency position allocation broadens the availability of quality care and services to all individuals, regardless of preferred language, cultures, and health beliefs. (For more information on the CLAS standards, please refer to <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>)

Comment: Several commenters expressed support for our proposal that all applicant hospitals be required to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care.

Response: We thank the commenters for their support.

Comment: A few commenters expressed support for the aims of the National CLAS Standards, but also raised concerns about requiring hospitals to attest to a uniform benchmark. A commenter argued that these criteria can be difficult to measure objectively, and recommended that CMS modify the application requirement so that hospitals are still eligible for residency positions if they attest that they support and are making progress toward meeting the National CLAS standards. Another commenter requested that hospitals be granted flexibility in demonstrating their commitment to culturally and linguistically appropriate training, and argued that many of the CLAS standards overlap with requirements that hospitals already meet, including the Internal Revenue Service (IRS) requirements for 501(c)(3) hospitals; the Joint Commission Standards related to language access and interpreter services; and ACGME core competency requirements. Another commenter cited similar requirements and provided several examples of initiatives that its own members have undertaken, but asserted that the concept of a national standardized or mandated curriculum is inappropriate, and that teaching hospitals should have the freedom to design and implement their own educational programs.

Response: We appreciate commenters' feedback and support. We acknowledge that other accreditation boards list some of the same requirements as the National CLAS standards requirements, but we believe that the National CLAS standards are more aligned with the Administration's commitment to addressing healthcare barriers, which include that residents are educated and trained in culturally and linguistically appropriate policies and practices. However, we will continue to consider further adjustments going forward if appropriate. For additional information about implementing the National CLAS standards within your organization to help

advance and sustain culturally and linguistically appropriate services, please visit

<https://thinkculturalhealth.hhs.gov/>.

After consideration of the comments we received, we are finalizing our proposal that all applicant hospitals would be required to attest that they meet the National CLAS Standards.

h. Payment for and Aggregation of Additional FTE Residency Positions Awarded Under Section 126 of the CAA

Section 1886(h)(9)(D) requires that CMS pay a hospital for additional positions awarded under this paragraph using the hospital's existing direct GME PRAs for primary care and OB/GYN programs and non-primary care programs consistent with the regulations at §413.77. However, similar to our implementation of section 5503 in the CY 2011 OPPS final rule (75 FR 72192) with respect to the application of direct GME PRAs for primary care and nonprimary care residents, we proposed that a hospital that receives additional positions under section 126 of the CAA would be paid for FTE residents counted under those positions using the same primary care and nonprimary PRAs for which payment is made for FTE residents subject to the 1996 FTE cap.

We received no comments on our proposal that additional positions received under section 126 of the CAA would be paid using the same primary care and nonprimary care PRAs which are used with respect to FTE residents subject to the 1996 cap, therefore we are finalizing as proposed. We will revise Worksheet E-4 to add a line on which hospitals will report the number of FTEs by which the hospital's FTE caps were increased for direct GME positions received under section 126 of the CAA.

i. Conforming Regulation Amendments for 42 CFR 412.105 and 42 CFR 413.79

Section 126 of the CAA, under subsection (b), amends section 1886(d)(5)(B) of the Act to provide for increases in FTE resident positions for IME payment purposes as well.

Specifically, a new section 1886(d)(5)(B)(xii) of the Act was added, stating that for discharges occurring on or after July 1, 2023, if additional payment is made for FTE resident positions



distributed to a hospital for direct GME purposes under section 1886(h)(9) of the Act, the hospital will receive appropriate IME payment based on the additional residency positions awarded using the same IME adjustment factor used for the hospital's other FTE residents. We proposed conforming amendments to the IME regulations at 42 CFR 412.105 to specify that effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in 42 CFR 413.79(p) are met.

We received no comments on our proposed amendments to 42 CFR 412.105 to implement section 1886(d)(5)(B)(xii) of the Act with respect to IME payments. Therefore, we are finalizing our proposal to revise 42 CFR 412.105 by specifying that effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in 42 CFR 413.79(p) are met. We will revise Worksheet E Part A to add a line on which hospitals will report the number of FTEs by which the hospital's FTE caps were increased for IME positions received under section 126 of the CAA.

We also proposed to amend our regulations at 42 CFR 413.79 to specify that-- (1) for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS; and (2) FTE resident cap positions added under section 126 of the CAA (Pub. L. 116-260) may be used in a Medicare GME affiliation agreement beginning in the 5<sup>th</sup> year after the effective date of those FTE resident cap positions.

Comment: A commenter supported our proposal to allow residency positions added under section 126 of the CAA to be used in a Medicare GME affiliation agreement beginning in the 5<sup>th</sup> year after the effective date of the hospital's section 126 of the CAA award. Several

commenters recommended additional regulatory action to ensure that after 5 years, residency positions remain allocated to programs where 50 percent of training takes place in a HPSA and be used for rural and primary care priorities. These commenters further recommended regulatory action to ensure that residency positions awarded under section 126 of the CAA not be repurposed for different strategic directions of the hospital. A commenter requested clarification whether residency positions, once awarded, are program-specific, and whether they may be used to support fellowships.

Response: We thank the commenters for their feedback. When a hospital applies for residency positions under section 126 of the CAA, it is attesting that the residency positions will be used for a specific program. Therefore, the residency positions awarded under section 126 of the CAA should be used for training residents in the program associated with the hospital's section 126 of the CAA application. Furthermore, section 126 of the CAA requires that not later than September 30, 2025, and again not later than September 30, 2027, the Comptroller General of the United States conduct a study and submit to Congress a report on the implementation of section 126 of the CAA.

In response to the comment that CMS take regulatory action to ensure that after 5 years the awarded residency positions are not being used for purposes other than those for which they were awarded, at this time, we are not including any additional requirements that must be met 5 years after the effective date of a hospital's section 126 award. However, we will consider additional guardrails for future rulemaking if residency positions awarded under section 126 are not being used for their intended purposes. In response to the question regarding fellowships, hospitals may apply for residency positions for fellowships under section 126.

After consideration of the comments we received, and for the reasons previously discussed, we are finalizing our proposed amendments to 42 CFR 413.79.

j. Prohibition on Administrative and Judicial Review

Section 126 of the CAA, under clause (c), prohibits review of section 1886(h)(9) of the Act. Specifically, it amends section 1886(h)(7)(E) of the Act by inserting “paragraph (9),” after “paragraph (8),”. Therefore, we proposed that the determinations and distribution of residency positions under sections 1886(d)(5)(B)(xii) and 1886(h)(9) of the Act are final without administrative or judicial review.

We received no comments on the proposal that determinations and distribution of residency positions under sections 1886(d)(5)(B)(xii) and 1886(h)(9) of the Act are final without administrative or judicial review, and therefore are finalizing our proposed policy.

k. Report by the Comptroller General

We noted in the proposed rule that section 126(d) of the CAA requires the Comptroller General of the United States to conduct a study and submit to Congress two reports on section 126, after the 5-year period of implementation is complete. No comments were received regarding this requirement.

l. Application Process for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25510 through 25511), we proposed that an application would be considered timely for additional residency positions effective July 1 of a fiscal year if it is completely submitted by January 31 of the prior fiscal year. We also proposed that the following information be submitted on an application to be considered completely submitted:

- The name and Medicare provider number of the hospital.
- The name of the Medicare contractor to which the hospital submits its Medicare cost report.
- The residency program for which the hospital is applying to receive an additional position.

- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Including copies of Worksheets E, Part A, and E-4).

- If the hospital qualifies under “Demonstrated Likelihood” Criterion 1 (New Residency Program), which of the following applies:

- Application for approval of the new residency program has been submitted to the ACGME or the American Board of Medical Specialties (ABMS) by the application deadline for that year.

- The hospital has submitted an institutional review document or program information form concerning the new residency program in an application for approval of the new program by the application deadline for that year.

- The hospital has received written correspondence by the application deadline for that year from the ACGME or ABMS acknowledging receipt of the application for the new residency program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

- If the hospital qualifies under “Demonstrated Likelihood” Criterion 2 (Expansion of an Existing Residency Program), which of the following applies:

- The hospital has approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

- The hospital has submitted by the application deadline an institutional review document or program information form for the expansion of the existing residency training program.

- Identification of the category that describes the hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act):

(I) The hospital is located in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act) or is treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act.

(II) The reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii) of the Social Security Act) is greater than the otherwise applicable resident limit.

(III) The hospital is located in a State with a new medical school (as specified in section 1886(h)(9)(B)(ii)(III)(aa) of the Act), or with additional locations and branch campuses established by medical schools (as specified in section 1886(h)(9)(B)(ii)(III)(bb) of the Act) on or after January 1, 2000.

(IV) The hospital serves areas designated as health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary.

- The HPSA (if any) served by the residency program for which the hospital is applying and the HPSA score for that HPSA.

- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following:

“I hereby certify that the hospital is a Qualifying Hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act).

“I hereby certify the “demonstrated likelihood” that the hospital will fill the position made available under section 126 of Division CC of the Consolidated Appropriations Act, 2021 within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary (per section 1886(h)(9)(B)(i) of the Social Security Act).

“I hereby certify that the hospital agrees to increase the number of its residency positions by the amount the hospital’s FTE resident caps are increased under section 126 of Division CC of the Consolidated Appropriations Act, 2021, if awarded positions (per section 1886(h)(9)(C)(ii) of the Social Security Act).

“I hereby certify that if the residency program for which the hospital is applying serves a geographic or population Health Professional Shortage Area (HPSA), that the hospital has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in that HPSA, any such locations serve the designated underserved population of that HPSA in the case of a population HPSA, and in the residency program for which the hospital is applying, at least 50 percent of the residents training time over the duration of the program occurs at those locations in the HPSA.

“I hereby certify that the hospital meets the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).

“I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.”

We also proposed that the completed application be submitted to CMS using an online application system under development. A link to the online application system as well as instructions for accessing the system and completing the online application process will be made

available on the CMS Direct GME website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME>.

Comment: Many commenters expressed concern that an award notification date as late as January 31 of the fiscal year of the FTE increase would leave teaching hospitals without the time needed to recruit resident candidates that would be funded with those awards, as the recruitment process begins several months earlier. Some commenters noted that January 31 is the last day that hospitals can amend their residency quotas for national resident matching purposes; they argued that, without knowing in advance how many residency positions they will receive under section 126, hospitals would have difficulty adjusting their program sizes for the purposes of matching with residents, which would affect their ability to recruit new residents to their programs.

Several commenters recommended approaches to better align the application and award process with the timing of accreditation decisions and the national residency matching timeline. Commenters also recommended flexibility where appropriate to accommodate differing fiscal years. All commenters that wrote about the notification date requested that it be moved forward and offered a range of alternative dates, from October 1 of the fiscal year in which the residency positions will be effective to no later than early or mid-December of the fiscal year the residency positions are effective. A commenter recommended postponing the application deadline for the first round to March 31, 2022.

Response: We appreciate commenters bringing this issue to our attention. We agree with the suggested date of March 31st as the application deadline. With regards to the date of the announcement of residency positions distributed under section 126, the Secretary is required to notify hospitals of the number of positions distributed by January 31 of the fiscal year of the increase. However, in light of the commenters' concerns, we will consider completing this announcement earlier if possible.

After incorporating the final policy described previously, in order to be considered for an increase in its FTE resident caps under section 126, each qualifying hospital must submit a complete and timely application. An application is considered timely for additional residency positions effective July 1 of the applicable fiscal year if it is submitted by March 31 of the prior fiscal year. (For example, for awarded residency positions which will be effective July 1, 2023 (FY 2023), the completed application must be submitted by March 31, 2022 and hospitals will be notified of the increases they are awarded by January 31, 2023.) The following information must be submitted on the application in order for it to be considered complete:

- The name and Medicare provider number (CCN) of the hospital.
- The name of the Medicare Administrative Contractor to which the hospital submits its Medicare cost report.

- The residency program for which the hospital is applying to receive an additional position(s).

- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Including copies of Worksheets E, Part A, and E-4).

- If the hospital qualifies under “Demonstrated Likelihood” Criterion 1 (New Residency Program), which of the following applies:

- Application for accreditation of the new residency program has been submitted to the Accreditation Council for Graduate Medical Education (ACGME) (or application for approval of the new residency program has been submitted to the American Board of Medical Specialties (ABMS)) by March 31, 2022.

- The hospital has received written correspondence from the ACGME (or ABMS) acknowledging receipt of the application for the new residency program, or other types of communication concerning the new program accreditation or approval process (such as notification of site visit) by March 31, 2022.



- If the hospital qualifies under “Demonstrated Likelihood” Criterion 2 (Expansion of an Existing Residency Program), which of the following applies:

- The hospital has received approval by March 31, 2022 from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

- The hospital has submitted a request by March 31, 2022 for a permanent complement increase of the existing residency training program.

- The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

- Identification of the categories that describe the hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act):

- (I) The hospital is located in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act) or is treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act.

- (II) The reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii) of the Social Security Act) is greater than the otherwise applicable resident limit.

- (III) The hospital is located in a State with a new medical school (as specified in section 1886(h)(9)(B)(ii)(III)(aa) of the Act), or with additional locations and branch campuses established by medical schools (as specified in section 1886(h)(9)(B)(ii)(III)(bb) of the Act) on or after January 1, 2000.

- (IV) The hospital serves an area designated as a health professional shortage area (HPSA) under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary).

- The HPSA (if any) served by the residency program for which the hospital is applying and the HPSA ID for that HPSA.

- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following:

“I hereby certify that the hospital is a Qualifying Hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act).”

“I hereby certify the “demonstrated likelihood” that the hospital will fill the position made available under section 126 of Division CC of the Consolidated Appropriations Act, 2021 within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary (per section 1886(h)(9)(B)(i) of the Social Security Act).”

“I hereby certify that if my application is for a currently accredited residency program, the number of full-time equivalent (FTE) positions requested by the hospital does not exceed the number of positions for which the program is accredited.”

“I hereby certify that if my hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME, the number of FTE positions requested by the hospital does not exceed the number of previously approved unfilled residency positions.”

“I hereby certify that if my application is for a residency training program with more than one participating site, I am only requesting the FTE amount that corresponds with the training occurring at my hospital, and any FTE training occurring at nonprovider settings consistent with 42 CFR 413.78.”

“I hereby certify that the hospital agrees to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased under section 126 of Division CC of the Consolidated Appropriations Act, 2021, if awarded positions (per section 1886(h)(9)(C)(ii) of the Social Security Act).”

“I hereby certify that (choose one):

In the geographic HPSA the hospital is requesting that CMS use for prioritization of its application, at least 50 percent of the program’s training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the population of the HPSA and are physically located in the HPSA.

In the population HPSA the hospital is requesting that CMS use for prioritization of its application, at least 50 percent of the program’s training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the designated underserved population of the HPSA and are physically located in the HPSA.

In the geographic HPSA the hospital is requesting that CMS use for prioritization of its application, at least 5 percent of the program’s training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the population of the HPSA and are physically located in the HPSA, and the program’s training time at those sites plus the program’s training time at Indian or Tribal facilities located outside of the HPSA is at least 50 percent of the program’s training time.

In the population HPSA the hospital is requesting that CMS use for prioritization of its application, at least 5 percent of the program’s training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the designated underserved population of the HPSA and are physically located in the HPSA, and the program’s training time at those sites plus the program’s training time at Indian or Tribal facilities located outside of that HPSA is at least 50 percent of the program’s training time.

None of the above apply.”

“I hereby certify that the hospital meets the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).”

“I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under Federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.”

The completed application must be submitted to CMS using an online application system. A link to the online application system as well as instructions for accessing the system and completing the online application process will be made available on the CMS Direct GME website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME>.

We note that we have modified the application so that hospitals no longer need to furnish a HPSA score. Instead, when applicants include the HPSA ID associated with the geographic or population HPSA included in their application the HPSA score will automatically populate. In preparing its application for additional residency positions, hospitals should refer to HRSA’s Find Shortage Areas by Address (<https://data.hrsa.gov/tools/shortage-area/by-address>) to obtain the HPSA ID of the HPSA served by the program and include this ID in its application. Using this HPSA Find Shortage Areas by Address, applicants may enter the address of a training location (included on the hospital’s rotation schedule or similar documentation), provided the location chosen participates in training residents in a program where at least 50 percent (5 percent if an Indian and Tribal facility is included) of the training time occurs in the HPSA. Each year in November, prior to the beginning of the application period, CMS will request

HPSA ID and score information from HRSA so that recent HPSA information is available for use for the application period. CMS will only use this HPSA information, HPSA ID's and their corresponding HPSA scores, in order to review and prioritize applications. To assist hospitals in preparing for their applications, the HPSA information received from HRSA will also be posted when the online application system becomes available on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME>.

The information will also be posted on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices>. Click on the link on the left side of the screen associated with the appropriate final rule home page or “Acute Inpatient—Files for Download.”

The burden associated with this information collection requirement is the time and effort necessary to review instructions and register for the electronic submission system as well as the time and effort to gather, develop and submit various documents associated with a formal request of resident position increases from teaching hospitals to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA); and as discussed in section III. of this final rule with comment period, the burden associated with these requests is captured in an information collection request currently available for public review and comment. The 60-day notice published on October 22, 2021 (86 FR 58664).

Lastly, we received public comments that were outside the scope of the GME proposals included in the FY 2022 IPPS/LTCH PPS proposed rule. These comments were related to: Medicare GME cap policies, promoting legislation to modernize and expand GME funding, incentivizing collaborative and team-based environments for health care practitioners, facilitating care delivery across states, funding for interprofessional primary care teams, rural recruitment and rotations for specialty residencies and fellowships, analysis of GME self-funding, large primary care group practices and preceptorships. Because we consider these public comments to

be outside the scope of the proposed rule, we are not addressing them in this final rule. We may consider these public comments for possible proposals in future rulemaking.

#### 4. Implementation of Section 127 of the CAA, “Promoting Rural Hospital GME Funding Opportunity”

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106-113) (BBRA) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) stating that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area, or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital’s cap on the number of FTE residents under subsection (F), in an appropriate manner in order to encourage training of physicians in rural areas. Section 407(c) of Pub. L. 106-113 was effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000 interim final rule with comment period (65 FR 47026, 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39828, 39902 through 39909) where we implemented section 407(c) of Pub. L. 106-113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME.

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital’s FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an

existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57027), we finalized a revision to the regulations at § 413.79(k) (and which, in turn, affect IME adjustments under § 412.105(f)(1)(x)) to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital would be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation would take effect. However, as previously stated, due to the statutory language at sections 1886(d)(5)(B) and 1886(h)(4)(H)(iv) of the Act as implemented in our regulations at §§ 412.105(f)(1)(v)(F) and 413.79(d)(7), except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, FTE residents in a rural training track (RTT) program at the urban hospital are subject immediately to the 3-year rolling average for direct GME and IME. In addition, under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time).

Since implementation of the rural training track provision from the BBRA of 1999, stakeholders and advocates of residency training in rural areas have raised concerns about inequities and unintended consequences of the BBRA provision. First, the BBRA provision allows an urban hospital to receive additional cap slots based on the time that residents in the RTT train at the urban hospital. However, the provision does not specify that the Secretary

provide a cap adjustment for rural hospitals participating in RTTs. As a result, unless the RTT program was new, the rural hospital could not receive FTE resident cap increases, resulting in direct GME and IME payments going only to the urban hospital for the urban portion of the training, with no attending funding going to the rural hospital for the rural portion of the training. Second, the statutory provision does not specify that the Secretary may provide a cap adjustment to urban hospitals or rural hospitals when an urban hospital adds additional rural locations to already existing RTTs. Third, the provision stated that the Secretary would adjust the caps of an urban hospital that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area. Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine programs in the “1-2 format” (meaning, residents in the 1-2 format receive their first year experience at a core family medicine program in an urban area, and their second and third year experiences at another site, which may or may not be rural). Because the ACGME has historically accredited family medicine programs in the 1-2 format, CMS interpreted the provision to mean that the development of rural tracks in specialties other than family medicine may not be feasible. Fourth, residents added to an RTT were previously not exempt from the 3-year rolling average for IME and direct GME. We believe that section 127 of the CAA remedies each of these concerns, as we explain in more detail in this final rule with comment period.

a. Cap Adjustment for Urban and Rural Hospitals Participating in Rural Training Track Programs

As amended by the BBRA, section 1886(h)(4)(H)(iv) of the Act provided for IME and direct GME FTE resident cap adjustments for an urban hospital that establishes separately accredited rural tracks; however, the statute did not provide for a similar adjustment to rural hospitals participating in rural tracks. Specifically, section 1886(h)(4)(H)(iv) of the Act refers to the case of a hospital that is not located in a rural area but establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area. Because of this



explicit incentive and permission for FTE resident cap adjustments for an urban hospital that establishes a rural track, the rural track does not need to be new for Medicare payment purposes, as it otherwise would in order for the urban hospital to qualify for the FTE resident cap adjustments. That is, under section 1886(h)(4)(H)(iv) of the Act, if an urban hospital already had an accredited family medicine residency program, it could establish from that existing family medicine program, for the first time, a rural track, and, assuming all applicable requirements are met, that urban hospital could receive IME and direct GME FTE resident cap adjustments.

However, with regard to a rural hospital participating in the second and third years of training in the rural track, since the BBRA language did not mention cap adjustments to rural hospitals, only if the program is new for Medicare payment purposes can the rural teaching hospital also receive an FTE resident cap adjustment for the program. Under § 413.79(e)(3), any time that a rural hospital participates in training residents in a new program, the rural hospital may receive an increase to its FTE resident caps. We refer readers to the FY 2010 IPPS/LTCH PPS final rule for the criteria identifying a new program for Medicare payment purposes (74 FR 43908 through 43917)). In this case, a rural track established from an already existing urban family medicine program would not meet the newness requirement for the rural hospital. Consequently, Division CC, section 127 of the CAA 2021 revised section 1886(h)(4)(H)(iv) of the Act to state that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, the Secretary must adjust in an appropriate manner the limitation under subparagraph (F) for such hospital *and each such hospital located in a rural area* that participates in such a training. This revision provides for cap adjustments for both the urban teaching hospital and the rural teaching hospital(s). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25513), we proposed that each time an urban hospital and rural hospital establish an RTT program for the first time, even if the RTT program does not meet the newness criteria for Medicare payment purposes, both the urban and rural hospitals may receive a rural track FTE limitation. For example, Urban Hospital A has an existing internal medicine

program. In July 2023, it partners with Rural Hospital 1 to create a RTT from the existing internal medicine program. We proposed that both Urban Hospital A and Rural Hospital 1 may receive adjustments to their resident caps (rural track FTE limitations) to reflect their portions of FTE residents training in the RTT. We proposed to make various changes throughout the regulations text at 42 CFR 413.79(k) “Residents training in rural track programs” to accommodate the rural track FTE limitations for both urban and rural hospitals. We also provide examples in this final rule with comment period, regarding how the rural track FTE limitations are calculated, according to the same methodology already in place at 42 CFR 413.79(k)(1) and as previously explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57028).

b. Cap Adjustments When the Urban Hospital Adds Additional Rural Training Tracks

As previously stated, under section 1886(h)(4)(H)(iv) *prior* to enactment of the CAA, if an urban hospital already had an accredited family medicine residency program, it could, for the first time, establish a rural track from that existing family medicine program and, assuming all applicable requirements were met, such hospital could receive the IME and direct GME FTE resident cap adjustments. Because section 1886(h)(4)(H)(iv) of the Act gave this explicit permission for FTE resident cap adjustments to an urban hospital that establishes a rural track, the rural track program does not need to be new for Medicare payment purposes in order for the urban hospital to qualify for the FTE resident cap adjustments. (We refer readers to the FY 2010 IPPS/LTCH PPS final rule for the criteria identifying a new program for Medicare payment purposes (74 FR 43908 through 43917)). However, after establishing its first RTT, the urban hospital can receive a rural track limitation adjustment for additional established RTTs only if those additional programs are “new” for Medicare payment purposes. As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25513), we believe that section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act such that it permits us to adjust the resident caps of an urban hospital wishing to create additional RTTs *after establishing its first RTT*, while also adjusting the resident caps of the rural hospital(s) added by creating the subsequent RTTs.

Section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act to add a new subclause which states that for cost reporting periods beginning on or after October 1, 2022, in the case of a hospital not located in a rural area that *established or establishes* a medical residency training program (or rural tracks) in a rural area . . . adjust in an appropriate manner the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training. Because the law now states “established or establishes,” *both past tense and future tense*, we believe the statute grants the Secretary unique authority not previously held; that is, the authority to *prospectively* allow (under certain circumstances) cap adjustments to *existing RTTs expanded in a cost reporting period beginning on or after October 1, 2022*. That is, the provision gives explicit permission to adjust the RTT limitations of an urban hospital wishing to create additional RTTs *after establishing its first RTT*, while also adjusting the resident caps of the additional rural hospital(s) added by creating the second (or third, etc.) RTT. We believe this new statutory authority is separate and distinct from the statute’s requirement that, for IME and direct GME payment purposes, *caps can be adjusted only for new teaching urban hospitals and for rural hospitals with new programs* under section 1886(h)(4)(H)(i) of the Act. That is, in general, urban hospitals becoming teaching hospitals for the first time and rural hospitals may receive cap adjustments only if the program(s) in which they train residents is “new” in accordance with Medicare rules (as explained in detail at 74 FR 43908 through 43917).

Therefore, under the explicit authority under section 127 of the CAA, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25513) we proposed to prospectively allow increases to the IME and direct GME caps of both the participating urban and rural hospitals that *expand a qualifying RTT*. We proposed that if, in a cost reporting period beginning on or after October 1, 2022, an urban hospital with an existing RTT (“hub”) adds an additional RTT (“spoke”) to the existing urban core program of the same specialty, the urban and rural hospitals may receive adjustments to their rural track FTE limitation. (For ease of reference, we are referring to the urban core hospital as the “hub” and the one or more RTTs as the “spokes” associated with that

urban “hub.”) For example, Urban Hospital A has an existing family medicine program. In 2015, Urban Hospital A partnered with Rural Hospital 1 to create a RTT from the existing family medicine program and received a rural track FTE limitation to reflect the time that residents training in the RTT spent at its facility. In July 2023, Urban Hospital A partners with Rural Hospital 2 in a different rural area of the state, to create an additional family medicine RTT (adding another “spoke” to the existing urban program “hub.”) We proposed that both Urban Hospital A and Rural Hospital 2 may receive adjustments to their resident caps (rural track FTE limitations) to reflect the portion of the time that FTE residents in the second family medicine RTT “spoke” spend at their respective facility. We believe that allowing prospective adjustments to RTT FTE limitations for additional RTT “spokes” added in cost reporting periods beginning on or after October 1, 2022 is an efficient means of addressing rural healthcare workforce shortages, by allowing already experienced and successful urban “hub” RTTs to branch out and partner with additional rural communities, rather than relying solely on starting RTTs from scratch. That is, with the ability for CMS to provide funding for additional spokes, it should be easier for urban hospitals that already have one RTT to reach rural areas more quickly and efficiently with the addition of more spokes, rather than starting brand new “hubs”.

However, we proposed to limit the increases to the urban and rural hospitals’ RTT FTE limitations only in the instance where additional residents are recruited to add a *new rural “spoke” RTT*, and *not* to allow increases to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT “spoke.” We believe it is appropriate to do so because section 127 of the CAA states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program where greater than 50 percent of the program occurs in a rural area, the Secretary shall *consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8)*, prescribe rules for the application of such subparagraphs with respect to such a program and, in accordance with such

rules, *adjust in an appropriate manner* the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training. That is, the statute directs the Secretary to adjust the cap (the limitation under subparagraph (F)) in an appropriate manner. As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25514), we believe that “appropriate” means not rendering the RTT FTE limitations meaningless. If we would allow adjustments to the RTT FTE limitations at any time, for any type or any amount of expansion even to already existing rural site “spokes,” there would, in essence, not be any RTT FTE limitation at all. As a matter of public policy, as long as the FTE resident caps (that is, the “limitation under subparagraph (F)”) are in place, we believe that CMS should be judicious with providing for additional funded cap slots, as that, in turn, encourages thoughtful residency program expansion among hospital stakeholders. Therefore, we proposed to limit the provision of an increase to the urban and rural hospitals’ RTT FTE limitations only to the instance where additional residents are recruited to add a new rural RTT “spoke” to the existing urban “hub”, and *not* to allow increases under this section to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT “spoke.” As with the general FTE resident caps, since the slots associated with the RTT FTE limitation are fungible, urban and rural hospitals with multiple RTT “spokes” may reduce the number of FTE residents training at one track and “spoke” in order to accommodate an increase in training and funding at another track and “spoke.” For example, Urban Hospital A has an existing family medicine program. In 2015, it partnered with Rural Hospital 1 to create a RTT from the existing family medicine program. Urban Hospital A received a cap/rural track FTE limitation to reflect residents in the RTT training at its facility. In July 2023, Urban Hospital A receives permission from the ACGME to permanently expand this family medicine RTT by 2 FTE residents, to train at both Urban Hospital A and Rural Hospital 1. We proposed NOT to allow an adjustment to the rural track FTE limitation of Urban Hospital A and Rural

Hospital 1 for the addition of 2 FTE residents, because this would be an expansion of an already existing RTT “spoke.”

We also note that if the urban hospital already has an existing RTT in one specialty and an associated rural track FTE limitation, the urban hospital may also receive an adjustment to its rural track FTE limitation if it starts another RTT in a different specialty, because starting a RTT in a different specialty would not be an expansion of the already existing RTT. For example, Urban Hospital A has an existing family medicine program. In 2015, it partnered with Rural Hospital 1 to create a RTT from the existing family medicine program and, as a result, received a cap/rural track FTE limitation adjustment to reflect residents in the RTT training in its facility. In July 2023, Urban Hospital A partners once again with Rural Hospital 1 to create a RTT in internal medicine. We proposed that both Urban Hospital A and Rural Hospital 1 may receive adjustments to their cap/rural track FTE limitations to reflect the time that residents train in the internal medicine RTT “spoke” in their respective facilities. Thus, Urban Hospital A and Rural Hospital 1 would have cap/rural track FTE limitations reflecting FTE residents training in both a family medicine RTT and an internal medicine RTT.

c. Removal of Requirement that Rural Track Must Be “Separately Accredited”

Previously, section 1886(h)(4)(H)(iv) stated that the Secretary would adjust the caps of an urban hospital that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area. Historically, the ACGME has separately accredited family medicine programs in the “1-2 format” (meaning, residents in the 1-2 format receive their first year experience at a core family medicine program, and their second and third year experiences at another site, which may or may not be rural). Because the ACGME has only accredited family medicine programs in the 1-2 format, hospitals have not been able to seek additional funding opportunities for rural tracks developed in specialties other than family medicine. Since implementation of the original BBRA provision, stakeholders have expressed concern that FTE cap adjustments have not been permitted for sending residents to rural areas if

the program was not a separately accredited family medicine RTT. Section 127 of the CAA removes the requirement that the rural track be “separately accredited.” Specifically, section 1886(h)(4)(H)(iv)(II) now states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, or establishes an accredited program where more than 50 percent of the training takes place in a rural area, the Secretary may adjust the resident cap in an appropriate manner. (Residency programs, whether they are “rural tracks” or any other program, must still be accredited under the law in order to receive IME and direct GME payments; see section 1886(h)(4)(H)(iv)(II) of the Act). Therefore, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25514), we proposed that effective for cost reporting periods beginning on or after October 1, 2022, so long as the program in its entirety is accredited by the ACGME, regardless of the specialty, it may qualify as an RTT and urban and/or rural hospitals may receive rural track FTE limitations, assuming all other requirements are met.

d. Requirement that Greater Than 50 Percent of the Program Occurs in a Rural Area

Under existing regulations at 42 CFR 413.79(k)(1) and (2), the urban hospital establishing the RTT may only receive a cap/rural track FTE limitation to count residents in the RTT if the urban hospital rotates residents to either a rural hospital or rural nonprovider site, for more than 50 percent of the duration of the program. As described in detail in rules implementing the original BBRA provision (see the August 1, 2000 interim final rule with comment period (65 FR 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39902 through 39909) where we implemented section 407(c) of Pub. L. 106-113), we adopted this greater than one-half duration rule based on the fact that residents training in separately accredited 1-2 family medicine RTTs spend greater than 50 percent of their training time in rural areas. We also wanted to ensure that cap adjustments would not be allowed for minimal rotations to rural areas. Section 1886(h)(4)(H)(iv)(II) is amended by section 127 of the CAA which states that in the case of a hospital not located in a rural area that established or establishes

a medical residency training program (or rural tracks) in a rural area or *establishes an accredited program where greater than 50 percent of the program occurs in a rural area*, the Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25515), we believe section 127 of the CAA now requires in statute what CMS has required in regulation; that is, we proposed that in order for urban or rural hospitals to receive FTE cap adjustments for residents training in RTTs, the residents must be in “an accredited program where greater than 50 percent of the program occurs in a rural area.” We believe that a “medical residency training program (or rural tracks)” refers to what the ACGME currently separately accredits as a 1-2 program; family medicine residencies that typically would have a first year in an urban hospital and second and third years in a rural hospital/setting. These separately accredited 1-2 family medicine RTTs may continue to maintain their RTT FTE limitations, assuming all applicable requirements are met. However, we proposed that an “accredited program where greater than 50 percent of the program occurs in a rural area” is the new statutory authorization for development of rural tracks in specialties *other than* family medicine, because eligibility for cap adjustments is no longer tied exclusively to “separately accredited”, 1-2 programs. Specifically, as long as a program in its entirety is accredited by the ACGME, whether the program is in family medicine or in another specialty, and the residents spend more than 50 percent of the entire program in a rural area, then prospectively for cost reporting periods beginning on or after October 1, 2022, we proposed to also provide additional slots to any program in any specialty. Therefore, for all accredited specialties, we proposed to allow an urban hospital to include in its FTE count, not to exceed its rural track FTE limitation, residents training in the urban hospital that are designated to rotate to a rural area for greater than 50 percent of the duration of the particular program. In addition, we proposed that a rural hospital that is partnered with the urban hospital in the RTT would similarly include in its FTE count, not to exceed its rural track FTE limitation, the time



residents train in the rural hospital only if the residents rotate to a rural area for greater than 50 percent of the duration of the particular program. For example, greater than 50 percent of the duration of a 3-year family medicine program would be more than 18 months rotating to a rural area; greater than 50 percent of the duration of a 4-year psychiatry program would be more than 24 months training in a rural area.

e. Exemption from the 3-Year Rolling Average During the 5-Year Rural Track FTE Limitation Window

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital's FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

In addition, as stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57028), under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, or for rural hospitals, if the rural track meets the definition of a new program).

As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25515), we believe that section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act to provide for

an exemption from the 3-year rolling average of the urban hospital and rural hospital during the 5-year growth window for FTE residents participating in rural tracks. Specifically, section 1886(h)(4)(H)(iv)(II) of the Act states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program where greater than 50 percent of the program occurs in a rural area, *the Secretary shall consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program. Subparagraph (F) is the FTE resident cap, and subparagraph (G) refers to the 3-year rolling average. This italicized language is the same as that used at section 1886(h)(4)(H)(i) regarding providing exemptions from the FTE resident cap and 3-year rolling average for new teaching hospitals starting new residency programs. That is, section 1886(h)(4)(H)(i) states: “(i) New facilities.—The Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995.”* The previous rural track language at section 1886(h)(4)(H)(iv) did not mention subparagraph (G); therefore, the law did not exempt from the rolling average any residents participating in a rural track, even during the cap building window as we explained in the August 1, 2003 IPSS final rule (68 FR 45456 through 45457). Because section 127 of the CAA amends section 1886(h)(4)(H)(iv) to add in new subclause (II) which contains language modeled on the language for providing for FTE resident cap and rolling average exemptions in the case of new programs started on or after January 1, 1995, we proposed that similarly, during the 5-year cap growth window for RTTs, the FTE residents participating in the RTT either at the urban hospital or a rural hospital would not be included in a hospital’s 3-year rolling average calculation during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track. That is, just as residents in new programs are exempt from the 3-year rolling average

until the cost reporting period that coincides with or follows the start of the sixth program year, similarly, effective for RTTs started in cost reporting periods beginning on or after October 1, 2022, for each rural track started, full-time equivalent residents at an urban hospital or rural hospital in a rural track program would be excluded from the rolling average calculation during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

f. Changes to the Regulations Text

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25516), although section 127 of the CAA directly amends section 1886(h) for direct GME, and does not specifically refer to amendments for IME, the existing language at section 1886(d)(5)(B)(viii) of the Act states that rules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi). Accordingly, the statutory authority to make corresponding changes to IME for rural tracks already exists. Clause (v) refers to the IME resident caps, and clause (vi) refers to the 3-year rolling average. Therefore, we proposed to apply to the IME payment the new authority under section 1886(h)(4)(H)(iv) of the Act to allow both urban and rural hospitals to receive IME rural track FTE limitations, as well as an exemption from the IME 3-year rolling average for FTE residents during the 5-year cap building window. We are making appropriate changes to the regulations text for IME at 42 CFR 412.105(f)(1)(v)(F) and 412.105(f)(1)(x) to mirror the following proposed regulations text changes for direct GME:

- We proposed to modify the definition of Rural Track FTE limitation at 42 CFR 413.75(b) to add “or rural hospital”.
- We proposed to remove the requirement at 42 CFR 413.79(d)(7) that FTE residents in the rural track are included in the 3-year rolling average during the 5-year cap building window.
- We proposed to make various changes throughout the regulations text at 42 CFR 413.79(k) “*Residents training in rural track programs.*”

g. Documentation Required for Medicare Administrative Contractor (MAC) to Pay for RTTs

We will amend or clarify as necessary the Medicare cost report, CMS-2552-10, Worksheets E, Part A for IME and E-4 for direct GME, to accommodate additional rural track limitations. With this new authority to pay for more Rural Track Programs (RTPs - see explanation in response to comments later in this section as to why CMS is using the term “RTP”), MACs may face an increase in requests for adjustments to interim rates as hospitals first build these programs. While, as with payment for any GME program, hospitals must maintain and, upon a MAC’s request, submit applicable documentation, to make review and processing of these new RTP payment requests more manageable, we are reiterating the documentation requirements here. We proposed that the urban and rural hospitals must provide, upon request, to its MAC the following (Note: In response to a comment we received on the following bullet points, we have modified the language in these bullet points to reflect our response to that comment in this final rule with comment period):

- The ACGME accreditation for the program as a whole (that is, both urban and rural training components), and documents showing whether the urban and rural participating sites are starting the RTP for the first time in this particular specialty, or whether the urban and rural hospital already have an RTP in this specialty, but are adding additional participating sites to the RTP.

- A list of all urban and rural hospital and nonprovider training sites in the RTP.
- Resident rotation schedules (or similar documentation) showing that residents in the specified RTP spend greater than 50 percent of their training in a geographically rural area in the 5-year growth window in order to receive IME and direct GME rural track FTE limitations. In the instance where only a subset of the residents in the particular program are participating in the RTP, and the training time of the RTP residents is included in the main rotation schedule for the entire program, the hospital must specifically highlight the names of the residents and their urban and rural training locations on the main rotation schedule, so that the MAC can easily identify

which residents are training in the RTP, where they are training, and be able to verify that over 50 percent of their training time is spent in a rural area.

- The number of FTE residents and the amount of time training in all 5 program years at both the urban and rural settings since establishment of a Rural Track Program (based on the rotation schedules), so that this information is available to the MAC when needed in auditing the accuracy of the RTP FTE cap limitation established by the hospital in the cost reporting period that coincides with or follows the start of the sixth program year of the RTP.

Following are examples of how the urban and rural hospital’s rural track FTE limitations would be calculated:

Example 1: Urban Hospital and Rural Hospital are participating sites in an accredited rural track program. The program is in internal medicine (3 years minimum accredited length), and is accredited for a total of 6 residents, 2 in each program year (PGY). The residents spend PGY1 at Urban Hospital, and then the PGY2s and PGY3s rotate to a rural area, to train at both Rural Hospital and Rural Clinic (a nonprovider site). The PGY2 and PGY3 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent of the duration of the 3 year program in the rural area. Therefore, the Urban Hospital qualifies to receive a cap/rural track FTE limitation adjustment. Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Rural Clinic. The rotations and the cap calculation are as follows:

YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital
PGY2 0	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
PGY3 0	PGY3 0	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9),	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9),	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9),

		2 @ .05 Urban Hospital (.10)	2 @ .05 Urban Hospital (.10)	2 @ .05 Urban Hospital (.10)
TOTAL 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 6.0	TOTAL 6.0
				5 Year Total = 24

Urban Hospital's 5 YEAR FTE TOTAL = 11.1

Rural Hospital's 5 YEAR FTE TOTAL (includes time at Rural Clinic) = 12.9

5 Year FTE Total = 24

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0

PGY 2s = 2.0

PGY 3s = 2.0

Step 2:  $2.0 \times 3$  (minimum accredited length) = 6

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years:  $6 \times [11.1/(24)] = 2.76$ .

Step 4: Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years:  $6 \times [12.9/(24)] = 3.24$

$2.76 + 3.24 = 6.0$ , the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. Rural Hospital's rural track FTE limitation is 3.24. (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the Urban Hospital and Rural Hospital exclude the FTE residents from the 3-year rolling average calculation on their Medicare cost reports.)

Example 2: Urban Hospital and Rural Hospital are participating sites in an accredited rural track program. The program is in psychiatry (4 years minimum accredited length), and is

accredited for a total of 8 residents, 2 in each program year (PGY). The residents spend PGY1 at Urban Hospital, and then the PGY2s and PGY3s and PGY4s rotate to a rural area, to train at both Rural Hospital and Rural Clinic (a nonprovider site). The PGY2 and PGY3 and PGY4 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent (that is, more than 24 months) of the duration of the 4 year program in the rural area. Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Rural Clinic. The rotations and the cap calculation are as follows:

YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital
PGY2 0	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
PGY3 0	PGY3 0	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)
PGY4 0	PGY4 0	PGY4 0	PGY4 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY4 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
TOTAL 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 8.0	TOTAL 8.0
				5 Year Total = 28

Urban Hospital's 5 YEAR FTE TOTAL = 11.5

Rural Hospital's 5 YEAR FTE TOTAL (includes time at Rural Clinic) = 16.5

5 Year FTE Total = 28

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0

PGY 2s = 2.0

PGY 3s = 2.0

PGY4s = 2.0

Step 2:  $2.0 \times 4$  (minimum accredited length) = 8

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years:  $8 \times [11.5/(28)] = 3.29$ .

Step 4: Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years:  $8 \times [16.5/(28)] = 4.71$

$3.29 + 4.71 = 8.0$ , the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 3.29. Rural Hospital's FTE cap adjustment is 4.71. (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the Urban Hospital and Rural Hospital exclude the FTE residents from the 3-year rolling average calculation on their Medicare cost reports.)

Example 3: Refer to Example 1 (as previously described), where Urban Hospital and Rural Hospital are participating sites in an accredited internal medicine rural track program. The program is in internal medicine (3 years minimum accredited length), and is accredited for a total of 6 residents, 2 in each program year (PGY). Urban Hospital's rural track FTE limitation is 2.76. Rural Hospital's FTE cap adjustment is 3.24. In July 2023, Urban Hospital partners with Second Rural Hospital in a different rural part of the state to create another internal medicine RTT (that is, Urban Hospital internal medicine "hub" is adding another "internal medicine RTT "spoke"). Urban Hospital adds 2 FTE residents to train in PGY1 at the Urban Hospital, and then the PGY2s and PGY3s rotate to a rural area, to train at both Second Rural Hospital and Second Rural Clinic (a nonprovider site). The PGY2 and PGY3 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent of the duration of the 3 year program in the rural area.



Therefore, Urban Hospital qualifies to receive another rural track FTE limitation. Second Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Second Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Second Rural Clinic. The rotations and the cap calculation are as follows:

YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital
PGY2 0	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
PGY3 0	PGY3 0	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)
TOTAL 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 6.0	TOTAL 6.0
				5 Year Total = 24

Urban Hospital's 5 YEAR FTE TOTAL = 11.1

Second Rural Hospital's 5 YEAR FTE TOTAL (includes time at Second Rural Clinic) = 12.9

5 Year FTE Total = 24

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0

PGY 2s = 2.0

PGY 3s = 2.0

Step 2: 2.0 x 3 (minimum accredited length) = 6

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years:  $6 \times [11.1/(24)] = 2.76$ .

Step 4: [NOTE: As we explain in the summary of comments and responses, as a result of responding to one comment, we realized that the original Step 4 as included in the proposed rule contained errors. Therefore, we are replacing the language of Step 4 of the proposed rule with the following corrected language in this final rule with comment period]. Second Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years:  $6 \times [12.9/(24)] = 3.24$ .  $2.76 + 3.24 = 6.0$ , the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. *This second rural track FTE limitation is added to Urban Hospital's first rural track FTE limitation for a total rural track FTE limitation of 5.52 (2.76 + 2.76).* Second Rural Hospital's FTE cap adjustment is 3.24 (we note that Second Rural Hospital does not have a previous RTP FTE limitation). (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the hospitals exclude the FTE residents from the 3-year rolling average calculation *and the cap on the IME IRB ratio* on their Medicare cost reports.)

We invited comments on our proposals. Following is a summary of the comments received and our responses to those comments.

Comment: Commenters were overall very pleased with CMS's proposed implementation of section 127 of the CAA, and believe it addresses the teaching concerns of rural hospitals in a significant way. However, the commenters disputed CMS's concern that allowing expansion of existing programs might render RTT cap limitations meaningless. Commenters argued that nothing in section 127 of the CAA precludes CMS from providing a one-time adjustment opportunity to existing rural RTT spokes (rural providers). Commenters noted that CMS states in the IPPS proposed rule, "Because the law now states 'established or establishes,' *both past tense and future tense*, we believe the statute grants the Secretary unique authority not previously held; that is, the authority to *prospectively* allow (under certain circumstances) cap adjustments to

*existing RTTs expanded in a cost reporting period beginning on or after October 1, 2022"*

(emphasis added; 86 FR 25513). Many commenters urged CMS to create an exceptions process that would allow hospitals with existing RTTs to demonstrate that the only way they could train more residents at a rural hospital was to expand an existing RTT. They suggested that CMS could consider making this a one-time exception per program and limit the total number of residents allowed to 3.0 FTEs per program.

Response: We appreciate the commenters' support for our proposals. However, we disagree with how the commenters are interpreting "established or establishes." We do not believe the past tense includes general expansions of existing programs. Rather, for the first time, the law allows adding additional sites to an already "established" RTP. As we stated in the proposed rule, "... the provision gives explicit permission to adjust the RTT limitations of an urban hospital wishing to create additional RTTs *after establishing its first RTT*, while also adjusting the resident caps of the additional rural hospital(s) added by creating the second (or third, etc.) RTT ... Therefore, under the explicit authority under section 127 of the CAA, we are proposing to prospectively allow increases to the IME and direct GME caps of both the participating urban and rural hospitals that *expand a qualifying RTT*. We are proposing that if, in a cost reporting period beginning on or after October 1, 2022, an urban hospital with an existing RTT ("hub") adds an additional RTT ("spoke") to the existing urban core program of the same specialty, the urban and rural hospitals may receive adjustments to their rural track FTE limitation" (86 FR 25513). That is, the new authority not previously available allows for an expansion of an existing, already "established" RTT by adding *additional participating sites* (not previously allowed). Section 127 of the CAA does not delineate an exceptions process as requested by commenters, even if an exception is limited to 3 FTEs or some other relatively small number. In the absence of such a delineation, we will not permit exceptions in some cases, but deny them in other cases. We interpret the clause in section 127 that the Secretary's rules shall be "consistent with the principles of subparagraph (F)" as a demonstration of Congressional

intent to retain the FTE caps. Furthermore, this interpretation is consistent with our past interpretations of the principles of subparagraph (F), under which we have not permitted the addition of residents to an already existing program, whether at an urban or a rural hospital (see for example, May 12, 1998 (63 FR 26328, 26334, and 26335). Accordingly, we believe that allowing an exceptions process for expansions of RTPs at existing rural participating sites is inconsistent with our longstanding interpretations of subparagraph (F), and would render the FTE caps meaningless.

Comment: Numerous commenters provided feedback on the terminology CMS used in the proposed rule to describe different constructs of rural training and the manner in which they are accredited. For example, several commenters noted that CMS uses multiple terms to refer to possibly the same concept regarding “rural training track,” or “rural training track program.” The commenters recommend that CMS be careful in using these terms interchangeably, and define each separately, if they have a distinctive meaning for CMS. A commenter suggested that CMS clarify the difference between a separately accredited program and a track within a program that is already accredited, as follows:

- Separately accredited rural track programs (traditional ‘RTTs’ or integrated rural tracks as described in the FY2003 Final Rule; or ‘RTPs,’ Rural Track Programs in the new ACGME language just published in May 2021. (See <https://acgme.org/What-We-Do/Accreditation/Medically-Underserved-Areas-and-Populations/>))
- Urban programs with not-separately-accredited rural tracks (‘RTs,’ not programs)
- We consider ‘tracks’ of urban programs that do not place residents for training in rural locations for >50 percent of their training time to be ‘pathways.’

Response: We appreciate the comments encouraging consistent terminology, and we agree that in this final rule with comment period, we can improve the clarity and consistency in the language and the terms we used to describe programs in which residents rotate to rural areas. As pointed out in the comments, historically we have referred to the separately accredited family

medicine programs which were eligible for the FTE cap adjustments under the BBRA of 1999 as “Rural Training Tracks” (RTTs), or “Rural Training Track Programs.” (See 65 FR 47026, 47033 through 47037 August 1, 2000) and the FY 2002 IPPS final rule (66 FR 39828, 39902 through 39909) and (68 FR 45456 through 45457 August 1, 2003). However, section 127 of the CAA shifts eligibility for FTE cap adjustments away from “separate accreditation” to an “accredited program where greater than 50 percent of the program occurs in a rural area.” Accordingly, going forward, so long as the training is not an expansion of an existing site’s program, CMS’ and the MACs’ focus for determining an urban and rural hospital’s eligibility for FTE cap adjustments is documentation showing that specific residents actually spend greater than 50 percent of the duration of their training in the program in a geographically rural area. CMS and the MACs will no longer look for evidence of “separate accreditation”. We have spoken with the ACGME and we have reviewed the terminology on the ACGME’s website, and we intend to use the terminology “Rural Track Program” (RTP) in this final rule with comment period to describe the type of program that could qualify for IME and direct GME FTE cap adjustments. Specifically, at <https://acgme.org/What-We-Do/Accreditation/Medically-Underserved-Areas-and-Populations/>, the ACGME defines Rural Track Program (RTP) as follows: **ACGME Rural Track Program (RTP)** – An ACGME-accredited program with a unique 10-digit identifier in which residents/fellows gain both urban and rural experience with more than half of the education and training for each resident/fellow taking place in a rural area (any area outside of a Core-Based Statistical Area (CBSA)).

This definition of RTP includes the key point that the residents (or fellows, if applicable) spend more than half of their training in a geographically rural area. However, this current definition contains two points that CMS and the MACs will not require: 1) a unique 10-digit identifier, which we understand is characteristic of the separately accredited 1-2 programs, and 2) that “each” resident/fellow spends more than half of the education and training in a rural area. Our understanding is that, while it is certainly possible for a program to be designed such that

“each” resident in the program is designated to spend more than 50 percent of the time in the rural area, it is also common for only a subset of residents within an entire accredited program to be designated for the rural training experience. Therefore, if only a subset of the number of residents for which a program is accredited is slated for the RTP, then, based on rotation schedules, the MAC would verify those residents and that their training experience consists of greater than 50 percent of the time in a rural area, and would calculate the FTE cap adjustment based on that proportion of FTEs spending more than 50 percent of their time in the rural area. Nevertheless, as stated previously, we are using the term RTP to refer to programs that, at least for a subset of the residents, meet the statutory requirement for greater than 50 percent of the training occurring in a rural area, and therefore, the urban and rural hospital could qualify for IME and direct GME rural track FTE limitations.

We are adding a new definition to the regulations at 42 CFR 413.75(b) for *Rural Track Program* as follows: “*Rural Track Program* means, effective for cost reporting periods beginning on or after October 1, 2022, an ACGME-accredited program in which all, or some, residents/fellows gain both urban and rural experience with more than half of the education and training for the applicable resident(s)/fellow(s) taking place in a rural area as defined at 42 CFR 412.62(f)(iii). In the finalized regulations text at 42 CFR 412.105(f)(1)(v) and (x) and 42 CFR 413.79(k), effective for a cost reporting period beginning on or after October 1, 2022, if those programs (either the whole program, or a subset of residents in the program) consist of greater than 50 percent of the training time in a rural area, we will use the term “Rural Track Program”. Conversely, in the same regulations text, when referring to programs where less than 50 percent of the training occurs in a rural area, we will use the term “program,” with no mention of “rural”.

Comment: A commenter was concerned that in the absence of distinct ACGME criteria identifying programs where greater than 50 percent of the training occurs in a rural area, CMS should devise concrete criteria for identifying programs eligible for FTE cap adjustments. The commenter recommended that CMS require that a new ‘director’ be named in supporting

materials for any newly created RTP but allow the program's 'director' to be any of the following in ACGME terms: a 'Program Director,' an 'Associate Program Director,' or even a participating 'site director' of a rural track that is not separately accredited. The same commenter requested that CMS define a not separately accredited rural track as "an organized and deliberate urban residency program strategy to produce physicians to rural practice as indicated by **all** the following:

- A **name** for the rural track
- A director;
- A **program-specific goal** or objective(s) to recruit, nurture, educate, train, or encourage residents toward rural practice, including a separate NRMP number or another process for assigning individual residents to this track early in the first program year; and
- A description that explicitly articulates a **rural focus**, including a rotation schedule that demonstrates how the track will meet the 50 percent threshold for assigned residents training in a rural location."

Response: In order to provide maximum flexibility to stakeholders, we believe it is appropriate for us to adhere to the criteria specified in section 127 of the CAA, rather than impose additional regulatory conditions for payment. We expect ACGME to develop additional criteria, which we believe is likely to occur in the coming years, as both the industry and the ACGME gain more experience with operating RTPs in a variety of specialties. Therefore, we are not adopting the commenter's suggested criteria.

Comment: A commenter requested that CMS confirm that as long as the residency program in its entirety is accredited by ACGME, there is no separate accreditation requirement or designation or recognition for the program to qualify as an RTT, above and beyond what is required under Medicare regulations. The commenter also requested that CMS confirm how it intends to treat RTTs that become immediately eligible as of October 1, 2022, due to meeting all regulatory requirements with the exception of the "separate accreditation" requirement.

Response: As we stated in response to the previous comment, we would use the ACGME’s term “Rural Track Program” to refer to programs that are ACGME-accredited in their entirety, and where residents (either all, or a subset) spend greater than 50 percent of their training in the program in a rural area. We also do not understand why special consideration is needed for programs that become eligible for payment as an RTP immediately on October 1, 2022. As we stated, a hospital that believes it qualifies for an RTP FTE limitation should approach its MAC showing it meets the greater than 50 percent rural training requirement, and the MAC may adjust the hospital’s interim rates so that effective for a cost report starting on or after October 1, 2022, the hospital could receive increased IME and direct GME payment as appropriate.

Comment: Some other commenters recommended using ACGME terms like “participating hospital” and to avoid the term “sponsor”. The commenters noted that many, if not most, residency programs involve multiple participating hospitals and both provider and non-provider ambulatory sites, and that the sponsoring institution may not necessarily be a hospital. Some commenters also noted that in the Examples 1 and 2 on pages 25516-18 of the proposed rule, CMS refers to hospitals that “jointly sponsor” programs. The commenters noted that the ACGME does not use the term “joint sponsor,” and instead refers to hospitals as “participating sites” in an accredited program. In Example 3, a commenter corrected CMS’s wording to indicate that Urban Hospital partners with Second Urban Hospital in a different part of the State to “create”, and not to “sponsor,” another internal medicine RTT. A commenter also noted that the ACGME only allows one organization to serve as the Sponsoring Institution of an ACGME-accredited program, and that education and training in each accredited program takes place in participating sites. A couple of other commenters noted that use of the term “core” and “hub” for the urban hospital are unnecessarily urban-centric, and suggest that the language be changed instead to ‘networks’ of multiple participating urban and rural hospitals and ambulatory sites.



Response: We appreciate the commenters' corrections and have made the suggested corrections in Examples 1, 2, and 3. We have consulted the ACGME's "Glossary of Terms," dated April 15, 2020 ([https://www.acgme.org/portals/0/pdfs/ab\\_acgmeGLOSSARY.pdf](https://www.acgme.org/portals/0/pdfs/ab_acgmeGLOSSARY.pdf)). After considering the commenters' suggestions, we believe it is best to use terms that are already defined in the ACGME's Glossary. We found the following relevant definitions:

- **Primary clinical site:** The primary facility designated for clinical instruction in the program.
- **Participating site:** An organization providing educational experiences or educational assignments/rotations for residents/fellows. Examples of participating sites include: a university; a medical school; a teaching hospital, including its ambulatory clinics and related facilities; a private medical practice or group practice; a nursing home; a school of public health; a health department; a federally qualified health center; a public health agency; an organized health care delivery system; a health maintenance organization (HMO); a medical examiner's office; a consortium; or an educational foundation.

Accordingly, in this final rule with comment period and going forward, rather than refer to the "core" and "hub" for the urban hospital, and "spoke" for the rural training sites, in this final rule with comment period, we instead will refer to the urban hospital(s) as the "primary clinical site," and will refer to the various other training locations as either the "rural hospital participating site," if the site is a rural hospital, or the "rural non-provider participating site" if the site is an ambulatory clinic, or some other non-hospital site. For illustrative purposes, had we used this new terminology in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25515), we would have written the language as follows:

We are proposing that if, in a cost reporting period beginning on or after October 1, 2022, an urban hospital with an existing ~~RTT~~ RTP ("primary clinical site") adds an additional ~~RTT~~ ("spoke") rural "participating site" to the existing urban ~~core program~~ RTP of the same specialty, the urban and rural hospitals may

receive adjustments to their rural track FTE limitation. ~~(For ease of reference, we are referring to the urban core hospital as the “hub” and the one or more RTTs as the “spokes” associated with that urban “hub.”)~~ For example, Urban Hospital A (primary clinical site) has an existing family medicine program. In 2015, Urban Hospital A partnered with Rural Hospital 1 (rural hospital participating site) to create a ~~RTT~~ RTP from the existing family medicine program and received a rural track FTE limitation to reflect the time that residents training in the ~~RTT~~ RTP spent at its facility. In July 2023, Urban Hospital A (primary clinical site) partners with Rural Hospital 2 (an additional rural hospital participating site) in a different rural area of the State, to create an additional family medicine ~~RTT~~ RTP ~~(adding another “spoke” to the existing urban program “hub.”)~~ We are proposing that both Urban Hospital A and Rural Hospital 2 may receive adjustments to their resident caps (rural track FTE limitations) to reflect the portion of the time that FTE residents in the second ~~family medicine RTT “spoke”~~ rural hospital participating site RTP spend at their respective facility.

Comment: A commenter reviewed our proposed reiterated criteria for hospitals to seek MAC approval to receive payment for RTPs (see 86 FR 25516), and made the following suggested edits:

1. ~~The accreditation for the “spoke,~~ “Approval of the urban program’s rural track from the ACGME and information whether the track is in the same specialty as an RTT/RTP program that the urban hospital already has, or whether the “spoke” track is a newly created ~~RTT~~ rural track in a different specialty.
2. Intern and resident rotation schedules (or similar documentation) showing that residents in ~~each particular RTT program (both hub and spokes overall)~~ the specified rural track spend greater than 50 percent of their training in the initial

residency period in a geographically rural area in order to receive IME and direct GME rural track FTE limitations.

3. The number of FTE residents and the amount of time training in all program years at both the urban and rural settings since establishment of the particular “spoke of any already accredited RTT/RTP or approved not-separately-accredited RT, so that the MAC may be able to verify the RTT cap and appropriately adjust the rural FTE limitation.

Response: We appreciate the commenter’s suggestions, and will revise the criteria as follows:

- The ACGME accreditation for the program as a whole (that is, both urban and rural training components), and documents showing whether the urban and rural participating sites are creating the RTP for the first time in this particular specialty, or whether the urban and rural hospital already have an RTP in this specialty, but are adding additional participating sites to the RTP.

- Intern and resident rotation schedules (or similar documentation) showing that residents in the specified RTP spend greater than 50 percent of their training in a geographically rural area in the 5-year growth window order to receive IME and direct GME rural track FTE limitations. In the instance where only a subset of the residents in the particular program are participating in the RTP, and the training time of the RTP residents is included in the main rotation schedule for the entire program, the hospital must specifically highlight the names of the residents on the main rotation schedule, and highlight their urban and rural training locations, so that the MAC can easily identify which residents are training in the RTP, and be able to verify that over 50 percent of their training time is spent in a rural area.

- The number of FTE residents and the amount of time training in all 5 program years at both the urban and rural settings since establishment of a Rural Track Program (based on the rotation schedules), so that this information is available to the MAC when needed in auditing the

accuracy of the RTP FTE cap limitation established by the hospital in the cost reporting period that coincides with or follows the start of the sixth program year of the RTP.

We note that under the second bullet, we removed the phrase “in the initial residency period” and changed it to “in the 5-year growth window” because we believe that is what the commenter intended to say (we note the phrase “initial residency period” as defined at 42 CFR 413.79(a) does not make sense in this context).

Comment: A commenter requested that CMS confirm that a hospital that is physically located in an urban area but treated as rural for purposes of payment under the IPPS as implemented in §412.103 would be considered urban for purposes of meeting the requirements for the RTT provision and would be eligible for both DGME and IME cap adjustments as an urban hospital should it successfully partner with a hospital physically located in a rural area.

Response: Hospitals physically located in urban areas, but that are reclassified to rural areas under 42 CFR 412.103 are treated as rural for IPPS payment purposes, which includes IME. This is because 42 CFR 412.103 affects payments under section 1886(d) of the Act, which are the IPPS payments, and IME is an add-on to the teaching hospital’s IPPS payment. However, 42 CFR 412.103 does not affect direct GME because direct GME is addressed under section 1886(h) of the Act. This means that such a hospital is rural for IME purposes, but it is urban for direct GME purposes (because it is still physically located in an urban area). Therefore, we are not confirming the commenter’s statement that the urban hospital reclassified as rural under 42 CFR 412.103 would be considered urban for the purpose of meeting the RTP requirements. Rather, the hospital would be rural for IME and urban only for direct GME. We did not propose any changes to this policy. Thus, as long as an urban hospital retains its 412.103 reclassification, CMS would treat that hospital as rural for section 1886(d) purposes, which includes all ramifications to the IME adjustment.

With regard to urban hospitals that are reclassified as rural under §412.103 and participate in RTPs, there are challenges associated with correctly determining the payment

implications for an RTP that has, as its primary clinical site, or even as a participating site, a hospital that is rural for IME purposes, but is urban for direct GME purposes. For instance, in determining whether greater than 50 percent of residents' training time occurs in an urban area or a rural area, would the training that occurs in this hospital that is rural for IME but urban for direct GME be counted towards the urban portion or the rural portion? The answer is that for the purpose of qualifying for an adjustment to only the IME FTE limitation, the residents' training time spent in the urban hospital reclassified as rural under 42 CFR 412.103 could count toward the rural portion of training time. However, the hospital would be in the awkward position of needing to send those same residents to train in a geographically rural participating site in order to separately meet the greater than 50 percent rural training requirement to qualify for the adjustment to the direct GME FTE limitation. Urban hospitals reclassified as rural under 42 CFR 412.103 that wish to participate in RTPs may decide that it is preferable both from an educational and economic standpoint to synchronize the time spent in geographically rural participating sites, so that the IME and direct GME rotations would be synchronized as well. It would also be much easier to document the training time to the MAC for the purpose of receiving the IME and direct GME FTE limitation adjustment.

Comment: A commenter noted that in the proposed rule, we stated that "as with the general FTE resident caps, since the slots associated with the RTT FTE limitation are fungible, urban and rural hospitals with multiple RTT "spokes" may reduce the number of FTE residents training at one track and "spoke" in order to accommodate an increase in training and funding at another track and "spoke" (86 FR 25514). The commenter requested clarification on how the "fungible" aspect would work in the following example: Urban Hospital A and Rural Hospital 1 decide to adjust the RTT limitation partnership between the two hospitals by adding additional family medicine residents and reducing the number of internal medicine residents. The commenter requested confirmation that this single RTT cap limitation across two hospitals cross-training multiple specialties is what is intended by this example.

The commenter also requested confirmation regarding a second example demonstrating the fungible nature of the rural track FTE limitation. The commenter noted that CMS includes a more formal example (Example 3, 86 FR 25518) later in the preamble. In Example 3, which builds on Example 1, Urban Hospital forms a second rural training track in internal medicine with “Second Rural Hospital.” According to Example 3, Urban Hospital’s first rural track FTE limitation and second rural track FTE limitation are added together to form a single rural track FTE limitation *for that particular specialty* (internal medicine). CMS includes a note that the “*second rural track FTE limitation is added to Second Rural Hospital’s first rural track FTE limitation for a total rural track FTE limitation of 6.48 (3.24 + 3.24)*” (emphasis by CMS; 86 FR 25519). However, there is no indication in the earlier part of Example 3 of the origin of Second Rural Hospital’s first rural track FTE limitation, and in particular whether it came from the same specialty or a different specialty. The commenter believed the intent is to demonstrate that Second Rural Hospital’s first rural track FTE limitation was in a different specialty (not internal medicine), and the two distinct specialty rural track FTE limitations get added together to, again, form a single RTT cap limitation that was created via multiple specialties. The commenter requested confirmation that this single RTT cap limitation for Second Rural Hospital across multiple specialties is what is intended by this example.

Response: Regarding the first example, we partially confirm the commenter’s general understanding, that if Urban Hospital A and Rural Hospital 1 receive RTP cap limitations for both family medicine and internal medicine, the two FTE cap limitations calculated as a result of each respective specialty may be added for a total RTP cap limitation at each respective hospital, not across both hospitals. Then, within each respective hospital’s total RTP FTE cap limitation, the actual number of residents in each RTP may be reduced in one specialty, and increased in another specialty. For example, if a hospital has a total RTP FTE cap limitation of 6, consisting of 3 from a family medicine RTP, and 3 from an internal medicine RTP, the hospital could choose to reduce the family medicine RTP to 2 FTEs, and increase the internal medicine RTP to

4 FTEs, while still staying within the total RTP FTE cap limitation of 6. However, we disagree with the commenter's belief that a "single RTT cap limitation across two hospitals cross-training multiple specialties" is permissible. There is no "single RTP cap limitation across two hospitals." Rather, each hospital, whether urban or rural, has its own IME and direct GME RTP FTE limitations; we are not creating Medicare GME affiliation agreements specific to sharing RTP FTE limitations. We note that, as with regular FTE caps, hospitals are free to increase or decrease FTE residents in any specialty at any location, but Medicare would only pay each hospital for no more FTEs than the amount in their RTP FTE limitations.

Regarding the commenter's second request for confirmation referencing Example 3 on page 25518 and 25519 of the proposed rule, we have reviewed this Example 3, and realize that we made an error. As the commenter notes, Example 3 does build on Example 1. Urban Hospital forms a second rural track FTE limitation in internal medicine with "Second Rural Hospital." According to Example 3, Step 4, Urban Hospital's first rural track FTE limitation and second rural track FTE limitation are added together to form a single rural track FTE limitation *for that particular specialty* (internal medicine). CMS includes a note that the "*second rural track FTE limitation is added to Second Rural Hospital's first rural track FTE limitation for a total rural track FTE limitation of 6.48 (3.24 + 3.24)*" (emphasis by CMS; 86 FR 25519). However, that is incorrect, because Second Rural Hospital *had no previous rural track FTE limitation (it was First Rural Hospital in Example 1 that already had a rural track FTE limitation of 3.24, but First Rural Hospital is NOT part of Example 3; rather, Second Rural Hospital is at issue, and in fact is just receiving a rural track FTE limitation of only 3.24 for the first time)*. It is Urban Hospital that, under Example 3, has two rural track FTE limitations which are added together to form a total rural track FTE limitation for Urban Hospital of 5.52 (2.76 + 2.76). The intent of this Example 3 was to show how the limitations are calculated when "Urban Hospital internal medicine 'hub' adds another 'internal medicine RTT 'spoke'" ((86 FR 25518) or, in terms used in this final rule with comment period, urban primary clinical site added

a second rural hospital participating site but for the same specialty program). We are rewriting Step 4 of Example 3 in this final rule with comment period as follows:

Step 4: Second Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years:  $6 \times [12.9/(24)] = 3.24$ .  $2.76 + 3.24 = 6.0$ ; therefore, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. *This second rural track FTE limitation is added to Urban Hospital's first rural track FTE limitation for a total rural track FTE limitation of 5.52 (2.76 + 2.76).* Second Rural Hospital's FTE cap adjustment is 3.24 (we note that Second Rural Hospital does not have a previous RTP FTE limitation). We note that this calculation is done separately for IME and direct GME caps respectively per 42 CFR 412.105(f)(1)(x) for IME and 42 CFR 413.79(k) for direct GME. Also note that during these 5 program years, the hospitals exclude the FTE residents from the 3-year rolling average calculation *and the cap on the IME IRB ratio* on their Medicare cost reports.

At this point, Urban Hospital has a RTP FTE limitation of 5.52, while First Rural Hospital from Example 1 has a RTP FTE limitation of 4.71, and Second Rural Hospital from revised Example 3 has a RTP FTE limitation of 3.24. Each hospital's RTP FTE limitations for IME and direct GME respectively belong to each hospital, and are derived from a single specialty, internal medicine. Thus, there are not yet any slots to be fungible. The slots can be fungible when there is more than one specialty RTP. We can elaborate on Example 3 further, and imagine that Urban Hospital and First Rural Hospital decide to create a new RTP in pediatrics. Five years pass, and both Urban Hospital and First Rural Hospital receive RTP FTE limitations associated with the pediatrics RTP, and that Urban Hospital's RTP FTE limitation has increased from 5.52 to 8.0, and First Rural Hospital's RTP FTE limitation increased from 3.24 to 6.0. After some more time, Urban Hospital and First Rural Hospital believe there is a need to expand their complement of residents training in their existing internal medicine RTP. However, since adjustments to RTP FTE limitations are not provided for expansions of existing programs,



they decide to reduce the complement of pediatrics residents by 1.0, and increase the complement of internal medicine residents training in the RTP at Urban Hospital and First Rural Hospital by 1.0. Thus, both Urban Hospital and First Rural Hospital maintain training levels within their respective existing RTP FTE limitations. This demonstrates the fungible nature of each hospital's RTP FTE limitations, when there is more than one RTP specialty.

Comment: A commenter requested that CMS comment on the following example. Urban Hospital A has an internal medicine RTT with two rural hospitals (Rural Hospital X and Rural Hospital Y). Urban Hospital A has an internal medicine RTT limitation of 5.0, which was established by expanding its internal medicine program by 15 rural track residents, training 5.0 FTE residents in Urban Hospital A and rotating 5.0 FTE residents to Rural Hospital X and 5.0 FTE residents to Rural Hospital Y. After the RTT cap for the program was established, Urban Hospital A decides to rotate more residents to Rural Hospital X (increase to 6.0) and fewer residents to Rural Hospital Y (decrease to 4.0). Rural Hospital X would be training above its internal medicine RTT limitation. Rural Hospital Y would be training below its internal medicine RTT limitation. The commenter believed that Urban Hospital A would retain its internal medicine RTT limitation of 5.0, even if the number of residents training in Rural Hospital X and Rural Hospital Y changed. The commenter also believed that Rural Hospital X and Rural Hospital Y could form an affiliated group and aggregate their FTE caps such that Rural Hospital X raises its FTE cap by 1.0 and Rural Hospital Y lowers its FTE cap by 1.0 to accommodate Urban Hospital A's rotation change. The commenter requested confirmation that an urban hospital's RTT cap limitation for a single specialty would not change, even if its spokes altered the amount of training occurring at each spoke hospital, and that the spoke hospitals may form a Medicare affiliated group agreement to share rural track FTE limitation "space."

Response: In the situation where the FTEs at the Urban Hospital's portion of the RTP do not change, but there is a change at the Rural Hospitals, such that there is an increase of FTEs at one Rural Hospital with a decrease at another Rural Hospital, we agree that Urban Hospital's

RTP FTE limitation and payment would not change, because it is still sending the same amount of FTEs to a rural area for greater than 50 percent of the program. However, payment to the Rural Hospitals would change. Rural Hospital X would be training in excess of its RTP FTE limitation, and would not be paid for the amount of FTEs in excess of its RTP FTE limitation. While Rural Hospital Y would now have “room” under its RTP FTE limitation, it would receive payment only for the number of FTEs in the RTP it trains. As we mentioned previously, effective October 1, 2022, we are not permitting the formation of Medicare GME affiliated groups for the purpose of aggregating and cross-training RTP FTE limitations. First, we believe Medicare GME affiliated groups for RTPs are premature at this point, as only starting October 1, 2022 would hospitals have the first opportunity to add additional participating sites. Subsequently, there would be the 5-year cap building period in which Medicare GME affiliations are not permitted, even under existing Medicare GME affiliation agreement rules (42 CFR 413.79(f)). Second, before we create Medicare GME affiliation agreements unique to RTPs, we believe it would be best to first modify the Medicare cost report form to add spaces for the hospitals to indicate the number of any additional RTP FTEs, and the caps applicable to those FTEs. We also wish to assess flexibility within a hospital’s own total RTP FTE limitation, before sharing those slots with other hospitals. We would need to be vigilant to ensure that the RTP FTE limitations are not comingled with regular FTE cap adjustments currently used in Medicare GME affiliation agreements. Therefore, we believe it is best to reassess allowing Medicare GME affiliation agreements for RTP FTE limitations at some point in the future.

Comment: A commenter noted that CMS stated in the proposed rule that RTTs will be prospectively exempt from the rolling average “for RTTs started in cost reporting periods beginning on or after October 1, 2022” (86 FR 25515). Several commenters believe this effective date will adversely impact many programs just developed with HRSA funding this past 2 years, and special consideration should be given for 7 programs expected to begin July 1, 2022. The commenters recommended that the effective date should be aligned with the start of the

academic year, so that the rolling average should instead be “effective for RTTs starting in Academic Year 2022-23 (July 1, 2022) and beginning with their cost reports starting on or after October 1, 2022....” Another commenter suggested that FTEs in RTTs be prorated such that the rolling average would not apply for portions of cost reporting periods on or after October 1, 2022.

Response: First, we acknowledge an error that we made in the proposed rule with regard to the effective date of the exemption from the rolling average. That is, a commenter noted that CMS stated in the proposed rule that RTTs will be prospectively exempt from the rolling average “for RTTs started in cost reporting periods beginning on or after October 1, 2022” (emphasis added, 86 FR 25515). In fact, section 127 of the CAA states “for cost reporting periods beginning on or after October 1, 2022...;” the law does not state that for RTTs “started in” cost reporting periods beginning on or after October 1, 2022. This means that even for RTTs started prior to October 1, 2022, so long as the urban hospital and rural hospital are within the 5-year growth window for FTE residents participating in the RTT, the earliest a hospital can first benefit from the rolling average exemption is a hospital’s first cost reporting period beginning on or after October 1, 2022. We also note that the law changes the heading at section 1886(h)(4)(H)(iv)(I) to be “cost reporting periods beginning before October 1, 2022,” ; the statutory effective date is explicit. We cannot allow hospitals to prorate and exclude FTEs from the rolling average for the portion of the cost reporting period that occurs after October 1, 2022, because the law does not say “for portions of cost reporting periods on or after October 1, 2022.” The law also does not specify that special consideration be given to programs with a start date of July 1, 2022. We understand any disappointment related to waiting for the rolling average exemption in the first cost reporting period starting on or after October 1, 2022, but we cannot alter this statutory effective date. Therefore, new programs started on July 1, 2022 would still be subject to the rolling average for the cost reporting period that started prior to October 1, 2022. Only effective with a hospital’s cost reporting period starting on or after October 1, 2022 would

the new rules regarding not needing separate accreditation for the RTT or exemption from the rolling average apply.

Comment: A commenter pointed out that CMS uses the authority within section 1886(d)(5)(B)(viii) of the Act, which specifies “[r]ules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi)” to exempt new teaching hospitals from being held to the IME intern and resident-to-bed (IRB) ratio cap during the cap-building period. Since section 1886(d)(5)(B)(vi)(I) is the part of the statute that imposes the IRB ratio cap, the commenter believes that CMS has authority under section 1886(d)(5)(B)(viii) to also grant an exemption to RTTs from the IRB ratio cap during their cap-building windows and should exercise its authority to do so.

Response: We agree that urban and rural hospitals within a 5-year cap building period for an RTP would not apply the IME IRB ratio cap during the cost reporting periods prior to the beginning of the applicable hospital’s cost reporting period that coincides with or follows the start of the sixth program year of each RTP. The commenter refers to section 1886(h)(4)(H) of the Act, called “Special rules for application of subparagraphs (F) and (G).” Subparagraph (F) is the FTE resident cap for direct GME, and subparagraph (G) refers to the 3-year rolling average for direct GME. Section 1886(h)(4)(H) provides the authority for CMS to exempt new teaching hospitals first establishing new programs from applying the FTE caps and the 3-year rolling average during the 5-year cap building period. Section 1886(h)(4)(H)(iv) provides the special authority for exemptions for RTPs. Similarly, on the IME side, section 1886(d)(5)(B)(viii) refers to subsection (h)(4)(H) in order to exempt new teaching hospitals first establishing new programs from applying the IME FTE cap (section 1886(d)(5)(B)(v)), the IME 3-year rolling average (section 1886(d)(5)(B)(vi)(I)), and the IME IRB ratio cap (section 1886(d)(5)(B)(vi)(II)). Thus, by specifying that rules similar to the rules of subsection 1886(h)(4)(H) shall apply, the statute exempts RTPs within their 5-year cap building period from application of the FTE caps, the 3-year rolling average for IME and direct GME, and

effective for cost reporting periods beginning on or after October 1, 2022, the IRB ratio cap for IME as well.

Comment: A commenter expressed concern regarding the implementation of a new OMB definition of non-metropolitan (that is, ‘rural’ and ‘not urban’, (micropolitan = <100,000 population)), and how it may impact RTPs. The commenter suggested CMS outline a policy that covers RTPs and changes to CBSAs that inevitably occur every census from population change.

Response: Currently, CMS has made no proposals to adopt such OMB changes. If and when CMS does propose changes similar to those proposed by OMB, we would address their ramifications in proposed rulemaking at the appropriate time. In the meantime, we refer readers to existing policy regarding changes resulting from census data; see 42 CFR 413.79(k)(7), implemented in the August 22, 2014 IPPS final rule (79 FR 50111 through 50117).

Comment: Some commenters encouraged CMS to include RTT programs within consortium agreements with urban hospitals for inpatient rotations and FQHCs for outpatient clinics, as this would provide needed physicians for FQHCs with waiting lists of untreated patients, and would foster the training of primary care physicians.

Response: CMS does not have any specific rules regarding RTPs and inclusion or exclusion within consortium agreements, so we are unclear as to why CMS would need to do so now. To the extent that there are FQHCs located in rural areas, RTP training time spent in such FQHCs would be counted in the portion of the RTP that is in the rural area.

#### h. Final Policies and Changes to the Regulations Text

We are finalizing our proposed policies with minor adjustments but no substantive policy changes. We are also finalizing changes to the regulations text for IME at 42 CFR 412.105 to mirror regulations text changes for direct GME, and we are finalizing changes to the direct GME regulations as follows:

- We are adding a new definition of Rural Track Program at 42 CFR 413.75(b).

- We are finalizing the modification to the definition of Rural Track FTE limitation at 42 CFR 413.75(b) to add “or rural hospital”.

- We removed the requirement at 42 CFR 413.79(d)(7) that FTE residents in the RTP are included in the 3-year rolling average during the 5-year cap building window, and at 42 CFR 412.105(a)(1)(i), we are stating that in cost reporting periods beginning on or after October 1, 2022, FTE residents in the RTP are exempt from the cap on the IRB ratio during the 5-year cap building window.

- We are finalizing various changes throughout the regulations text at 42 CFR 413.79(k) “*Residents training in rural track programs.*”

## 5. Implementation of Section 131 of the CAA; Addressing Adjustment of Low Per Resident Amounts (Direct GME) and Low FTE Resident Caps (Direct GME and IME) for Certain Hospitals

Section 131 of the CAA provides us with the opportunity to reset the low or zero direct GME per resident amounts of certain hospitals, and to reset the low IME and direct GME FTE resident caps of certain hospitals. Regarding direct GME PRAs, section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period PRA that is calculated by dividing a hospital’s allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital’s cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). For hospitals that became teaching hospitals after 1984, section 1886(h)(2)(F) of the Act states that “the Secretary shall, for the first such period for which it has such a residency training program and is participating under this title, provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.” The regulations at 42 CFR 413.77(e)(1) implement this provision, stating that the per resident amount is based on the lower of the amount specified in paragraph (e)(1)(i) or paragraph (e)(1)(ii) of that section, subject to the provisions

of paragraph (e)(1)(iii) of this section. In other words, the new teaching hospital's PRA generally will be based on the lower of its actual GME costs per FTE in its base period, or the weighted average PRA of existing teaching hospitals located in the same core-based statistical area (CBSA) as the new teaching hospital. Under section 1886(h)(2)(D) of the Act, once the PRA is established in a base period, no changes are made to it; it is only updated for inflation in each subsequent year.

The calculations of both direct GME payments and the IME payment adjustment are affected by the number of FTE residents that a hospital is allowed to count. Congress, through the Balanced Budget Act of 1997 (Pub. L. 105-33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997.

#### a. Background on Establishment of PRAs and FTE Resident Caps for Hospitals Hosting Residency Training

Section 1886(h)(2)(F) of the Act does not require a hospital to incur costs, be the program sponsor, or train a certain minimum number of FTE residents, in order to become a teaching hospital. Accordingly, under the regulations at 42 CFR 415.152, "Teaching hospital" is defined as a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry. Our historical policy is that if a hospital has residents that are training in an approved GME residency program(s), and if the training is according to a planned and regular

schedule (that is, not spontaneous or random), then we consider the hospital to be a teaching hospital, even if--

- It is not incurring the costs of the residents' salaries and fringe benefits,
- It is not the sponsor of the program,
- It is only training a very small number of FTE residents, and
- The program in which the residents are training does not have to be a "new" program

under Medicare rules.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25520), in the past, a number of hospitals have found themselves in the situation of establishment of a low PRA, when they served as a training site for only small numbers of residents from programs sponsored by a medical school or another hospital. In many cases, these hospitals did not incur any salaries for those residents and may have incurred only insignificant overhead costs associated with the residents' presence at their facilities and, therefore, their PRAs were either very low or \$0. Such low PRAs preclude meaningful direct GME payment in the future if these hospitals expand their training of residents and incur significant costs associated with the training. Section 131(a) of the CAA amends section 1886(h)(2)(F) of the Act to direct the Secretary, for such hospitals with such extremely low or \$0 PRAs that meet certain criteria, to establish new PRAs using the methodology described in 42 CFR 413.77(e) if the hospital trains resident(s) in a cost reporting period beginning on or after its enactment (December 27, 2020) and before the date that is 5 years after enactment (December 26, 2025). In accordance with 42 CFR 413.77(e), a new teaching hospital's PRA is based on the lower of its actual GME costs per FTE during a specific base year, or the weighted average PRA of existing teaching hospitals located in the same core-based statistical area (CBSA) as the new teaching hospital. Similar to the establishment of low PRAs, in the past, a number of hospitals have found themselves in the situation of establishing low (but greater than zero) direct GME and IME FTE caps when they served as training sites for only small numbers of residents. The statute does not require that a hospital train a certain



minimum number of FTE residents in order to establish permanent caps. Hospitals wishing subsequently to participate in training residents in a significant manner were precluded by low FTE resident caps from receiving meaningful IME and direct GME payments. Section 131(b) of the CAA addresses this problem by amending section 1886(h)(4)(H)(i) to add new subclauses (III) and (IV) to direct the Secretary, for hospitals that meet certain criteria and that have very low FTE resident caps, to “adjust” – that is, redetermine – those caps if the Secretary determines that the hospital begins training residents in a program year beginning on or after enactment (December 27, 2020) and before 5 years after enactment (December 26, 2025).

b. Hospitals Qualifying to Reset their PRAs

Section 131(a) of the CAA also amends section 1886(h)(2)(F) of the Act to add a new clause (iii) to describe the categories of hospitals that qualify to receive a replacement PRA. For ease of reference, we will refer to these hospitals as Category A and Category B. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25520), a Category A Hospital is one that, as of the date of enactment (December 27, 2020), has a PRA that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997. Typically, a Category A hospital is one that trained less than 1.0 FTE in its most recent cost reporting period ending on or before December 31, 1996, and received a very low or \$0 PRA. A Category B Hospital is one that, as of the date of enactment (December 27, 2020), has a PRA that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before the date of enactment (December 27, 2020). This new subclause provides that the Secretary shall in lieu of these low PRAs, establish a new PRA in accordance with the process described in § 413.77(e), for each such hospital if the hospital **trains at least 1.0 FTE** (in the case of a Category A hospital) or **more than 3.0 FTEs** (in the case of a Category B hospital) (emphasis added). The recalculation period begins on December 27, 2020, and ends 5 years later.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25520 through 25521), we proposed that to redetermine the PRA, the training occurring at a Category A Hospital or a Category B Hospital need not necessarily be training residents in a *new* program; the residents may be in either an approved program that is “new” for Medicare IME and direct GME purposes, or may be in an existing approved program. This is because the new subclause does not state that the training be in a “new” program, and furthermore, CMS’s current policy is that for a hospital which starts training residents for the first time, the PRA can be established based on the training of residents in either a “new” approved program, or an existing approved program. However, for a Category A Hospital, we proposed not to reset its PRA until we determine that the Category A Hospital trains at least 1.0 FTE, and that training must occur in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years after enactment). Similarly, for a Category B Hospital, we proposed not to reset its PRA until we determine that the Category B Hospital trains more than 3.0 FTEs, and that training must occur in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years after enactment). Because new section 1886(h)(2)(F)(iii) uses the word “trains”, we interpret this to require “continuous” training, and therefore, we proposed that for both Category A and B Hospitals, it is not relevant whether they may have trained at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period or periods prior to December 27, 2020. While we proposed that such previous training of at least 1.0 FTE or greater than 3.0 FTEs would not preclude resetting of a Category A Hospital’s PRA or a Category B Hospital’s PRA, we proposed that the relevant factor in determining when to reset their PRAs would be if and when the hospital trains the requisite amount of FTE residents in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and 5 years after (December 26, 2025). For example, a Category A Hospital trains 6.05 FTEs in its cost reporting period beginning on January 1, 2020. The Category A Hospital trains 5.95 FTEs in its cost reporting period beginning on January 1, 2021. We proposed that we would reset this

Category A Hospital's PRA effective with its cost reporting period beginning on January 1, 2021. In a second example, a Category B Hospital trains 6.05 FTEs in its cost reporting period beginning on January 1, 2020. The Category B Hospital trains 2.0 FTEs in its cost reporting period beginning on January 1, 2021. Then the Category B Hospital trains 3.25 FTE in its cost reporting period beginning on January 1, 2022. We proposed that we would reset this Category B Hospital's PRA effective with its cost reporting period beginning on January 1, 2022. Once reset, in the absence of additional legislation, the PRAs for either a Category A Hospital or a Category B Hospital are permanent, subject to annual inflation updates under 42 CFR 413.77(c)(1).

We refer readers to section II.B.5.f. of this final rule with comment period for a summary of the policies we are finalizing after consideration of public comments, on redetermination of PRAs provided under section 131 of the CAA.

#### c. Calculating the Replacement PRA and Cost Reporting Requirements

Consistent with the new statute, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25521), we proposed to calculate the replacement PRA using the existing regulations in place at 42 CFR 413.77(e). First, we proposed to use as the PRA base period the first cost reporting period beginning on or after December 27, 2020 in which either the Category A Hospital or Category B Hospital trains their requisite threshold FTEs; that is, at least 1.0 FTE is trained at Category A Hospital, and more than 3.0 FTEs are trained at Category B Hospital. Then, as 42 CFR 413.77(e)(1) states, we proposed to amend the regulations to add a new §413.77(e)(1)(iv) to establish the replacement PRA as the LOWER OF--

- The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's replacement base year cost reporting period; and
- The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care

and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

- If there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

We will issue instructions to the MACs and to hospitals to provide for an orderly process of request and review for the purpose of receiving replacement PRAs. When the hospital trained the requisite number of FTEs in a particular cost reporting period, upon submission of that cost report, the hospital will notify its MAC that it believes a replacement PRA can be determined. The MACs of the Category A and Category B Hospitals will review the GME costs and FTE counts reported in the Medicare cost report, rotation schedules supporting the FTE counts, etc. to determine at what point the requisite threshold of FTE residents are trained. As required under 42 CFR 413.20 and 413.24, hospitals must provide sufficient documentation to ensure proper payment (for GME, this includes, but is not limited to, rotation schedules and training agreements). We note that newly amended section 1886(h)(2)(F) of Act makes two points regarding cost reporting. First, clause 1886(h)(2)(F)(ii) states that in the case of a hospital that trains residents and has not entered into a GME affiliation agreement (as defined by the Secretary for purposes of paragraph (4)(H)(ii)), on or after the date of enactment of this clause, the Secretary shall not establish an FTE resident amount until such time as the Secretary determines that the hospital has trained as least 1.0 FTE resident in an approved medical residency training program in a cost reporting period. Medicare GME affiliation agreements, as implemented in the regulations at 42 CFR 413.79(f), permit teaching hospitals that cross train residents in the same programs to aggregate and share their FTE resident caps to facilitate movement of residents and reimbursement for that training. Entering into a Medicare GME

affiliation agreement is a voluntary and conscious action on the part of a hospital. Therefore, even if a hospital trains less than 1.0 FTE (and this would be any hospital, not just a Category A Hospital or a Category B Hospital), but has entered into a Medicare GME affiliation agreement for that training, we stated in the proposed rule that we believe the law is directing the Secretary to establish a PRA for that hospital. Thus, effective for a cost reporting period beginning on or after enactment (December 27, 2020), we proposed to establish a PRA in the instance where a hospital trains less than 1.0 FTE and that hospital has entered into a Medicare GME affiliation agreement for that training. However, in the instance where a hospital did **not** enter into a Medicare GME affiliation agreement for that training, we proposed to establish a PRA only when a hospital trains at least 1.0 FTE. We proposed to amend the regulations at 42 CFR 413.79(f) to reflect this new provision.

Second, section 1886(h)(2)(F)(iv) states that for purposes of carrying out this subparagraph for cost reporting periods beginning on or after the date of the enactment of this clause, a hospital shall report full-time equivalent residents on its cost report for a cost reporting period if the hospital trains at least 1.0 full-time equivalent resident in an approved medical resident training program or programs in such period. Accordingly, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25521 through 25522), we proposed that both a Category A Hospital and a Category B Hospital must accurately report FTEs on the IME Worksheet E, Part A and the direct GME Worksheet E-4 of CMS-Form-2552-10, when either category of hospital trains at least 1.0 FTE on or after December 27, 2020. We further proposed that *all* hospitals, even if they do not classify as Category A or Category B Hospitals, must enter the FTE counts on Worksheets E, Part A and E-4 of the CMS-Form-2552-10, for cost reporting periods during which the hospital trains at least 1.0 FTE. In addition, the hospital must provide the information required by the Interns and Residents Information System (IRIS) software for a cost report that contains at least 1.0 FTE on Worksheets E, Part A (IME) and E-4 (direct GME). We proposed this rule regardless of whether or not such hospital incurs the costs or is the program sponsor,

because we believe that a PRA is established when a hospital trains at least 1.0 FTE (or, if there is a Medicare GME affiliation agreement, even less than 1.0 FTE). We proposed to amend the regulations at 42 CFR 413.78(b), with a cross-reference to 42 CFR 413.77(e) and 413.79(f), to require that effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if: (1) in the absence of a Medicare GME affiliation agreement, a hospital trains at least 1.0 FTE in an approved program or programs; or (2) if there is a Medicare GME affiliation agreement, a hospital trains less than 1.0 FTE in an approved program or programs. As we stated in the proposed rule, this proposed regulation would put hospitals on notice that they would establish a PRA when they report FTE residents on their Medicare cost report beginning on or after December 27, 2020.

On a technical note, newly added clause 1886(h)(2)(F)(v) states that as appropriate, the Secretary may consider information from any cost reporting period necessary to establish a new FTE resident amount. Keeping in mind the regulations regarding predicate facts at 42 CFR 405.1885, our policy has been to refer, but not make changes, to a hospital's "true" base year under 42 CFR 413.77(e), even if that base year cost report is beyond the 3-year reopening rules. For example, if, in 2019, a MAC discovered that a hospital trained a small number of FTE residents in its 2005 cost reporting period, the MAC would use the 2005 cost report and documentation to obtain direct GME costs (if any, or \$0) and the FTE resident(s), determine a cost per FTE, and compare that to the 2005 weighted average PRA of the other teaching hospitals in the same CBSA, even though the 2005 cost report was beyond the 3-year reopening period. In accordance with 42 CFR 413.77(e), the MAC would establish the LOWER of the two amounts to be the hospital's base year PRA. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), we proposed to continue to be consistent with our existing predicate fact regulations going forward, such that we would not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation we would need to establish

a PRA. However, because section 131 of the CAA directs the Secretary to replace a Category A Hospital's PRA or a Category B Hospital's PRA if the hospital trains at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period beginning on or after such date of enactment and before the date that is 5 years after, we proposed to amend the regulations at 42 CFR 413.77(e) to use as the PRA base year for a Category A Hospital the cost reporting period beginning on or after December 27, 2020 and before December 26, 2025 in which that hospital trains at least 1.0 FTE, and for a Category B Hospital, the cost reporting period beginning on or after December 27, 2020 and before December 26, 2025 in which that hospital trains more than 3.0 FTEs. In determining whether a hospital trained the requisite thresholds of 1.0 or more than 3.0 FTEs, we proposed not to round up; that is, an FTE count of 0.99 would not be rounded up to be at least 1.00 FTE. Rather, the FTE count would have to equal at least 1.00 without rounding applied. Similarly, an FTE count would have to add to be greater than 3.00 without rounding rules applied.

d. Hospitals Qualifying to Reset their FTE Resident Caps

Section 131(b) of the CAA 2021 amends section 1886(h)(4)(H)(i) of the Act to add new subclauses (II) through (V) to describe the categories of hospitals that qualify to receive a replacement PRA. For ease of reference, we continue to refer to these hospitals as Category A and Category B. As explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), a Category A Hospital is one that, as of the date of enactment (December 27, 2020), has an IME and/or direct GME FTE resident cap that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997. Typically, a Category A hospital is one that did train less than 1.0 FTE in its most recent cost reporting period ending on or before December 31, 1996, and therefore, received FTE caps of less than 1.0 FTE (along with a very low or \$0 PRA). A Category B Hospital is one that, as of the date of enactment (December 27, 2020), has an IME and/or direct GME FTE resident cap that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or after

October 1, 1997, and before the date of enactment (December 27, 2020). The new subparagraphs (III) and (IV) provide that the Secretary shall adjust the FTE resident cap in the manner applicable to a new approved medical residency training program, which under subparagraph (V), states that the adjustment to the FTE resident cap shall be made in a manner consistent with the methodology, as appropriate, in § 413.79(e). The Secretary shall adjust the FTE resident caps if the hospital “begins training” at least 1.0 FTE (in the case of Category A) or “begins training” more than 3.0 FTEs (in the case of Category B) in a program year beginning on or after such date of enactment and before the date that is 5 years after such date of enactment (emphases added).

Unlike our preceding proposal regarding resetting the PRAs of Category A and B Hospitals, where a training program does not necessarily need to be new, in the case of resetting the FTE resident caps, we did propose that the FTE resident caps would only be reset when a Category A Hospital or Category B Hospital “begins training” FTE residents in a new residency program(s) (see our discussion of the definition of “new program” at 42 CFR 413.79(l) and 74 FR 43908 through 43917). Specifically, we emphasize that the new subparagraphs (III) and (IV) state that the Secretary shall adjust the FTE resident caps in the manner applicable to a new program if the Secretary determines the hospital “begins training” the requisite number of FTE residents (emphasis added). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), we proposed that “begins training” means *future* training in a new program *for the first time on or after enactment*. We proposed that for both Category A and B Hospitals, it is not relevant whether they may have trained at least 1.0 FTE or more than 3.0 FTEs in a new program in a cost reporting period or periods prior to December 27, 2020; rather, we proposed that the relevant factor in determining the timing of resetting their FTE resident caps would be if the hospital *first begins training* the requisite amount of FTE residents at some point in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and 5 years after (December 26, 2025). For example, a Category A Hospital trains 6.05 FTEs in a new program in



its cost reporting period beginning on January 1, 2017. Category A Hospital trains 15.95 FTEs in its cost reporting period beginning on January 1, 2021. We proposed that we would NOT reset this Category A Hospital's FTE resident caps effective with its cost reporting period beginning on January 1, 2021, because it first began training residents in a new program prior to its cost reporting period beginning on or after enactment, and continued to train FTE residents in the new program after enactment. Rather, in order to qualify for a replacement FTE resident cap, both a Category A Hospital and a Category B Hospital would have to wait to start training residents in a new program in a cost reporting period beginning on or after enactment; if they started training residents in a new program at some point prior to enactment, we proposed that they would not qualify to receive replacement FTE resident caps. For example, a Category A Hospital wanted to start training residents in a new program, but delayed doing so because it believed it could not support a new residency program with IME and direct GME FTE resident caps of less than 1.0. With the enactment of section 131 of the CAA, this Category A Hospital receives accreditation to start a new residency program, and begins to train at least 1.0 FTE resident in the new program on July 1, 2022. We proposed to replace the small FTE resident caps of this Category A Hospital with new FTE resident caps in accordance with the regulations for calculating FTE resident caps for new programs at 42 CFR 413.79(e). We proposed to apply the same policy for a Category B Hospital that waits to train more than 3.0 FTE residents in a new program in a cost reporting period on or after December 27, 2020.

e. Calculating the Replacement FTE Resident Caps and Cost Reporting Requirements

Consistent with the new statutory provisions, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25523), we proposed to calculate the replacement FTE resident caps using the existing regulations in place at 42 CFR 413.79(e)(1). First, we proposed to use the first program year of the 5-year cap building period in which either the Category A Hospital or Category B Hospital "begins training" their requisite threshold FTEs; that is, the program year beginning after December 27, 2020 in which at least 1.0 FTE begins to train at Category A Hospital, and

the program year beginning after December 27, 2020 in which more than 3.0 FTEs are trained at Category B Hospital. Then, as 42 CFR 413.79(e)(1) states, we proposed to calculate the FTE resident caps based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to each qualifying hospital's cap for new residency training program(s) would be equal to the sum of the products of--

- The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate;

- The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

- The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

We will issue instructions to the MACs and to hospitals to provide for an orderly process of request and review for the purpose of receiving replacement FTE resident caps. The MACs of the Category A and Category B Hospitals will review the FTEs reported in the Medicare cost reports, as well as rotation schedules, information regarding any nonprovider-site training, and accreditation information, etc.) to determine at what point the requisite threshold of FTE residents are trained. As required under 42 CFR 413.20 and 413.24, hospitals must provide sufficient documentation to ensure proper payment (for GME, this includes, but is not limited to, rotation schedules and training agreements, and ACGME accreditation information).

Prospectively, consistent with new section 1886(h)(4)(H)(i)(II) of the Act, we proposed not to establish permanent FTE resident caps for hospitals training residents in new programs begun on or after December 27, 2020, until we determine that in a cost reporting period

beginning on or after December 27, 2020, the hospital trains at least 1.0 FTE in a new medical residency program. We proposed to amend the regulations at 42 CFR 413.79(e) to reflect this new provision. We proposed this for all hospitals that do not yet have caps triggered. Therefore, permanent FTE caps for new programs would no longer be triggered if the amount of FTEs being trained by a hospital in the new program equates to less than 1.0 FTE.

As with the resetting of the PRAs, newly added section 1886(h)(4)(H)(i)(V) states that as appropriate, the Secretary may consider information from any cost reporting period necessary to make such an adjustment to the limitation. Going forward, we proposed to continue to be consistent with our existing predicate fact regulations at 42 CFR 405.1885, such that we would not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation we would need to establish the FTE resident caps.

We invited comments on our proposals regarding resetting the applicable PRAs and FTE resident caps. Following are the comment summaries and our responses:

Comment: Many commenters expressed support for our proposals for defining Category A and Category B hospitals and how we would reset PRA and cap.

Response: We appreciate the commenters' support for our proposals.

Comment: Several commenters were concerned with the CMS suggestion that Medicare Audit Contractors (MACs) could use "predicate facts" to establish a new FTE resident amount, using whatever "contemporaneous documentation we would need to establish a PRA" or "contemporaneous documentation we would need to establish the FTE resident caps." (p. 25522, 25524). This leads to confusion as to how and why CMS will decide which facts are predicate facts, and which ones are not. Commenters stated that hospitals may be discouraged from availing themselves of the opportunities set out in section 131 of the CAA if MACs may find records of past training that will leave them with an extremely low PRA or FTE cap. They requested clarification as to how CMS and the MACs will decide what predicate facts are

relevant, as well as assurances that MACs will not be encouraged to search for predicate facts that may suppress hospitals' GME support from Medicare.

Response: We believe the commenters misinterpreted the language in the proposed rule regarding "predicate facts." In the proposed rule, we did not propose any new policy regarding predicate facts, nor did we propose any new review procedures that are different from already existing policy. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), we merely proposed to "continue to be consistent with our existing predicate fact regulations" at 42 CFR 405.1885, under which our policy has been to refer, but not make changes, to a hospital's "true" base year under 42 CFR 413.77(e), even if that base year cost report is beyond the 3-year reopening rules.... Going forward, we propose to continue to be consistent with our existing predicate fact regulations, such that we would not reopen cost reports beyond their 3-year reopening period, *but would refer to and use whatever contemporaneous documentation we would need to establish a PRA*" (emphasis added). This means that the MACs are not hindered by the fact that a cost report is not reopenable, but instead have the flexibility to still consider documentation available from that time frame of that non-reopenable cost report. Accordingly, hospitals that believe they have PRAs set based on a small amount of FTEs, and/or have small FTE caps from a cost report prior to enactment more likely have nothing to lose, and would gain from providing contemporaneous documentation to the MAC for an assessment of its reset eligibility. If a hospital does not provide documentation and does not engage with the MAC at all, then it certainly would be left with a PRA or caps that it believes is "low". The intent of section 131 of the CAA is to provide reset opportunities where there previously were none. Nevertheless, as with existing policy, documentation that hospitals provide to the MAC must meet sufficiency standards; newly added clause 1886(h)(2)(F)(v) does not include an exceptions language waiving otherwise standard documentation practices. In response to the following comments, we include more details on the types of documentation that we require or consider acceptable.

Comment: Many commenters provided feedback regarding the review process CMS and the MACs would use to determine eligibility for PRA or FTE cap resets. Several commenters stated they believe the public should have an opportunity to comment on the process before it is finalized by CMS, perhaps even via an interim final rule with comment period. Commenters also expressed concerns and confusion as to which hospitals will be eligible for PRA or cap resets, and that hospitals that do meet the statutory criteria could be “overlooked” by the MACs for possible eligibility for a reset. Some commenters urged CMS to publish a list of all hospitals that may have inadvertently triggered a PRA or caps. The following are some scenarios that the commenters posited:

- What if a hospital did not report a small number of FTE residents on its cost report because it was under the impression that it had not established a new residency program and was not eligible for Medicare DGME or IME reimbursement, and the hospital has received a notice of provider reimbursement for that cost reporting period?

- How would CMS treat a hospital that did not report its low number of FTE residents on an old cost report because it did not believe it was eligible for DGME or IME reimbursement; or that did not report residents but if they had, would have a \$0 or minimal PRA and low FTE cap?

- What does it mean to “have” a PRA or “have” FTE caps “as of enactment?”

- How would CMS treat hospitals that trained a resident but never reported FTEs on their cost reports?

- What if a hospital triggered a PRA but the MAC did not determine and finalize a PRA on a settled cost report?

- What if a hospital’s cap building period was triggered prior to enactment, but the 5-year window closed in a cost report after enactment?

- What type of documentation would CMS require, given that the statutory provision stretches back to determinations made in 1996, and contemporaneous documentation from the time period of the cost report may be difficult to obtain?

Response: We acknowledge there are complexities in implementing section 131 of the CAA, and believe the commenters raised fair points in their comments. In general, the primary challenges we and the MACs face in implementing section 131 of the CAA are managing myriads of review requests in an efficient and timely manner, competing MAC priorities for review, and dealing with old documentation, most likely from cost reports that are no longer within the 3-year reopening period. Our final policies try to balance these considerations. We believe that it is incumbent on a hospital to approach its MAC to request a PRA or cap reset; we are not instructing MACs to reach out to individual hospitals. We also distinguish between cost reports that are no longer reopenable, cost reports that have been settled but are still open or reopenable, and cost reports that have not yet been settled.

- Settled but Open or Reopenable Cost Reports

First, in this final rule with comment period, to manage the volume of review requests, we are finalizing policies related to PRA and FTE cap determinations from cost reports that have been settled but are still open or reopenable, and cost reports that have not yet been settled, with one exception related to the 1996 FTE caps (explained in greater detail in this section). We believe the MACs' workload will be considerable from these relatively more recent categories of cost reports alone, and in order to spread the workload, we will instruct MACs to first only accept PRA or FTE cap review requests from hospitals where the base year or cap setting cost report is open or reopenable.

We are seeking comment on how to handle reviews of PRAs or FTE caps from cost reports beyond the 3-year reopening period (with the exception of Category A and Category B hospitals that agree with the HCRIS posting, as discussed below).

(1) Use of HCRIS to Assist in Determining Reset Status

On the points raised by commenters about which hospitals will be eligible for PRA or cap resets, and that CMS should publish a list of hospitals and their status, we will post a file on the CMS website containing an extract of the HCRIS cost report worksheets on which the FTE counts, caps, and PRAs, if any, would have been reported, starting with cost reports beginning in 1995 (although as we stated previously, we are instructing MACs to only first accept reviews of PRAs or FTE caps from open or reopenable cost reports, with the exception of a Category A hospital or a Category B hospital that agrees with what is/is not reported in the HCRIS posting). This file will be made available on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices>. Click on the link on the left side of the screen associated with the appropriate final rule home page or “Acute Inpatient—Files for Download.” This file will also be made available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME>. Use of the HCRIS extract provides a national, standard source for MAC determinations.

If a hospital wishes to receive a PRA or cap determination from its MAC for a possible reset of an open or reopenable cost report, the hospital must consult the web posting first. In cases where no PRA or caps are reported on a settled cost report, or when PRAs or caps are reported without any FTEs, and cost report is settled but reopenable, the hospital gets the benefit of a reset without further review by the MAC. Examples of hospitals that would qualify for a reset based on the HCRIS extract without need for further MAC review are as follows:

- The hospital’s cost report in HCRIS that ended on or before December 31, 1996 shows an FTE count of less than 1.0 for either IME or direct GME (Category A).
- The hospital’s cost report in HCRIS that began on or after October 1, 1997, and before enactment of section 131 of CAA shows an FTE count of not more than 3.0 for either IME or direct GME (Category B).

- A hospital's employee(s) recall that residents were trained at the hospital, but no FTEs were reported on any settled Medicare cost report, as shown in HCRIS.
- A hospital where FTEs are reported on a settled cost report, but the FTE cap lines are not filled (this hospital would be eligible for new FTE caps).
- A hospital with FTEs reported on a settled cost report, but the PRA lines are not filled in on that earliest cost report where FTEs are reported (this hospital would be eligible for a new PRA).
- A hospital with a PRA reported on a settled cost report, but no FTEs are reported on the earliest cost report in which the PRA is reported, so the amount of FTEs used to determine that PRA cannot be determined (this hospital would be eligible for a new PRA).

We believe that allowing resets in the circumstances stated previously demonstrates our willingness to fulfill Congressional intent to allow eligible hospitals their second chance at meaningful IME and direct GME reimbursement, and further indicates that we and the MACs intend to be fair and reasonable throughout the implementation process. As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25523), MACs would calculate the replacement PRAs and/or FTE resident caps using the existing regulations in place at 42 CFR 413.77(e) and 42 CFR 413.79(e)(1), but after the MAC confirms that either the Category A Hospital or Category B Hospital trains their requisite threshold FTEs in a new program(s) started after December 27, 2020.

#### (2) One-Time Deadline to Request Reconsideration and Review by the MAC for Possible Category B Hospitals

If, for open or reopenable cost reports, there is a PRA and/or FTE caps reported on the HCRIS web posting, and the potential Category B hospital believes its PRA in fact was established based on not more than 3.0 FTEs, or its IME and/or direct GME FTE caps were based on not more than 3.0 FTEs, a hospital has a **1-time opportunity** to request reconsideration by its MAC which **must be submitted electronically and received by the MAC on or before**



**July 1, 2022.** We are providing this lead time for this 1-time submission to assist hospitals in ensuring that they include complete and unambiguous documentation supporting their assertion that the HCRIS cost report information is incorrect. We also believe this approach encourages only review requests with realistic chances for reset eligibility under section 131 of the CAA. (See response regarding documentation required). The MAC would review the information within a specified timeframe to be determined by CMS and make a determination as to the hospital's eligibility for a PRA and/or FTE cap reset based on the adequacy of the documentation submitted by July 1, 2022. The decision issued by the MAC to the hospital would be final. If the MAC determines that the FTEs reported are greater than 3.0 respectively, the hospital is NOT eligible for a PRA or FTE cap reset. Hospitals that disagree with the MAC's determination could appeal to the Provider Reimbursement Review Board for review, assuming that all conditions for appeal are met.

### (3) Cost Reports Not in HCRIS or Not Yet Settled

There may be situations where a cost report is not in HCRIS web posting, or even if the cost report is in the HCRIS web posting, there is no PRA or no FTE caps reported because the cost report has not yet been settled and/or the MAC has not yet determined the PRA or the FTE caps. Such a hospital must submit a request to the MAC by July 1, 2022 requesting that the MAC issue a determination regarding possible reset eligibility for the PRA and/or FTE caps using cost reports that began prior to enactment. The review request must be received by July 1, 2022, and must include complete and unambiguous documentation for FTE counts and for FTE cost and payment information (see response regarding documentation requirements). The MAC would use existing regulations at 42 CFR 413.77(e) and 42 CFR 413.79(e)(1) to determine the hospital's PRA and FTE caps from the cost report(s).

For cost reports that began during CY 2020 (but still prior to enactment of the CAA) and are subject to PHE submission deadlines, the hospital must file its cost report with complete and unambiguous supporting GME documentation to the MAC by July 1, 2022 in order to receive

consideration for possible PRA or FTE cap reset. MACs will reject incomplete or untimely submissions, with no opportunity for a later or 2<sup>nd</sup> MAC review.

If the MAC determines that the FTEs are greater than 3.0, the hospital is NOT eligible for a PRA or FTE cap reset. Hospitals that disagree with the MAC's determination may appeal to the Provider Reimbursement Review Board assuming that all conditions for appeal are met.

Accordingly, for the purpose of implementing section 131 of the CAA, in response to the comment asking what it means to "have" a PRA or "have" FTE caps "as of enactment," we are clarifying that "having a PRA" means that there is a PRA reported in HCRIS from a cost reporting period beginning prior to enactment, or if not in HCRIS or not yet determined, the MAC determines the PRA based on the hospital's request by July 1, 2022, but from a cost reporting period beginning prior to enactment. If the PRA base period cost report begins prior to enactment, we believe it is acceptable if it ends after enactment. This is because section 131(a)(iii) states, ". . . in the case of a hospital that, as of such date of enactment, **has an approved FTE resident amount . . .** in any cost reporting period **beginning** on or after October 1, 1997, and **before the date of enactment . . .**" (emphasis added). Thus, a hospital's PRA could have been initiated when training no more than 3.0 FTEs in a cost report beginning prior to enactment on May 1, 2020, and ending April 30, 2021 (after enactment). Similarly, we are clarifying that "having FTE caps as of enactment" means that the 5-year cap building window would close in a cost reporting period that *began before enactment*, although the cost report may end after enactment. This is because section 131(b)(IV) states, "in the case of a hospital that, as of the date of the enactment of this subclause, has a limitation under subparagraph (F), **based on a cost reporting period beginning . . . before such date of enactment . . .**" (emphasis added). For example, if a hospital's 5-year cap building window closed June 30, 2021, but that was during the hospital's cost report beginning October 1, 2020 (prior to enactment) and ending September 30, 2021 (after enactment), this hospital would "have" FTE caps as of enactment.

#### (4) PRA Base Periods Initiated Prior to Enactment, with Cap-Building Period Ending After Enactment

Commenters requested clarification regarding when a hospital's cap building period was triggered prior to enactment, but the 5-year window closes in a cost report with a *start date after enactment*. The following policies apply. As we stated previously, in response to the comment asking what it means to "have" a PRA and "have" FTE caps "as of enactment," if the PRA base period cost report begins prior to enactment, we believe it is acceptable if it ends after enactment. Similarly, "having FTE caps as of enactment" means that the 5-year cap building window would *close in a cost reporting period that began before enactment*, although the cost report may end after enactment. That is, the 5-year cap building window would have to close during a cost reporting period that *started prior to enactment*. For example, if a hospital's 5-year cap building window closed June 30, 2021, but that was during the hospital's cost report beginning October 1, 2020 (which started prior to enactment) and ending September 30, 2021 (after enactment), this hospital would "have" FTE caps as of enactment. Under existing regulations at 42 CFR 413.79(e)(1), the year for determining new program caps is the third year of the new program's existence for programs started prior to October 2012, and the fifth year of new program's existence for programs started after October 2012. Therefore, only hospitals whose *third or fifth program year ENDS in a cost reporting period that started PRIOR to enactment* would qualify under section 131 of the CAA for a possible FTE cap reset. The law does not allow consideration for FTE cap reset for a hospital whose FTE cap setting year (that is, the cost report following the close of the 5-year cap building window) begins after enactment. Therefore, there can be situations where a hospital might be eligible for a PRA reset, as the PRA base period occurred prior to enactment, while the same hospital is NOT eligible for FTE cap resets, since the relevant cost reporting period for setting that hospital's FTE caps in accordance with 42 CFR 413.79(e)(1) would not even occur until some time after enactment. For example, a hospital for the first time trains 2.0 FTE residents in a new program in its cost reporting period

beginning January 1, 2019 and ending December 31, 2019. The new program started on July 1, 2019. This FYE December 31, 2019 would be the PRA base period, so the hospital would “have” a PRA “as of enactment”. The 5-year cap building window would end on June 30, 2024, during the hospital’s cost report that began January 1, 2024. Since the 5-year cap building window ends in a cost report that starts after enactment, this hospital does not have a FTE cap “as of enactment,” and would not qualify under section 131 for an FTE cap reset.

Therefore, hospitals submitting documentation to their MACs by July 1, 2022 for a determination regarding PRA or FTE cap reset must include documentation showing that the PRA base period started prior to December 27, 2020, and that the 5-year cap building window ended in a cost reporting period that started prior to December 27, 2020. Such documentation includes the following:

- The date that residents in a new program first rotated into this hospital (see August 27, 2009 IPPS final rule (74 FR 43908) for definition of new program).
- Whether that date was the first time residents began training at ANY rotational site for that program, or whether residents in that program had previously rotated to other sites before rotating into this hospital.

Comment: A commenter requested clarification on what documentation would be needed to demonstrate/obtain eligibility for a PRA or cap reset. The commenter stated that they have cost reports, but no longer have records of IRIS reports or rotation schedules.

Response: We are not creating new or different documentation requirements for the purpose of section 131 of the CAA, but continue to use our existing documentation requirements, discussed previously in the August 29, 1989 final rule (54 FR 40286, 40291 and 40304), the August 18, 2006 IPPS final rule (71 FR 47869, 48077), and implemented at 42 CFR 413.75(d). We stated that a rotation schedule is the primary documentation that can be used to support the direct GME and IME resident counts but other similar documentation may be acceptable (71 FR 48077). The rotation schedule is prepared by the Program Director for each

program for each program year. As such, there is only one rotation schedule for each approved program for each program year and all the hospitals to which the residents in that program rotate must use that same schedule. 42 CFR 413.78(d) states, “The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.” If the hospitals to which the residents rotate have other than June 30 FYEs, the hospitals must use two rotation schedules which overlap that FYE.

We are including a list of documents necessary to demonstrate the FTEs from which a PRA would have been calculated or from which a FTE cap would have been calculated. The main documentation needed for FTE cap support and for the FTEs claimed on the earliest cost report which will be used to determine if the hospital meets the less than 1.0 FTE or not more than 3 FTEs requirement for the PRA is: the program approvals; the rotation schedules showing the location of the residents, either within hospitals or nonprovider sites per 42 CFR 413.78(g); the Intern and Resident Information System (IRIS) (to be used only as an audit tool until direct GME and IME counts on the IRIS and the cost report match); a resident’s Foreign Medical Graduate Examination in the Medical Sciences certificate (FMGEMS) status for direct GME under 42 CFR 413.75(b) and 42 CFR 413.80; information whether the resident is full-time/part-time at the hospital; agreements between the hospitals and program approval if the resident is floating from another hospital’s program.

Documentation to establish a PRA includes payroll and employment data indicating payment of residents’ salaries and fringe benefits if the hospital employs the residents, contracts with medical schools or other hospitals which employ the residents specifying the charges to the host hospital for these expenses and related invoices, evidence that the host hospital actually paid the charges from the medical school or other hospital, documentation of the expenses the host hospital paid for the portion of the teaching physicians’ compensation and fringe benefits related to teaching and supervision of the residents, and documentation supporting payment of other Medicare allowable costs that are directly related to operating the program (such as salaries of

the program director and other office staff associated with operating the program, and operating and overhead costs directly attributable to training the residents).

We understand that there may be some difficulty involved in procuring documentation in the case where the hospital seeking to reset its low PRA and FTE caps trained the residents for a minimal time, and may not have the official documents such as the rotation schedule.

Nevertheless, we want to be clear that unofficial copies or deviations from the official program rotation schedule and other substitutions will not be accepted. Hospitals seeking PRA and cap resets still must meet standard documentation requirements (per 42 CFR 413.20 and 413.24), and will have to work with the program primary clinical sites and program director to obtain definitive FTE information. In an effort to implement section 131 of the CAA in an accurate and administratively feasible manner, it is of utmost importance for hospitals to submit clear and acceptable documentation to their MACs by the July 1, 2022 deadline. The MACs' determinations will be based on documentation received by that date. Hospitals may supplement their documentation up until the July 1, 2022 deadline, but not after that date. We reiterate that we are not creating new or different documentation requirements for the purpose of section 131 of the CAA, but continue to use our existing documentation requirements, discussed previously in the August 29, 1989 final rule (54 FR 40291 and 40304), the August 18, 2006 IPPS final rule (71 FR 48077-78), and implemented at 42 CFR 413.75(d).

Comment: A commenter believed it is not appropriate for CMS to require that a teaching hospital permitted to have its PRA reset use a base period that has already begun at the time of the release of the IPPS proposed rule. The commenter asserted that hospitals want to know how CMS proposes to implement this provision, then see how the rules are finalized, and then avail themselves of the opportunity for a reset as applicable. This commenter requested that CMS permit a hospital to use any base period within the statutory 5-year window, including a base period that begins: (1) after enactment of the CAA; (2) after publication of the IPPS proposed rule; (3) after publication of the IPPS final rule; and (4) after CMS issues instructions to the

MAC and the community for carrying out this process. Then, the commenter recommended that CMS allow hospitals to request to have their PRAs reset based on an applicant hospital's next full cost reporting period following approval by CMS of its application and request.

Response: We understand the commenter's point that although hospitals can avail themselves of a PRA reset as early as after the enactment of the CAA, that initial cost report overlapping with or immediately following CAA enactment would still be when the hospital is unaware of how CMS intends to implement section 131 of the CAA. We agree with the commenter that a hospital should have some flexibility in determining the timing of its new PRA base period, to the extent that the statute permits. However, we note, that clause (iii)(II) of section 131 of the CAA directs the Secretary to reset a PRA "if the hospital trains at least 1.0" FTE or "more than 3.0" FTE "in a cost reporting period beginning on or after such date of enactment and before the date that is 5 years after such date of enactment." That is, the timing of the revised PRA base period is dependent upon when the hospital trains at least 1.0 FTE or more than 3.0 FTE (as applicable) in the time frame of after enactment and 5 years after that. We also note that clause (iii)(II) of section 131 of the CAA directs the Secretary to use the methodology in the regulations at 42 CFR 413.77(e) to establish the revised PRA, which typically would mean use of the earliest cost report in which the hospital trains residents in an approved program. Therefore, we do not believe we can provide hospitals with the option to choose any cost reporting period occurring during the time frame of after enactment and 5 years after as the new PRA base period. However, we believe we can utilize the flexibility provided by section 131 of the CAA, clause (v), which states, "As appropriate, the Secretary may consider information from any cost reporting period necessary to establish a new FTE resident amount as described in clause (iii)" (emphasis added). Therefore, we believe it would be fair to allow a hospital to have the option of using as its new PRA base period cost report *the first cost reporting period beginning after issuance of this final rule with comment period*. That is, we are finalizing a policy that if the hospital already started training at least 1.0 FTE or more than 3.0 FTEs in a cost

reporting period beginning immediately following enactment, the hospital could choose to use either that cost report as the PRA base period, or the hospital could wait to see if the first cost reporting period beginning after issuance of this final rule with comment period may result in a more favorable PRA. If a hospital does not even start training at least 1.0 FTE or more than 3.0 FTEs until a cost reporting period that is *after* the first cost reporting period beginning after issuance of this final rule with comment period (but still within 5 years after enactment), then the hospital would not have a choice as to which cost reporting period to use as its new PRA base period; the hospital must use that second or subsequent cost reporting period after issuance of this final rule with comment period as its new PRA base period. We are revising the regulations at 42 CFR 413.77(e)(1)(iv) accordingly. We are also not requiring in the regulations at 42 CFR 413.77(e)(1) that residents be on duty during the first month of the PRA base period for teaching hospitals receiving a PRA reset, and for new teaching hospitals in general. We believe that requirement is no longer relevant, in light of the statutory focus on when at least 1.0 or more than 3.0 FTEs are trained.

Comment: A commenter noted that throughout the discussion in the proposed rule regarding the opportunity for a hospital to adjust its small IME and direct GME FTE caps, CMS uses words like “replace,” or “reset,” which implies that CMS would eliminate even the small amount of FTE cap that the hospital already has, and give a different cap. The commenter believed that Congress is directing CMS to allow a qualifying hospital to *add to* its existing direct GME or IME caps (not restart at zero).

Response: We have reviewed the language of section 131 of the CAA, and we note that section 1886(h)(4)(H)(i)(III) of the Act, as added by subsection 131(b), states that “the Secretary shall adjust the limitation”; it does not say ‘in lieu of’, as it does for the PRA, under clause 1886(h)(2)(F)(iii) of the Act, as added by subsection 131(a) of the CAA. Accordingly, we agree with the commenter that an eligible hospital would keep its IME or direct GME FTE caps of less than 1.0 or not more than 3.0, and any cap amount based on new programs would be added to the



original cap amounts. That is, new caps created based on new programs started after enactment and 5 years after would be added to the hospital's original caps, while the original PRA would be replaced by a new PRA from a base year after enactment and 5 years after. We are revising the regulations text at 42 CFR 413.79(e)(1)(vi) accordingly, to state that the adjusted FTE cap is equal to the sum of the original FTE cap and the products of three factors based on the new program(s).

Comment: A commenter expressed confusion regarding what situations CMS intends to exclude with the restriction that it would not reset the caps for a hospital that “first began training residents in a new program prior to its cost reporting period beginning on or after enactment and continued to train FTE residents in the new program after enactment” (86 FR 25522). The commenter was particularly concerned that CMS may be interpreting Congress's intent in using the phrase “begins training” to restrict the applicability of section 131 of the CAA to a much smaller set of hospitals than they believe was intended. Other commenters argued that by adding the term “first” or “first time”, in front of “begins training” CMS changes the entire meaning of the provision. These commenters asserted that the statute clearly indicates that beginning a new program should be the trigger, and they do not believe requiring a hospital to have never started a new program since its cap was set is in keeping with the statute. For example, it leaves hospitals with a cap of less than 3 (Category B hospitals) that started a new program after that cap was set, but before the law was enacted, with no recourse. The first commenter provided the following example and requested that CMS confirm their understanding that the section 131 of the CAA FTE cap resetting policy would be implemented for a hospital in this situation in the manner described.

*Example:*

Hospital A, which operates on a cost reporting period of July 1 through June 30, trained residents for the first time as of July 2003. During that residency program year, 2.7 FTE

residents from a new internal medicine program established at New Teaching Hospital B rotated to Hospital A.

- Hospital A continued to train that same number of FTE residents from that same program for the subsequent four residency program years. Hospital A did not train any additional residents in its hospital between July 2003 and June 2008. Hospital A had a DGME cap of 2.7 set as of July 1, 2008.

- Hospital A continued to train 2.7 FTE residents from that same internal medicine program established at New Teaching Hospital B every year between July 2008 and June 2018

- Beginning in July 2018 and during each residency year through June 2022, Hospital A trains 10.0 additional FTE residents from Existing Hospital C in the specialties of family medicine, emergency medicine, and general surgery. The family medicine residents are training in a newly established residency program that first began training residents in July 2018 while the emergency medicine and general surgery residents are training in and rotating from longstanding, existing residency programs.

- In its most recent cost report, Hospital A reports training 12.7 FTE residents and reports a DGME cap of 2.7

- Hospital A applies to CMS to have its cap reset under section 131 of the CAA's provision (based on having a cap of 2.7)

- Beginning in July 2022, Hospital A establishes a new three-year family medicine program approved for 15 positions, with 5 FTE residents in each program year with all FTE resident time countable and no rotations to any other hospitals

- Beginning in July 2025, Hospital A establishes a second new program, a 5-year general surgery program approved for 30 positions, with six FTE residents in its initial program year (July 2025 to June 2026) with all FTE resident time countable and no rotations to any other hospitals

The commenter requests that CMS confirm that Hospital A's DGME cap would be reset as of July 2027 as follows:

2.7 (existing DGME cap prior to enactment of CAA)  
+ 15 (representing cap adjustment for family medicine program started in July 2022)  
+ 30 (representing cap adjustment for general surgery program started in July 2025)  
= 47.7 (new DGME cap as of July 2027)

Response: We have reviewed the statute and we are convinced by the commenters that the statute does not require that a hospital wait to begin a new program until after enactment in order to be considered an eligible Category A or Category B Hospital. We are changing our proposed policy to not disqualify a hospital that started a new program prior to enactment from being eligible for a cap reset, so long as it also starts a new program after enactment. However, we would only give the cap adjustment for new programs started after enactment, not before enactment. Thus, Hospital A in the commenter's example would qualify as a Category B hospital, but its FTE resident caps of 2.7 would be adjusted upward to reflect only the family medicine program and general surgery program started after enactment (in 2022 and 2025 respectively), and NOT the family medicine program started in 2018.

Comment: A commenter requests clarification on the possible confusion of the use of "program year" and "cost reporting year": in one part of the preamble, CMS states that "adjustments will be available for a hospital that begins training more than 1.0 or 3.0 FTE in a *program year* beginning on or after the date section 131 of the CAA was enacted." The commenter stated this inconsistency is mirrored in the proposed regulatory changes to DGME and IME caps at 42 CFR 413.79(e)(1)(vi) and 42 CFR 412.105(f)(1)(vii)(B). The commenter requested that this be remedied or explained.

Response: We are not sure to which inconsistency the commenter is referring. We note that section 131 of the CAA specifically uses the term "program year." That is, section 131(b) of the CAA (adding new section 1886(h)(4)(H)(i)(III) of the Act), states, "In applying this clause in

the case of a hospital that, as of the date of enactment of this subclause, has a limitation . . . of less than 1.0 full-time equivalent resident, the Secretary shall adjust the limitation . . . if . . . the hospital begins training at least 1.0 full time equivalent residents in a **program year** beginning on or after such date of enactment. . . .” (emphasis added). Similar language is at section 1886(h)(4)(H)(i)(IV) of the Act, as added by the CAA, applicable when a hospital begins training more than 3.0 FTEs. Regardless, we are making changes to conform to our final policies at 42 CFR 413.79(e)(1)(vi) and 412.105(f)(1)(vii)(B).

Comment: Some commenters stated that CMS should ensure that the concept of “community support and redistribution of costs” not be applied under this provision. This principle, stating that Medicare will not reimburse for situations after another entity has paid for resident training, is not appropriate because it was statutory and regulatory actions that prevented hospitals from appropriate reimbursement for residency positions from Medicare. At a minimum, CMS should change its rules to allow hospitals in this situation to count the FTEs in the new program or programs established following enactment in setting its new cap during its 5-year cap-setting window.

Response: We disagree with the commenters that we should (even if we could) waive community support principles at 42 CFR 413.81, but also disagree with commenters that it would even be an obstacle. After all, the law would readjust the cap based on “new” programs started by the hospital and if the program is new and the hospital is incurring the cost from the start, then there is no concern of redistribution or community support.

Comment: A few of the commenters argued that CMS’s proposal limits eligibility to the Category A and Category B criteria set forth in subparagraphs iii and iv of CAA 2021 for hospitals that previously trained residents in the distant past. The commenters believed it was a critical omission, and that nothing in the drafting of subparagraphs ii, iii, and iv of the Act as added by the CAA indicates that a hospital’s eligibility is conditioned solely on whether a hospital falls into Category A or Category B. Otherwise, any hospital that has ever reported FTE

residents on a cost report but was unable to meet the technical requirements of Category A or Category B would be barred from establishing a new FTE resident cap, which we believe is contrary to the legislative intent of the Act. Therefore, the commenters requested that CMS clarify that a hospital that has previously reported FTE residents on a cost report may pursue a new FTE resident cap determination under a new residency program pursuant to subparagraph ii of the Consolidated Appropriations Act, 2021.

Response: We do not believe Congress gave us the authority to provide relief or waivers to categories beyond A and B. We believe that the CAA is unequivocally clear about the size of the caps that would be eligible for a reset; that is, for hospitals with caps set based on its 1996 cost report, the cap must be less than 1.0 FTE, and for hospitals with caps set in a cost reporting period between 1997 and prior to enactment, the cap must not be more than 3.0 FTE.

Comment: A commenter noted that section 131 of the CAA states, “A hospital shall report full-time equivalent residents on its cost report for a cost reporting period if the hospital trains at least 1.0 full-time equivalent residents in an approved medical resident training program or programs in such period.” The commenter questioned how a hospital would know that it “shall” and what happens if it does not. The commenter also questioned whether these hospitals would again have PRAs of \$0 and acquire caps without knowing it, after the 5-year window included in the legislation.

Another commenter stated that PRAs have not been proactively assigned to every hospital in the US, and under current regulations a PRA of \$0 is only discovered and established when a resident is first reported on a cost report. The commenter requested that until such time as hospitals have the opportunity for a certified audit financed by CMS prior to training residents, we recommend that all hospitals without a PRA or cap be assigned a PRA that is "the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter," or until a hospital can demonstrate its ability to train residents for less than that amount.

Response: Regarding how to treat hospitals in the future that inadvertently train small numbers of residents, we note that section 131 of the CAA specifies that “for cost reporting periods beginning on or after enactment, a hospital shall report full-time equivalent residents on its cost report if the hospital trains at least 1.0 full-time equivalent residents in an approved medical residency program or programs in such period.” In the proposed rule, we interpreted this to mean that Congress was putting hospitals on notice that they are obligated to be aware of and report their residents to CMS on the cost report for training as minimal as 1.0 FTE. We also believe that section 131 of the CAA is unequivocally clear that a qualifying hospital’s cap or PRA must be in effect “as of enactment,” which means that it would have been (or should be determined) from a cost reporting period that started prior to enactment. Thus, we believe section 131 of the CAA is *not meant to provide relief to hospitals that trigger low caps or PRAs after enactment*. As stated previously, we are also no longer requiring in the regulations at 42 CFR 413.77(e)(1) that residents be on duty during the first month of the PRA base period for teaching hospitals receiving a PRA reset, and for new teaching hospitals in general. We are finalizing our proposed interpretation of these clauses, and accordingly, we do not believe we have flexibility to “forgive” or “ignore” caps or PRAs triggered after enactment, even when the training is not more than 1.0 FTE.

Regarding the comment that prior to the MAC audit for a new teaching hospital’s PRA, the hospital should be assigned the census region PRA, we note that policy is already in effect per Transmittal 1923, CR 10240 (page 5), which states: “. . . the MAC shall use the latest available census region PRA issued by CMS for the census region in which the new teaching hospital is located, updated for inflation to the base period of the new teaching hospital, for the purpose of calculating and paying DGME interim rates. However, once the hospital submits its base year cost report, the MAC shall calculate and assign the appropriate PRA to the new teaching hospital (as part of the normal cost report settlement process for the new teaching hospital).”

Comment: A commenter requested that once a hospital resets its FTE cap under section 131 of the CAA, it should have certainty that no audits will revisit prior training, while another commenter stated that redeterminations under section 131 of the CAA should be binding unless the provider concealed material information, or the provider appeals the determination. Another commenter recommended that hospitals with yet undiscovered low PRAs be subject to limited lookback (for example, 3 years) and only set a PRA when beginning the training of residents in the future. An additional commenter noted that CMS requires records of cost reports to be retained in their original or legally reproduced form for 5 years after the closure of the cost report, and strongly recommended that CMS use the record retention requirements to set a lookback window of 5 years when evaluating the cost reports of hospitals that are seeking to set a new PRA under these rules.

Response: As we stated in response to a previous comment, we must manage a significant workload resulting from implementation of section 131 of the CAA, and therefore, we are taking steps to try to mitigate that workload, including instituting a one-time deadline of July 1, 2022 for hospitals to request a reset for their PRAs or FTE caps. MACs will not consider late documentation, nor will MACs conduct second reviews. Hospitals that disagree with the MACs' determinations may appeal to the PRRB, assuming conditions to appeal are met. In addition, in this final rule with comment period, to manage the volume of review requests, we are finalizing policies related generally to more recent, open cost reports, and would accept comments after publication of this final rule with comment period regarding how to address the use of older cost reports to which some kind of limited "look back" policy could be applicable. Thus, we believe our final policy of one-time review is consistent with the commenters' requests that the MACs' determinations should not be revisited, and they should be binding, unless fraud is suspected. With regard to hospitals with "yet undiscovered low PRAs," these hospitals would follow the methodology outlined previously, where hospitals would use the HCRIS posting to

determine their status (or follow the policy in the section regarding cost reports not yet in the HCRIS posting or not yet settled).

A comment was submitted regarding the regulations related to new teaching hospitals and the impact of the ongoing pandemic and public health emergency (PHE). We are not addressing this comment at this time, as it is not in the scope of the proposed rule.

#### f. Summary of Finalized Policies with Regard to Section 131 of the CAA

After consideration of comments we received, we are finalizing the following policies with regard to section 131 of the CAA:

- In this final rule with comment period, we are finalizing policies for resets related to cost reports that are open, reopenable, or not yet settled. We will post a file on the CMS website containing an extract of the HCRIS cost report worksheets on which the FTE counts, caps, and PRAs, if any, would have been reported, starting with cost reports beginning in 1995. We are also seeking public comment regarding how to handle reviews of PRAs or FTE caps from cost reports that are beyond the 3-year reopening period (with the exception of Category A and Category B hospitals that agree with the HCRIS posting).

- Hospitals must first consult the HCRIS posting on CMS's website to determine reset eligibility. MACs will not reach out to hospitals.

- In cases where no PRA or caps are reported on a settled cost report, or when PRAs or caps are reported without any FTEs, and a cost report is settled but reopenable, the hospital gets the benefit of a reset without further review by the MAC.

- If, for open or reopenable cost reports, there is a PRA and/or FTE caps reported on the HCRIS web posting, and the hospital believes its PRA in fact was established based on not more than 3.0 FTEs, or its IME and/or direct GME FTE caps were based on not more than 3.0 FTEs, a hospital has a 1-time opportunity to request reconsideration by its MAC which must be submitted electronically and received by the MAC on or before July 1, 2022.



- Hospitals that disagree with the 1-time MAC determination may appeal to the PRRB, assuming all conditions for appeal are met.

- Eligible hospitals for resets are those only that have a PRA base period that started prior to enactment and/or FTE cap building window that occurred/closed in a cost reporting period that started prior to enactment (December 27, 2020).

- FTE cap resets will only be based on new programs started after enactment and 5 years after (by December 26, 2025).

- Hospitals that qualify for a PRA reset may use as the new PRA base period either the earliest cost reporting period beginning between enactment and 5 years after in which they train FTES in a new program, or the first cost reporting period beginning after issuance of this final rule with comment period. In any case, residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.

- Effective with cost reporting periods beginning on or after December 27, 2020, a PRA would be established if a hospital trains less than 1.0 FTE as a result of participating in a Medicare GME affiliation agreement. Otherwise, no PRA would be established until a hospital trains at least 1.0 FTE. In any case, residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.

- Effective with cost reporting periods beginning on or after December 27, 2020, a hospital must report training of less than 1.0 FTE on its Medicare cost report if that training is as a result of participating in a Medicare GME affiliation agreement. Otherwise, a hospital must report FTEs on its Medicare cost report when it trains at least 1.0 FTE.

- Hospitals eligible to reset their PRAs would get a new PRA replacing their old PRA(s); hospitals eligible to reset their FTE caps would receive an FTE cap adjustment equal to the sum of the original FTE cap and the new program FTE cap adjustment.

We are finalizing regulation text changes to the following:

- 42 CFR 413.77(e)(1)(iv) to reflect that hospitals qualifying for a PRA reset may use as the new PRA base period either the earliest cost reporting period beginning between enactment and 5 years after in which they train FTEs in a new program, or the first cost reporting period beginning after issuance of this final rule with comment period.

- 42 CFR 413.78(b) regarding when a hospital must report FTEs on its Medicare cost report.

- 42 CFR 413.79(e)(1) and (8) to reflect the circumstances under which a new program FTE cap would be established, and how an adjusted FTE cap would be calculated.

## C. Organ Acquisition Payment Policies

### 1. Background

#### a. History of Medicare Organ Acquisition Policies

The Medicare Program supports organ transplantation by providing an equitable means of payment for the variety of organ acquisition services. Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant, and separately reimburses transplant hospitals<sup>4</sup> (THs) for the organ acquisition costs on a reasonable cost basis (42 CFR 412.2(e)(4) and 412.113(d)).<sup>5</sup>

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<sup>4</sup> Under 42 CFR 482.70 a transplant hospital is a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

<sup>5</sup> In accordance with 42 CFR 412.113(d), organ acquisition costs incurred by hospitals with approved transplant programs are paid for on a reasonable cost basis.

Medicare's current organ acquisition policy is modeled after the kidney acquisition policy that was implemented for kidney transplants following the Social Security Amendments of 1972 (Pub. L. 92-603) that extended Medicare coverage to individuals with end stage renal disease (ESRD) who required dialysis or transplantation. In July 1973, CMS (then the Bureau of Health Insurance<sup>6</sup> (BHI)) issued Intermediary Letters (ILs) which set forth procedures and policies for Medicare reimbursement for kidney transplants. The IL 73-25<sup>7</sup> (July 1, 1973) set forth policies for the reimbursement for kidney transplants and dialysis, including policies for hospital reimbursement for the acquisition of a kidney from cadaveric and living donors for transplant into a Medicare beneficiary. In IL 73-25, the BHI commented that as it received and analyzed data and studied reimbursement methodology, it would develop and issue more detailed reimbursement instructions to support the delivery of quality services in an efficient manner. In July 1974, the BHI issued IL 74-23<sup>8</sup>, which set forth additional policies for Medicare reimbursement of kidney acquisition costs, many of which remain in place currently. In 1978, to clarify that the Secretary of the Department of Health and Human Services (the Secretary) has authority and to provide reimbursement for the costs incurred in connection with kidney donations, Congress enacted legislation that added special provisions relating to coverage under the Medicare Program for ESRD (Pub. L. 95-292). This legislation added section 1881 to the Social Security Act that set forth Medicare payment for kidney transplantation and the coverage of kidney procurement costs and living donor expenses, including Part A and Part B benefits for the living donor.<sup>9</sup> As CMS stated in the 1978 **Federal Register** (43 FR 44803), the purpose of section 1881 of the Act was to encourage kidney transplantation and the scope of Medicare

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<sup>6</sup> To implement the Medicare statute, the Social Security Administration was reorganized and the Bureau of Health Insurance (BHI) was established on July 30, 1965. The BHI then became responsible for the development of health insurance policy before the creation of the Health Care Financing Administration (HCFA), later renamed the Centers for Medicare & Medicaid (CMS). CMS Milestones 1937-2015 (July 2015).

<sup>7</sup> <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipp-pps-proposed-rule-home-page>

<sup>8</sup> Id.

<sup>9</sup> H. Rep. 95-549 (July 29, 1977), section III.B.; S. Report 95-714 (March 22, 1978), section III.B.

benefits to cover all reasonable preparatory, operation and post-operation expenses associated with a kidney donor, through the actual period of recovery.

Over the years through various rulings and national coverage determinations, Medicare has added coverage for transplantation of non-renal organs such as heart, liver or lungs; we modeled our reimbursement for the acquisition costs for non-renal organs based on our earlier kidney acquisition policies. Medicare's organ acquisition payment policy is mostly set forth in CMS Pub. 15-1, chapter 31,<sup>10</sup> the Provider Reimbursement Manual (herein referred to as PRM) and in Medicare regulations at 42 CFR 412.2(e)(4), 412.100, 412.113(d), 413.200, 413.202, and 413.203. The entities involved in organ acquisition, which we will further define and discuss herein, are THs, donor community hospitals (Medicare-certified non-transplant hospitals), organ procurement organizations (OPOs), some of which are hospital-based OPOs (HOPOs), and histocompatibility laboratories.

Section 1102 of the Act authorizes the Secretary to publish rules and regulations necessary for the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title. In this final rule, we are codifying into the Medicare regulations some longstanding Medicare organ acquisition payment policies, with clarifications where necessary, and codifying some new organ acquisition payment policies with modifications based on public comments. We are finalizing our proposals to move existing organ acquisition payment regulations, or portions of existing kidney acquisition regulations, within title 42 of the CFR part 412, subpart G and part 413, subpart H, to a new part 413, subpart L, so that all organ acquisition payment policies are housed together. We are also finalizing our proposal to codify into new subpart L certain policies

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<sup>10</sup> CMS Pub. 15-1, chapter 31 can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929> (Prior to the creation of chapter 31, the kidney acquisition policy was set forth in CMS Pub. 15-1, chapter 27, Outpatient Maintenance Dialysis Reimbursement).

pertaining to organ acquisition, as set forth in section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173) and section 17006 of the 21<sup>st</sup> Century Cures Act (Pub. L. 114-255), in accordance with their statutory effective dates. We are also finalizing our proposal to make conforming changes and technical corrections to the regulations, where necessary.

We are aware of OIG audits reporting that some OPOs have billed the Medicare Program for unallowable expenditures.<sup>11</sup> There have also been recent Congressional oversight interest and inquiries into OPO financial management.<sup>12</sup> We believe the provisions that follow will provide clarity and allow providers and stakeholders to more easily locate and understand organ acquisition payment policy, resulting in more accurate payment based on reasonable cost principles.

#### b. Overview of Medicare Reimbursement in Transplantation

Medicare reimburses THs for organ acquisition costs, the transplant surgery, inpatient, and post-transplant costs for the Medicare recipients, but through different payment systems. Medicare Part A pays for hospital costs of a transplant surgery and certain follow-up care through a DRG payment and the organ acquisition costs associated with a transplant on a reasonable cost basis. In general, Medicare Part B pays for the physician services and other services furnished to eligible Medicare beneficiaries. CMS established Conditions of Participation (CoP) for hospitals under 42 CFR part 482, subpart E. Transplant programs, located within a TH that has a Medicare provider agreement, must meet the applicable hospital CoPs at §§ 482.1 through 482.70 and the transplant program CoPs, located at §§ 482.72 through 482.104, and additional requirements in order to be eligible to participate in the Medicare Program.

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<sup>11</sup> <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>; <https://oig.hhs.gov/oas/reports/region9/90900087.pdf>; <https://oig.hhs.gov/oas/reports/region9/90500034A.pdf>; <https://oig.hhs.gov/oas/reports/region9/91102039.pdf>

<sup>12</sup> <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>; <https://www.young.senate.gov/newsroom/press-releases/young-joins-finance-committee-members-to-probe-us-organ-transplant-system>; <https://www.congress.gov/117/chr/CHRG-117hrg44569/CHRG-117hrg44569.pdf>

OPOs coordinate the procurement, preservation and transportation of organs from deceased donors, and maintain a system for locating prospective recipients for organ transplantation. Section 1138 of the Act sets forth hospital protocols for the identification of potential organ donors and the standards for OPOs. To be an OPO, an entity must meet the applicable requirements of both the Act and the Public Health Service Act (the PHS Act). The statutory functions of an OPO are also set forth in 42 U.S.C. 273; section 371 of the PHS Act. Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order to be reimbursed under the Medicare or Medicaid Program for certain organ procurement costs. CMS established Conditions for Coverage (CfCs) OPOs must meet in order to receive payment under Medicare or Medicaid for organ procurement costs in the regulations at 42 CFR part 486, subpart G. Section 1138(b)(1)(A) of the Act specifies that payment may be made for organ procurement costs only if the agency is a qualified OPO operating under a grant made under section 371(a) of the PHS Act or has been certified or re-certified by the Secretary as meeting the standards to be a qualified OPO. Among those requirements, each OPO must be a member of, participate in, and abide by the rules and requirements of the Organ Procurement Transplantation Network (OPTN) that are approved by the Secretary (see 42 CFR 486.320).

Medicare reimburses THs for organ acquisition costs under reasonable cost principles<sup>13</sup> under section 1861(v) of the Act, based on the TH's ratio of Medicare usable organs to total usable organs. Medicare authorizes payment to designated OPOs for kidney acquisition costs, under reasonable cost principles<sup>14</sup> in accordance with section 1861(v) of the Act, based on the OPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act).

Histocompatibility laboratories provide laboratory services to ensure compatibility between donor organs and potential recipients in preparation for transplants. Section

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<sup>13</sup> See 42 CFR 412.113(d); HCFA Ruling 87-1 (April 1987); CMS Ruling 1543-R (December 2006).

<sup>14</sup> Id. Section 1138(b)(1)(F) of the Act; 42 CFR 413.1(a)(1)(ii)(A); 413.200(a)

1881(b)(2)(A) of the Act authorizes Medicare reimbursement for the cost incurred by a histocompatibility laboratory in accordance with sections 1861(v) or 1886 of the Act (if applicable). Histocompatibility laboratories are either independent or hospital-based. A histocompatibility laboratory is “independent” unless it is considered a department of the hospital and subject to control of the hospital.<sup>15</sup> Section 413.200(a) requires the reasonable costs of services furnished by histocompatibility laboratories be reimbursed in accordance with the principles contained in 42 CFR 413.60 and 413.64.

## 2. Organ Acquisition Payment Policy

We received approximately 400 timely pieces of correspondence regarding the proposals and policies discussed in this section of this final rule with comment period. Comment summaries and responses are included in each lettered section.

### a. Terminology Notes and Proposed Definitions

#### (1) Use of Consistent Terminology

Throughout this final rule, we will use consistent terminology such as “transplant hospital” and “transplant program.” These terms have been defined in other CMS regulations at 42 CFR 482.70 as follows:

*Transplant hospital* means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

*Transplant program* means an organ-specific transplant program within a transplant hospital (as defined in this section).

The regulations in 42 CFR parts 412 and 413 had previously used “transplantation center” to mean a “transplant program.” Our PRM also uses “certified transplant center” to mean a TH, but we proposed to use consistent language in this rule to avoid confusion. In section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed

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<sup>15</sup> 43 FR 58371 (December 14, 1978).

conforming changes to some existing regulations to ensure that “transplant hospital” and “transplant program” are used consistently and as described in this section.

Comment: Some commenters expressed appreciation for CMS’ use of consistent terminology.

Response: We appreciate the commenters’ support. Throughout this final rule, we will refer to a hospital that has an approved organ-specific transplant program as a TH, and we will use “transplant program” to refer to the organ-specific program itself.

## (2) Definitions

In addition to the proposals to use consistent terminology, in the preamble to the proposed rule we proposed to add specific definitions into the regulations by adding § 413.400, entitled “Definitions,” to new subpart L of 42 CFR, part 413. We also proposed to move all definitions in existing § 413.200(b) "*Definitions*," to new § 413.400 to maintain this regulation with all other organ acquisition regulations in proposed new subpart L of part 413. Further, we proposed to revise some of the definitions proposed to be moved from § 413.200(b) to new § 413.400, as noted in the following discussion.

We received no comments on our proposal to move all definitions in existing § 413.200(b) to new § 413.400, thus we are finalizing our proposal as proposed.

For organ acquisition payment purposes, an “organ” means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine) as defined in 42 CFR 486.302. Effective October 1, 2004, organs also include pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173) requires Medicare to pay for items and services that are reasonable and necessary routine patient care costs related to acquisition and delivery of



pancreatic islet cells for transplantation into Medicare beneficiaries included in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplants.

We proposed to codify our definition for “organ” in § 413.400, new subpart L. We noted that the proposed definition of organ is for Medicare organ acquisition payment purposes and differs from the definition set forth in 42 CFR 486.302 CfC for OPOs.

The CMS OPO CfCs final rule (85 FR 77898 published December 2, 2020) defines “organ” under 42 CFR 486.302, to mean a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation. The OPO CfC final rule (85 FR at 77947) describes the inclusion in the performance measures for OPO certification of pancreata used for research in the definition of organ as necessary in order to meet the statutory requirements of section 371(c) of the Public Health Service Act that provides that pancreata procured by an OPO and used for islet cell transplantation or research shall be counted for purposes of certification or recertification (85 FR 77902). However, for Medicare payment purposes, an organ procured for research is not counted as a Medicare organ in Medicare’s share of organ acquisition costs, except where explicitly required by law. Therefore, in order to mitigate potential stakeholder confusion, we proposed a definition of “organ” for organ acquisition payment purposes that differs from the definition set forth in the OPO CfCs.

Comment: Several commenters requested CMS expand the definition of “organ” to include vascular composite allografts (VCAs), in alignment with the OPTN’s definition of organ applicable to the OPTN under 42 CFR 121.2, and be included in organ counts for OPOs and THs so Medicare can calculate a share of acquisition costs for VCAs. A few commenters suggested the proposed definition of organ reimbursement be expanded to include other clinical trials and disease states.

Response: Our definition of organ in §413.400 is for organ acquisition payment purposes that are outlined in the statute or adopted through the regulatory process to be paid outside of the

IPPS. We have historically not included VCAs in the definition of organ for OPO CfCs because VCA transplantation is generally very localized and rarely performed.<sup>16</sup> According to OPTN data, in 2019, only approximately 15 such transplants occurred, the vast majority being the transplantation of a uterus (12 transplants). In 2020, there were five VCA transplants; in 2021 (through November 19, 2021), there were four VCA transplants.<sup>17</sup> Although it is not clear from the OPTN data whether these VCA transplant recipients were Medicare beneficiaries, inclusion of VCAs as organs would require a separate assessment of the impact throughout all CMS policies and regulations, and could lead to changes that would be beyond the scope of this rule. Although we may reconsider this issue in the future if VCA transplants become more common procedures, we are not expanding the definitions of “organs” to include VCAs for organ acquisition payment purposes in this final rule.

As noted, the proposed definition at § 413.400 specifically included in the definition of “organ” pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) clinical trial. This rule implements Medicare’s payment for the acquisition and delivery of pancreatic islet cells for transplantation into Medicare beneficiaries included in a NIDDK clinical trial of islet cell transplants required by section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173). Section 733 requires routine costs, transplantation and appropriate related items and services for the acquisition and delivery of the pancreatic islet cell transplantation for Medicare beneficiaries who are participating in a clinical investigation of pancreatic islet cell transplantation. In light of this specific statutory requirement, we believe it would be

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<sup>16</sup> See 85 FR 77906. The OPTN database was accessed on July 11, 2020 and number of transplants for abdominal wall, head & neck (cranial facial), head & neck (scalp), GU: Penile, GU: Uterus, upper limb: Bilateral, upper limb: Unilateral, and VCA were counted for 2018 and 2019. In 2018, there were 11 transplants.

<sup>17</sup> <https://insights.unos.org/OPTN-metrics/>

inappropriate to expand the definition of organ in § 413.400 to include other clinical trials and disease states as commenters suggested.

After consideration of public comments, we are finalizing our definition of “organ” for acquisition payment purposes, as proposed, at § 413.400, in new subpart L, with modifications based on comments received to clarify the definition of pancreata for organ acquisition payment purposes, by adding the public law citation to the definition. In this regard, we are finalizing that an organ, for organ acquisition payment purposes, includes pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

In the proposed rule, we proposed to include the definition of Organ Procurement Organization (OPO) as it currently exists in § 413.200(b). As defined in 42 CFR 486.302, an OPO means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs. An OPO can be a HOPO or an independent OPO. An OPO is “independent” unless it is considered a department of the hospital and subject to control of the hospital.

Comment: Several commenters also requested we amend the proposed definition of “OPO” to reflect that the OPTN, and not the OPO, maintains the system for identifying and locating prospective beneficiaries for available organs.

Response: We appreciate the commenters’ suggestion; however, we respectfully disagree with modifying the definition as commenters suggest. OPOs do have a system for locating prospective beneficiaries for available organs. We do not believe our definition will cause confusion with respect to the separate functions of the OPTN. After consideration of the public comments we received, we are finalizing our proposed definition of “OPO” as proposed.

Additionally, we proposed to codify the definition of a hospital-based organ procurement organization (HOPO) as an OPO that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report (MCR).<sup>18</sup> The proposed definition is consistent with the description of HOPO in the PRM, and is commonly known in the organ acquisition and transplant community. We proposed to codify our proposed definition in § 413.400, new subpart L. As of March 12, 2021, there are 7 HOPOs in operation.<sup>19</sup>

We also proposed that a transplant hospital/HOPO (TH/HOPO) refers to a transplant hospital, or a transplant hospital that operates a HOPO (as defined previously in this section) and performs organ procurement activities as one entity reported on the transplant hospital's MCR. We proposed to codify our proposed definition in § 413.400 new subpart L.

Comment: A commenter recommended the definition of HOPO should be separate from the definition of TH/HOPO due to differences in various organ acquisition reporting and operational activity between a HOPO and a transplant program.

Response: We agree that there are differences in various organ acquisition reporting and operational activity between a HOPO and a transplant program. We note that in the proposed rule, we proposed a separate definition for "HOPO." However, we also proposed a definition of TH/HOPO, to indicate that a TH/HOPO means a transplant hospital and a transplant hospital with a hospital based OPO, which is an OPO owned and operated by the hospital. In this context, the HOPO is reimbursed through the transplant hospital's cost report as a department of the hospital and does not file a cost report separately from the transplant hospital nor is it reimbursed separately. We are codifying our proposed definitions of HOPO and TH/HOPO, as proposed, at § 413.400, in new subpart L.

In the proposed rule, we also proposed to revise the terminology "freestanding" as it currently exists in 42 CFR 413.200(b) in relation to OPOs, to be "independent OPO (IOPO)"

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<sup>18</sup> Hospital and Health Care Complex Cost Report, currently Form CMS-2552, OMB No. 0938-0050.

<sup>19</sup> Information available at <https://optn.transplant.hrsa.gov/members/>; accessed March 12, 2021.

because this terminology is more widely used in the industry. We also proposed to revise the IOPO definition by adding a third distinguishing factor. The proposed definition for an IOPO will mean an OPO that files a MCR separate from a hospital and meets all of the following: (1) is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees; (2) is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance); and (3) reports organ acquisition costs it incurs on the IOPO MCR.<sup>20</sup> In the preamble to the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to clarify that an IOPO that wishes to have the cost of its pre-transplant services reimbursed under Medicare must agree to certain requirements specified in 42 CFR 413.200(c). If an IOPO operates a histocompatibility laboratory, the costs of its histocompatibility laboratory are included on the IOPO's MCR. We received no comments on this proposal; therefore, we are codifying our proposed definition of IOPO, as proposed, at § 413.400, in new subpart L.

In the FY 2022 IPPS/LTCH PPS proposed rule, we stated that a histocompatibility laboratory performs laboratory services to determine the degree of histocompatibility between donor organs and potential recipients. We also proposed to include a definition of "histocompatibility laboratory" as it currently exists in § 413.200(b) with a technical correction. We proposed to make a technical correction to the cross-reference to § 413.2171(d) because this regulation citation is no longer correct. We proposed that "histocompatibility laboratory" means a laboratory meeting the requirements set forth in 42 CFR 493.1227 and providing the services for the acquisition of kidneys or other organs for transplantation. We received no comments on this proposal; therefore, we are finalizing our proposed definition of histocompatibility laboratory, as proposed, at § 413.400, in new subpart L.

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<sup>20</sup> Organ Procurement Organizations and Histocompatibility Laboratory, currently Form CMS-216, OMB. No. 0938-0102.

We proposed that standard acquisition charge (SAC) means a charge as defined in proposed new § 413.404 in section II.C.2.c. of this final rule with comment period. We received no comments on this proposal; therefore, we are codifying our proposed definition of SAC, as proposed, at § 413.400, in new subpart L.

We also proposed to add the definitions for “transplant hospital” and “transplant program” that currently exist in 42 CFR 482.70 in § 413.400, to new subpart L.

Comment: A few commenters supported our clarification of transplant hospital and transplant program.

Response: We thank the commenters for their support. We are codifying our proposed definitions for “transplant hospital” and “transplant program,” as proposed, at § 413.400, in new subpart L.

#### b. Provisions Related to Organ Acquisition Costs

##### (1) Proposed Items and Services Considered Organ Acquisition Costs

In this final rule with comment period, we are adding § 413.402(a) to new subpart L to specify that costs incurred in the acquisition of organs from a living donor or a cadaveric donor by the hospital or by an OPO, as appropriate, are organ acquisition costs. To make necessary policy revisions and clarifications of acquisition costs for kidneys as well as for non-renal organs, in the proposed rule we proposed to revise § 412.100(b), by removing the list of organ acquisition costs found in that paragraph and re-codifying them with some revisions by adding § 413.402(b) to new subpart L.

We proposed to codify at proposed § 413.402(b) that the costs of acquiring organs (kidneys and non-renal organs) covered by Medicare Part A are: (1) tissue typing, including tissue typing furnished by independent laboratories; (2) donor and beneficiary evaluation; (3) other costs associated with excising organs, such as general routine and special care services provided to the donor; (4) operating room and other inpatient ancillary services applicable to the donor; (5) preservation and perfusion costs; (6) OPTN registration fees; (7) surgeons' fees for

excising cadaveric organs (currently limited to \$1,250 for kidneys); (8) transportation of the excised organ to the TH; (9) costs of organs acquired from other hospitals or OPOs; (10) hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to admission); (11) costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs; and (12) all pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, surgeons' fees for cadaveric excisions, and the costs of physicians' services.

We proposed to apply the existing elements of kidney acquisition costs found in § 412.100(b) to all organs, with clarifying revisions as described. These items and services are currently specified in § 412.100(b) (for kidneys only) and also discussed in sections 3101, 3102, and 3103 of the PRM. We proposed to revise § 412.100(b) to reference that kidney acquisition costs are specified in new § 413.402(b) of this chapter.

We proposed to add § 413.402(b)(6) to new subpart L to include the costs for the OPTN registration of a beneficiary for a kidney transplant as specified in § 412.100(b)(6) and also include the costs for registration of a beneficiary for a non-renal transplant. The OPTN registration fee is assessed for all transplant candidates placed on the OPTN waiting list.<sup>21</sup> We proposed to limit these registration fees to the OPTN registration fee. Reasonable cost principles, as set forth in section 1861(v) of the Act and as specified in 42 CFR 413.1(b) and 413.9, do not permit Medicare to pay for duplicate services. In the proposed rule, we asserted that any registration fee outside of the OPTN registration fee would be considered unnecessary and duplicative under reasonable cost principles for Medicare organ acquisition costs.

Payment mechanisms for certain kidney acquisition costs differ depending on whether the donor is living or is cadaveric. Our provision will codify that surgeon fees are included as

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<sup>21</sup> The hospital CoPs at 42 CFR 482.45(b)(1) require each TH to be a member of the OPTN and abide by its rules, which for THs include registering potential transplant recipients on the OPTN registry as described in section 1.2.D of the OPTN Bylaws, available at [https://optn.transplant.hrsa.gov/media/1201/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf).

kidney acquisition costs paid through the Medicare cost report only when the kidney excision occurs with a cadaveric donor. When a living donor enters the hospital for the actual kidney excision—and the recipient is a Medicare beneficiary-- surgeon fees for excising the kidney are still considered kidney acquisition costs, but are not included as kidney acquisition costs on the cost report or paid through the cost report. Instead, the surgeon bills these surgeon fees to Medicare Part B using the transplant recipient's Medicare Beneficiary Identifier (MBI), and Medicare pays for living kidney donor surgeon fees through the claims processing system. Congress enacted section 1881(d) of the Act in 1978, which (in part) entitled living donors to benefits under Medicare Part B with respect to the kidney donation, as if the donor were eligible for Medicare, and allowed the Secretary to prescribe in regulation how that would occur. CMS regulations at 42 CFR 410.55 and 410.163,<sup>22</sup> require Medicare Part B to pay for medical and other health services furnished in connection with a kidney donation if the kidney is intended for a Medicare beneficiary with ESRD and without deductibles or co-insurance. As such, our proposed codification of Part A kidney acquisition costs related to donor surgeon fees only focuses on surgeons' fees for cadaveric excisions.

Section 371(b)(3)(F) of the PHS Act, 42 U.S.C. 273(b)(3)(F), requires that OPOs provide or arrange for the transportation of donated organs to transplant centers. We proposed to codify our longstanding policy in PRM section 3101 that Medicare covers the transportation of donated organs as an organ acquisition cost as authorized by section 371(b)(3)(F) of Public Health Service Act.

We proposed to add § 413.402(b) to new subpart L to specify the acquisition costs given at § 412.100(b) of this chapter, with minor clarifying revisions, and to revise § 412.100(b) to cross-reference § 413.402(b). We also proposed to make additional revisions, technical corrections and conforming changes to § 412.100 in sections II.C.2.b.(1). and II.C.2.m.(2). of this final rule with comment period.

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<sup>22</sup> 51 FR 41332.



Finally, we have received inquiries over the years from various stakeholders about whether costs resulting from services to living kidney donors with complications are organ acquisition costs. We proposed to codify that policy in § 413.402(c) in new subpart L, to provide greater clarity to stakeholders. We discuss details of our policy and proposed codification related to living donor complications in section II.C.2.e.(4). of this final rule with comment period.

Comment: Many commenters appreciated our proposals to codify policy and to locate organ acquisition policies in a common location in the regulations. However, several commenters were concerned that our proposal to limit registry fees to the OPTN fee at proposed at §413.402(b)(6) would shift costs of registry fees to transplant hospitals for living donors or donors participating in kidney-paired donations, would discourage living donor transplants, and could jeopardize health equity, particularly for kidney-only programs. Commenters requested that CMS not limit registry fees to the OPTN fee only and cited a 2014 letter from CMS that stated that transplant hospitals can engage in contracts with third-parties that provide services to facilitate transplantation and place the costs of those services on their cost reports. A commenter supported CMS not covering the fee charged by the current contractor that operates the OPTN, while other commenters supported CMS' covering that fee. A commenter objected to CMS referring to the OPTN contractor fee services as “duplicative” of the OPTN registry and described the services the contractor performs to facilitate and support organ transplantation.

Response: We appreciate commenters' support for our proposals to codify organ acquisition cost policies in one location in the Code of Federal Regulations and thank commenters for sharing their concerns about the proposed registry fee costs. We agree that the OPTN contractor and other registries can provide valuable services that support and encourage transplantation. After further researching registry fee information provided in the comments, we are clarifying that we cover as registry fees only the reasonable fees for actually registering a potential recipient for an organ transplant.

We also agree with commenters that the services other registries provide may differ from those provided by the OPTN. For example, we agree with commenters that third-party registries can provide services beyond those of the OPTN to facilitate living organ donation, particularly related to paired kidney donation, and increase a potential transplant recipient's ability to receive a living donor transplant. As such, we do not believe that all additional registry fees would be "duplicative" of the OPTN services. We believe covering the reasonable and necessary costs of registry fees that are not duplicative will support transplantation. Therefore, we are finalizing our proposal with modifications, so that Medicare covers as organ acquisition costs at §413.402(b)(6) the OPTN registration fee, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ or kidney transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature. We will monitor the registry fees reported and may refine our policy if needed in future rulemaking.

Comment: Many commenters disagreed with our proposal at §413.402(b)(8) that organ acquisition costs include costs to transport the excised organ to the transplant hospital, but excludes costs for transporting the cadaveric donor. Some commenters suggested that the exclusion of transportation costs for the cadaveric donor was a new policy proposal and believed that the proposal was eliminating costs for transportation of the cadaveric donor from the donor hospital to an OPO. Some commenters opined that the proposal would impede operations of OPOs that may operate organ recovery centers. Several commenters cited 42 U.S.C. 273(b)(3)(F), (requiring OPOs to provide or arrange for transportation of donated organs to transplant centers), and asserted that this section does not prohibit transportation of the donor (as opposed to individual organs) when the transportation is for the purpose of transplantation. A few commenters suggested that CMS permit transportation of the cadaveric donor to an off-site recovery facility when it could be proven that the overall costs of acquisition would be lower.

Commenters raised three other scenarios where a cadaveric donor may require transportation to another hospital: (1) when the donor hospital's protocol does not permit organ excision when cardiac death has occurred; (2) when clinical outcomes could be compromised because the donor hospital is not geographically located within reasonable proximity to needed transportation infrastructure, such as an airport, when the organ must be flown to the intended recipient; and (3) where the donor hospital does not have the capacity at that time to accommodate organ procurement. The commenters opined that in these situations, transporting the donor avoided the loss of transplantable organs or increased the likelihood of the organs' viability. Another commenter requested clarification as to whether it was permissible for the donor to be moved from the donor hospital to the transplant hospital. A commenter requested that the proposed codification of transportation costs remain as it was written in § 412.100(b).

Finally, a commenter sought clarification of transportation costs for transporting non-renal organs. The commenter noted that the non-renal organs travel with the surgeon on the plane, so there is no incremental cost for transportation of the organ. The commenter stated that it would be administratively burdensome for the OPO and the transplant hospital to apportion the transportation costs and requested exclusion of the non-renal transportation in this situation, as there is no "cost" associated with the organ transportation.

Response: The current Medicare organ acquisition payment policy does not include transportation costs for a cadaveric donor. However, we agree with commenters that 42 U.S.C. 273(b)(3)(F) does not prohibit Medicare from covering transportation of the cadaveric donor. We appreciate the scenarios commenters provided relating to transportation of a cadaveric donor and believe that broadening coverage of transportation costs would more strongly support organ procurement and transplantation. We also agree with commenters that it would be reasonable to allow transportation costs of a cadaveric donor when that donor is transported to avoid loss of potentially transplantable organs, or to preserve clinical outcomes.

The lack of clarity of the existing payment policy was evident in some of the comments, which is why we are being more specific in our codification of the payment policy regarding transportation costs. For the reasons noted in this section of this final rule with comment period, we are finalizing our proposed codification at § 413.402(b)(8) with modifications in response to public comments, to cover as an organ acquisition cost transportation of the excised organ to the transplant hospital, and of the cadaveric donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs. We believe this modification to our current policy is responsive to commenters' concerns, and will support organ procurement, address potential disparities in rural areas, and improve clinical outcomes.

Regarding the transportation of non-renal organs, the commenter described a scenario in which the commenter believed there is no additional cost incurred for organ transportation when the transplant team travels to procure and retrieve the organ. In this scenario we agree that there is not a transportation cost incurred for the organ and therefore no need to apportion the travel costs. However, under the general requirements at §§ 413.20 and 413.24 to maintain records for items submitted on the Medicare cost report for proper cost finding and payment, the OPO and transplant hospital would have to maintain accurate records for the number of organs procured without transportation costs and the number of organs procured with transportation costs in order to properly allocate overhead costs. We note that when an OPO does not incur transportation costs for all organs, the transportation costs for kidneys would be reduced from the accumulated costs statistic in order to equitably allocate overhead costs.

Comment: Commenters requested clarification of whether transportation of recovery staff, including donor family support staff, would be allowable organ acquisition costs. A different commenter referred to procuring multiple organs which had no incremental cost for transportation beyond the charter flight travel costs for the procurement team. This commenter stated that the OPO has no control over the cost of charter transportation, stating it would require

contracts with multiple transportation providers that may not be known to the OPO until the transportation has been arranged.

Response: We differentiate “transportation”, which refers to the organ or the cadaveric donor, from “travel,” which includes travel costs of physicians or other practitioners that recover organs under contract or arrangement with the OPO, as well as recovery personnel if necessary, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation. These reasonable travel costs are allowable organ acquisition costs under §413.402(b)(9) as they are costs of organs acquired from other hospitals or OPOs. If multiple organs are procured, the travel costs for the procurement team should be apportioned equitably to all organs.

We are concerned by the commenter’s statement that the OPO “has no control” over the cost of air charters, and we remind stakeholders that reasonable cost principles apply to all organ acquisition costs. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, as defined in 42 CFR 413.9. For example, in this scenario an OPO might have contracts with multiple transportation providers and could negotiate a reasonable price for air charters.

Comment: Several commenters were concerned that the specific language we used in proposing to codify allowable organ acquisition costs for proposed § 413.402(b)(3) (other costs associated with excising organs, such as general routine and special care services) and proposed § 413.402(b)(4) (operating room and other inpatient ancillary services) as set forth in section X.B.2.b.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, does not match the language that currently exists in the relevant sections of Chapter 31 of the Provider Reimbursement Manual (PRM) or may be subject to misinterpretation by a MAC auditor to apply only to living donors. Commenters requested clarification of whether the organ acquisition costs incurred for these services will be covered for both living and cadaveric donors.

Response: We agree with commenters that other costs associated with excising organs, such as general routine and special care services provided to the donor specified in proposed §413.402(b)(3) and operating room and other inpatient ancillary services applicable to the donor in proposed §413.402(b)(4) should be clarified to specify that they apply to both living and cadaveric donors. The commenters' suggestions are consistent with the existing policy and could avoid misinterpretation of the policy. Additionally, in reviewing the language, we realized that "special care services" was not clear, and we added language to give two examples (intensive care unit or critical care unit services) so providers could better understand.

Therefore, in response to commenters and to clarify language, we are finalizing our proposed regulation text with modifications to clarify the regulation text at § 413.402(b)(3) and §413.402(b)(4). The final regulation at §413.402(b)(3) now specifies that other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or cadaveric donor are organ acquisition costs. The final regulation at §413.402(b)(4) now specifies that operating room and other inpatient ancillary services applicable to the living or cadaveric donor are organ acquisition costs. After our regulations are effective, we will make conforming changes to the manual.

Comment: A commenter requested that CMS consider the full spectrum of "uncompensated costs" related to organ procurement and transplantation, including overhead and administrative costs.

Response: Overhead and administrative costs that may be allowable are allocated to allowable cost centers, including to organ acquisition cost centers. See 42 CFR 413.24(d), and also the cost reporting instructions for hospitals and for OPOs regarding how general and administrative (that is, overhead) costs are allocated (for hospitals, PRM 15-2, chapter 40, cost reporting instructions § 4020, and for OPOs PRM 15-2, chapter 33, cost reporting instructions §3311, available online at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935>). We have clarified the

regulation text at §413.402(a) to specify that there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.

Comment: A commenter questioned whether living donor specimen storage, recently required by the OPTN, will be covered as an organ acquisition cost.

Response: Prior to the OPTN implementing policy changes to align with the 2020 Public Health Services guidelines, hospitals and OPOs should have been following the Public Health Services guidelines. This cost associated with this specimen storage should be treated similar to all other specimen storage and not included as an organ acquisition cost.

Comment: A commenter requested that CMS consider “uncompensated” costs related to organ procurement and transplantation for pathologists and other specialists contracted under third party contracts that are indispensable to the organ recovery and transplantation process.

Response: Regarding the costs of pathologists and other specialists under third-party contracts, we are unclear what commenters are referring to, and without more context, are unable to modify the final rule to address this comment.

Comment: Many commenters believed that some of our proposals were intended to be retroactive rules to codify existing organ acquisition payment policy. Other commenters believed that the rules would be prospective from the effective date of the final rule and that the agency did not intend to establish retroactive rules.

Response: We did not propose to establish retroactive rules under section 1871(e)(1)(A) of the Act. Our final rules will generally be effective upon the effective date of the final rule. This FY 2022 IPPS final rule with comment period will be effective on the effective date specified in the **DATES** section of this final rule with comment period, unless a later date is specified. We note that a limited number of the final regulations expressly include the effective date of earlier statutes that have already established substantive standards. Specifically, the final rule at §413.406 includes an effective date of October 1, 2004, from section 733 the Medicare Modernization Act of 2003, as it relates to Medicare coverage of islet cell transplants. This is

not a new policy change nor would it now result in a substantive change, as the statute was already effective.

## (2) Cost Reporting, Billing, and Payment of Organ Acquisition Costs

Both THs and OPOs can acquire organs for transplantation; therefore, both THs and OPOs can have organ acquisition costs. A TH can acquire organs from either a cadaveric donor or a living donor, while OPOs acquire organs from cadaveric donors. In accordance with requirements at § 413.24(f), at the end of its fiscal year a TH/HOPO files an annual hospital cost report (currently Form CMS-2552)<sup>23</sup> and an IOPO files an annual OPO/histocompatibility cost report (currently Form CMS-216)<sup>24</sup>. Organ acquisition costs incurred by a TH/HOPO are included on the appropriate organ acquisition cost center on its hospital MCR. Organ acquisition costs incurred by an IOPO (or by a histocompatibility laboratory, as authorized in section 1881(b)(2)(A) of the Act and discussed in section II.C.2.d.(3). of this final rule with comment period) are included in the appropriate organ acquisition cost center on its MCR.

Currently, Medicare pays THs prospective payment amounts based on a DRG for the actual organ transplant; Medicare also reimburses THs for reasonable costs associated with acquiring organs for transplantation into Medicare beneficiaries (§ 412.113(d)). CMS excludes from the prospective payment amounts inpatient hospital organ acquisition costs for hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved THs, as specified in § 412.2(e)(4). Medicare makes payment for organ acquisition costs incurred by hospitals with approved transplantation programs on a reasonable cost basis, as specified in § 412.113(d), and in accordance with the principles of reasonable cost as set forth in section 1861(v) of the Act and in 42 CFR 413.1 and 413.9.

Currently, when the TH cost report is settled, the Medicare contractor calculates the Medicare organ acquisition costs by multiplying the total of all allowable organ acquisition costs

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<sup>23</sup> OMB No. 0938-0050, expires March 31, 2022.

<sup>24</sup> OMB No. 0938-0102, expires November 30, 2024.



by the ratio of Medicare usable organs to total usable organs, for each organ type. The contractor reconciles the TH's Medicare organ acquisition costs by comparing the total interim payment amounts paid for organ acquisition costs under § 413.64(f) to the total actual Medicare organ acquisition costs, and either pays amounts owed or collects from the TH any overpayment.

The statute at section 1881(b)(2)(A) of Act authorizes Medicare to pay THs for services provided by OPOs for kidney acquisition. Medicare does not directly reimburse OPOs as these services are not covered until the transplant occurs at the TH. OPOs receive an interim payment based on their kidney SAC which is paid directly to them by the TH that receives the kidney procured. Medicare pays IOPOs for kidney acquisition indirectly, through the reconciliation of actual costs incurred for kidney acquisition to actual kidney SAC payments received, as part of cost report settlement in accordance with § 413.200(e)(2), to ensure that the Medicare Program is paying its appropriate share. There is no explicit requirement for Medicare to pay IOPOs for non-renal organs in the same way; we do not currently reconcile and settle IOPO non-renal organ acquisition costs. Similar to kidney acquisition costs, IOPOs are paid an interim rate (SAC) directly by the TH (or other IOPO) which receives the non-renal organs the IOPO procures. Kidney and non-renal SACs are discussed in more detail in section II.C.2.c. of this final rule with comment period.

### (3) Services Not Considered Organ Acquisition Costs

Medicare does not pay for certain costs incurred by OPOs, in accordance with section 1861(v)(1)(A) of the Act, and in the proposed rule we proposed to establish rules identifying those specific items. These activities or services include incurred costs found to be unreasonable or unnecessary in the efficient delivery of health care services, and are not limited to:<sup>25</sup>

- Burial and funeral expenses for the cadaveric donor, including transportation of the cadaveric donor before and after excision for funeral services or for burial (burials and funerals

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<sup>25</sup> PRM 15-1, ch 31, § 3108.C.

are not costs of acquiring organs and are not mentioned in section 371(b)(3) of the PHS Act (42 U.S.C. 273(b)(3)), which lists a number of activities or services that OPOs perform)<sup>26</sup>;

- Costs associated with the transportation of a living donor<sup>27</sup> (there are programs outside of Medicare that may pay for transportation costs for living donors)<sup>28</sup>;
- Costs incurred prior to a potential cadaveric donor being declared dead;
- Fees or in-center payments for donor referrals (all hospitals are required to timely notify OPOs of imminent deaths;<sup>29</sup> PRM 15-2, chapter 40, section 4013 stipulates that, “No amounts or fees paid to a donor, their estate, heirs, or assigns in exchange for an organ or for the right to remove or transplant an organ are included in organ acquisition costs.”);
- Costs associated with OPO sponsored seminars where continuing education credits are given<sup>30</sup> except when the attendee is an OPO staff member; and
- Certain costs incurred for administrator's duties associated with professional organizations (when these costs are not reasonable).

Comment: A few commenters encouraged us to allow OPO-sponsored seminars with continuing education credits as allowable organ acquisition costs, noting that it would improve and advance the organ transplant system. Another commenter questioned whether seminars without continuing education credits would be covered.

Response: The reasonable cost of an OPO-sponsored seminar that provides continuing education credits, may be an allowable administrative and general cost (included as organ acquisition costs) limited to the OPO staff (as described at §486.326(b)) if the seminar is related to patient care and meets the requirements at §413.9. The reasonable cost of an OPO-sponsored seminar that provides continuing education credits to attendees who are not on the OPO's staff is

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<sup>26</sup> 42 U.S.C. 273(b)(3).

<sup>27</sup> 42 U.S.C. 273(b)(3)(F). This section requires OPOs to provide or arrange for the transportation of donated organs to transplant centers.

<sup>28</sup> 85 FR 59438, September 22, 2020; see also the National Living Donor Assistance Center website at <https://www.livingdonorassistance.org/About-Us/Mission-Background>.

<sup>29</sup> 42 CFR 482.45.

<sup>30</sup> See CMS Pub. 15-1, chapter 4 for more information regarding allowable costs of educational activities.

not an allowable organ acquisition cost as these costs are absorbed by the attendee or their employer and do not benefit the OPO.

The reasonable cost of an OPO-sponsored seminar that does not provide continuing education credits, regardless of whether it is provided to the OPO staff, may be an allowable administrative and general cost to the OPO if it relates to patient care and meets the requirements at §413.9.

OPO-sponsored seminar costs are the direct costs associated with providing the seminar such as retaining speakers, supplies, meeting room fees, and meals (excluding alcohol) where necessary.

Based on comments received, we are codifying at §413.402(d) that organ acquisition costs do not include OPO-sponsored seminar costs associated with attendees who are not on the OPO's staff and receiving continuing education credits.

Comment: A commenter requested that CMS clarify which Administrator's duties associated with professional organizations are not covered.

Response: Regarding certain costs incurred for administrator's duties associated with professional organizations, §413.9(a) allows Medicare coverage of costs that are reasonable and related to the care of beneficiaries, as discussed in the previous comment response. The reasonable cost of membership in professional organizations would be allowable if the function and purpose of the organization can be reasonably related to the development and operation of patient care facilities and programs, or the rendering of patient care services (see PRM 15-1, § 2138). Membership costs and costs related to the organization's meetings and conferences are allowable as described in § 2138.1. However, § 2138.4 notes that the Medicare Program will look to comparable providers as well as to the justification by the individual provider in determining the reasonableness of the claimed costs related to memberships. Costs to the Medicare Program for individuals serving in administrative roles for professional organizations may be more than the costs for an ordinary member of a professional organization, as those in

administrative roles for the organization may have to attend additional meetings, etc. as part of their duties. However, professional organization costs for those in administrative roles that are unreasonable would not be allowable. An example of unreasonable costs would be if an individual in an administrative role for a professional organization attended a meeting held at a luxury resort, where lodging costs were substantially more expensive than usual (see 42 CFR 413.9(c)(3)). We have revised the text in the preamble at II.C.2.b.(3) of this final rule with comment period to explain the rationale to exclude certain administrator duty costs that are not reasonable. As discussed at the end of section II.C.2.b.(3). of this final rule with comment period, after considering public comments, we have codified costs that are not related to organ acquisition at §413.402(d).

Comment: Several commenters stated that CMS should revise the preamble language pertaining to costs not covered by Medicare that reads, “Costs incurred prior to a potential donor being declared brain dead (healthcare costs incurred prior to declaration of death are the responsibility of the potential donor’s health insurance).” Commenters noted that some donors are declared dead based on cardiac or circulatory death, and the phrasing should not be limited to brain death only. Finally, we received several comments related to covering costs prior to declaration of death.

Response: We agree with commenters and have corrected the preamble text in this final rule in response to these comments. We agree with the commenters who stated that our language in section X.B.2.b.(3). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule about costs incurred prior to a potential donor “being declared brain dead” should be revised to read “being declared dead”, to include those donors who die from cardiac death. Finally, the summary of comments and responses related to covering costs prior to declaration of death are in section II.C.2.1. of this final rule with comment period.

Comment: A commenter supported the continued exclusion from Medicare coverage of the transportation of the cadaveric donor for burials or funerals; another commenter challenged

part of our rationale for non-coverage, writing that section 371(b)(3) of the PHS Act does not represent an all-inclusive list of allowable services for OPOs.

Response: We thank the commenter for supporting our policy. Regarding our rationale for non-coverage of transportation of cadaveric donors for funeral services or for burial, our policies regarding items and services that are covered as organ acquisition costs are based, in general, on whether the item or service is related to acquiring organs for transplantation. We agree with the commenter who stated that section 371(b)(3) of the PHS Act does not specify every item or service covered as an organ acquisition cost. When an item is not explicitly cited, we must determine if it meets the general principle of being related to acquiring organs for transplantation. Costs of transporting a donor for burial or for a funeral are not cited in the PHS Act as covered costs, but are also not costs of acquiring organs for transplantation. Therefore, we are maintaining our policy that transporting a deceased donor for a funeral or for burial is not related to the acquisition of organs, and is not an allowable cost.

In summary, effective for cost reporting periods beginning on or after the effective date of this final rule with comment period, we are finalizing the provisions made in section II.C.2.b. of this final rule with comment period as proposed, except for the following modifications:

- In § 413.402(a) to specify that there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.
- In § 413.402(b)(3) to specify that organ acquisition costs include other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or cadaveric donor.
- In § 413.402(b)(4) to specify that organ acquisition costs include operating room and other inpatient ancillary services applicable to the living or cadaveric donor.
- In § 413.402(b)(5) to clarify the regulation by adding the word “organ” so we are specifying that organ preservation and perfusion costs are organ acquisition costs.

- In § 413.402(b)(6) to specify that organ acquisition costs include Organ Procurement and Transplantation Network registration fees and the reasonable and necessary cost of other fees to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.

- In § 413.402(b)(8) to specify that organ acquisition costs include transportation of the excised organ to the transplant hospital; and of the cadaveric donor to procure organs when it is necessary to improve clinical outcomes or to avoid loss of potentially transplantable organs.

- In § 413.402(b)(12) to remove the reference to surgeons' fees for cadaveric excisions as it is duplicative of § 413.402(b)(7).

- In section II.C.2.b.(3). of this final rule with comment period, to change “declared brain dead” to read “declared dead”.

- In section II.C.2.b.(3). of this final rule with comment period, to indicate that the cost of OPO-sponsored seminars that provide continuing education credits is not covered unless the attendee is an OPO staff member.

- In section II.C.2.b.(3). of this final rule with comment period, to revise the rationale for not covering certain costs of administrator duties for those in professional organizations to indicate that costs that are unreasonable would be excluded.

While we did not propose to codify the items and services not covered as OPO organ acquisition costs described in the proposed rule, after consideration of the public comments we received seeking clarification or suggesting changes, we believe it is prudent to codify the list of examples of items and services not considered to be organ acquisition costs. As such, in this final rule we are codifying at §413.402(d), costs not related to organ acquisition in which we specify that items or services that are not related to acquiring an organ for transplantation, or that are not reasonable under section 1861(v)(1)(A) of the Act, or that are non-allowable administrative and general costs, or that are not related to patient care under 42 CFR 413.9 of the regulations are not considered organ acquisition costs. Examples of items or services that are not

organ acquisition costs include, but are not limited to: donor burial and funeral expenses, transportation of the cadaveric donor after organ procurement for funeral services or for burial; transportation costs for a living donor; fees or in-center payments for donor referrals; costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at §486.326(b)); and unreasonable costs incurred for administrator's duties associated with professional organizations.

#### c. Provisions Related to Standard Acquisition Charges

Because a number of the SAC comments received addressed proposals in multiple subsections, the comment summaries and our responses are at the end of section II.C.2.c. of this final rule with comment period.

##### (1) General

We proposed to clarify and codify Medicare's policy regarding TH/HOPO SACs in new subpart L, § 413.404, as discussed herein. The IL 74-23, issued in July 1974, set forth the policies and procedures for a hospital to develop standard kidney acquisition charges for the acquisition of kidneys from living or cadaveric donors. Over the years, as Medicare added coverage for non-renal transplants, Medicare used these same policies and procedures for THs to develop living and cadaveric SACs for non-renal organs and OPOs to develop cadaveric SACs for non-renal organs.

A SAC for an organ is an amount that represents the estimated costs a TH or an OPO expects to incur to acquire an organ. The SAC does not represent the actual acquisition cost for an individual organ. Instead, the SAC generally represents the average of the total organ acquisition costs associated with procuring either cadaveric donor organs or living donor organs, by organ type.

A TH or OPO cannot bill Medicare directly for the cost of procuring an organ because procuring an organ is not a covered service when performed independent of a Medicare covered transplant, and it is not always known at the time of organ procurement whether the potential

recipient is a Medicare beneficiary. However, the reasonable costs of procuring an organ are reimbursable when billed in connection with a Medicare covered transplant. When a TH bills Medicare for the transplant, it bills the DRG charge for the organ transplant and uses its SAC to bill Medicare for the procured organ (currently using revenue code 081X<sup>31</sup>). THs develop categories of living or cadaveric SACs, by organ type (for example, heart, liver or lung). When a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, we proposed that it must bill the receiving TH/HOPO or IOPO its SAC. We proposed to codify these provisions pertaining to SACs at proposed new § 413.404(a) in new subpart L.

## (2) Transplant Hospitals and HOPOs

We proposed to codify provisions pertaining to SACs for TH/HOPOs for living and cadaveric donors at proposed new § 413.404(b) in new subpart L, as described in this section.

### (a) Living Donor Standard Acquisition Charge

We proposed to codify Medicare's longstanding policy regarding a TH's standard acquisition charges for living donors at proposed new § 413.404(b)(3)(i) in new subpart L as discussed herein, because these policies remain relevant. THs must develop a SAC for living donor organs, by organ type (for example kidney, liver, or lung). THs/HOPOs must develop a SAC for cadaveric organs, by organ type. The living donor SAC is an average organ acquisition cost the transplant hospital incurs to procure an organ from a living donor. As medicine and transplantation have advanced, Medicare now covers transplants into beneficiaries from living donors for kidneys, lungs, and portions of livers or intestines, and a living donor SAC must be established for each of these organs.

A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare. The TH develops the initial living donor SAC for each living donor organ type, by estimating the reasonable and necessary organ acquisition costs it expects to incur

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<sup>31</sup> Medicare Internet Only Manual 100-04, Medicare Claims Processing Manual, Chapter 3, Section 90, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>.



for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period. The TH divides the estimated amount by the projected number of usable living donor organs to be procured by the TH during the hospital's cost reporting period. A TH calculates its subsequent years' living donor SAC for each living organ type by using the transplant hospital's actual organ acquisition costs for the living donor organ type from the prior year's MCR, adjusted for any changes in the current year. The TH divides these costs by the actual number of usable living donor organs procured by the TH during that prior cost reporting period. Currently, when a TH/HOPO furnishes an organ to another transplant hospital or OPO, it must bill the receiving TH or OPO its SAC, by organ type, or the hospital's standard departmental charges that are reduced to cost. The TH/HOPO includes the actual incurred cost for organ procurement services in the organ acquisition cost center on the hospital's MCR.

We proposed that the costs that may be used to develop the living donor SAC include, but are not limited to: costs of tissue typing services, including those furnished by independent laboratories; costs of physician pre-admission transplant evaluation services; OPTN registration fees; costs for donor and recipient evaluation and workup furnished prior to admission for transplantation; other costs associated with procurement, for example, general routine and special care services related to the donor; costs of operating room and other inpatient ancillary services related to the donor; preservation and perfusion costs; and transportation costs of the excised organ. We proposed to codify these provisions at proposed new § 413.404(b)(3)(i) in new subpart L.

(b) Cadaveric Donor Standard Acquisition Charge

In the proposed rule, we proposed to codify Medicare's longstanding policy regarding TH/HOPO standard acquisition charges for cadaveric donors and the costs that may be included in the cadaveric donor SAC in new subpart L, § 413.404(b)(3)(ii) because these policies remain relevant. The cadaveric donor standard acquisition charge (cadaveric

donor SAC) is an average cost that a TH/HOPO incurs to procure an organ from a cadaveric donor. The TH/HOPO calculates its initial cadaveric donor SAC for each cadaveric organ type, by estimating the reasonable and necessary costs it expects to incur in procuring cadaveric organs, combined with the expected costs of acquiring cadaveric organs from OPOs or other THs. The TH/HOPO divides this estimated amount by the projected number of usable cadaveric organs to be procured by the TH/HOPO within the TH's cost reporting period.

The TH/HOPO calculates its subsequent years' cadaveric donor SAC for each cadaveric organ type, by using the transplant hospital's actual organ acquisition costs for the cadaveric donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year. The TH/HOPO divides this estimated amount by the actual number of usable cadaveric donor organs procured by the TH/HOPO during that prior cost reporting period. "Usable" organs are discussed in section II.C.2.h.(2). of this final rule with comment period.

Where the TH/HOPO furnishes the organ to an OPO or another TH, the TH/HOPO uses its cadaveric donor SAC to bill the OPO or the TH receiving the organ. We also proposed that costs that may be used to develop the cadaveric donor SAC include, but are not be limited to: costs of organs acquired from other THs or OPOs; costs of transportation of the excised organs; surgeons' fees for excising cadaveric organs (currently limited to \$1,250 for kidneys); costs of tissue typing services, including those furnished by independent laboratories; preservation and perfusion costs; general routine and special care service costs; and operating room other inpatient ancillary service costs.

### (3) Independent OPO Standard Acquisition Charge

In the proposed rule, we proposed that new § 413.404(c) in new subpart L would specify Medicare's longstanding policy regarding IOPO standard acquisition charges for cadaveric donors because these policies remain relevant. An OPO is required under section

371(b)(1)(C) of the PHS Act (42 U.S.C. 273(b)(1)(C)) to have an agreement with the Secretary to be reimbursed under Medicare for the procurement of kidneys. The IOPO's Medicare contractor establishes the kidney SAC, which is considered an interim rate as currently specified in § 413.200(d) (proposed to be added to new subpart L as § 413.420(d)), and which consists of an estimate of the reasonable and necessary costs the IOPO expects to incur procuring cadaveric kidneys during the IOPO's cost reporting period. The contractor divides the estimated amount by the projected number of usable<sup>32</sup> cadaveric kidneys procured. The IOPO's Medicare contractor may adjust the kidney SAC during the year, if necessary, for cost changes. Because the contractor must establish and may adjust, if necessary, the kidney SAC, the IOPO cannot charge or change its kidney SAC without the contractor's approval.

The Medicare contractor develops an IOPO's initial kidney SAC based on the IOPO's budget information. The kidney SAC for subsequent years is based on the IOPO's cost report, that is, costs of operating during its prior cost reporting year and the number of usable cadaveric kidneys procured during that cost reporting period. These standard charges are the basis for the interim rate (that is, the kidney SAC) paid by the TH to the IOPO. When the IOPO bills the TH for its kidney acquisition services, the TH is responsible for paying the IOPO's interim rate (that is, its kidney SAC). The IOPO's submitted cost report is used to reconcile kidney acquisition costs under § 413.200(d) (proposed to be added as § 413.420(d)).

An OPO is required under (42 U.S.C. 273(b)(1)(B)) to have accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization. As such, an IOPO establishes non-renal SACs based on its costs of procuring organs, similar to procedures followed by transplant hospitals. An IOPO develops its SACs for each type of non-renal organ, by estimating the reasonable and necessary costs it expects

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<sup>32</sup> See discussion of usable organs in section II.C.2.h.(2). of this final rule with comment period.

to incur for services furnished to procure cadaveric donor non-renal organs during the IOPO's cost reporting period. The IOPO divides this estimated amount by the projected number of cadaveric donor non-renal organs the IOPO expects to procure within its cost reporting period.

When an IOPO receives an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The IOPO uses its own SAC and not the SAC paid to another IOPO, when billing a TH receiving the organ. For example, IOPO A has a SAC of \$35,000 and IOPO B has a SAC of \$50,000. IOPO A receives an organ from IOPO B and pays IOPO B their SAC of \$50,000. IOPO A furnishes the organ to the TH and bills the TH its SAC of \$35,000.

Comment: Some commenters provided feedback regarding "imported" organs, or organs one OPO receives from another OPO or from a transplant hospital. A commenter noted that when an OPO receives an organ from another OPO, the receiving OPO must pay the procuring OPO's SAC, but then only charge the TH its own SAC, regardless of whether the amount is higher or lower than the procuring OPO's SAC. The commenter opined that given the revised allocation methodologies now in use, there has been a dramatic increase in the number of organs exchanged between OPOs. Other commenters noted increased costs, such as transportation, due to the new allocation methodologies. A few commenters requested that an OPO's SAC for any imported organ (renal or non-renal) incorporate the cost of the imported organ to ensure that the OPO can bill the transplant hospital an amount sufficient to fully recoup the costs incurred for procuring the imported organ from another OPO. A commenter requested that CMS clarify whether OPOs will need to administratively handle all imported organs coming into the servicing OPO's area. By "administratively handle," it seems the commenter refers to the OPO's arrangement for the acquisition, preservation and transportation of donated organs, and procedures to obtain payment for organs provided to transplant hospitals.

Response: The costs of “imported” organs are recorded as organ acquisition costs, in accordance with the finalized rule at § 413.402(b)(9), since these are the costs of organs acquired from other hospitals or OPOs. If these costs are incorporated into the OPOs’ SACs, the OPO should be able to recoup its costs for imported organs transplanted into Medicare beneficiaries. The MAC calculates the IOPO’s kidney SAC based on its actual costs from the prior year. However, the IOPO can ask the MAC to adjust its kidney SAC during the year if it can support a change in the cost basis, such as might occur if the OPO has an increased amount of imported organ costs.

Likewise, because the IOPO develops its own SACs for non-renal organs by estimating its expected costs for the coming year, it can include the estimated cost of non-renal organs received from another OPO or TH in its expected acquisition costs when developing its non-renal SACs. We are clarifying that similar to our policy for IOPO kidney SACs, if an IOPO experiences cost changes, the IOPO is permitted to adjust the non-renal SAC amount during the year if it can support a change in the cost basis. Therefore, we are modifying the proposed regulation at §413.404(c)(1) to add paragraph (iii) to state that an IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

Finally, we are clarifying that our proposals did not make pronouncements as to whether an OPO is required to administratively process all imported organs coming into its servicing area. OPOs are required to administratively process organs pursuant to the allocation methodologies set forth by HRSA.

Comment: A commenter noted that there is no comparable reconciliation for non-renal organs procured by OPOs as there is for kidneys. The commenter stated that the only way a divergence of SAC-based revenue and actual costs is recognized is through the following year’s estimated SAC, and was concerned that continuation of this policy may result in fewer non-renal organs being made available for transplant. The commenter suggested CMS consider the policy further before codifying in the Code of Federal Regulations.

Response: We appreciate this comment, and agree that there is not currently a reconciliation for non-renal organs procured by OPOs as occurs with kidneys. Requiring reconciliation of non-renal organs could ensure that Medicare reasonable cost principles are followed, and may support non-renal organ transplantation. We did not propose to reconcile non-renal organs procured by OPOs; however, we will review this further and consider addressing in future rulemaking.

Comment: A commenter stated that several OPOs charge a SAC fee with add-ons to their non-renal SAC amounts, such as additional surgeon fees, transportation, or other extra costs. The same commenter opined that some non-renal SACs are over-inflated and questioned if the MACs could approve and publish the non-renal SACs. This commenter noted that with limited regulations, these issues could only be referred to the Office of Inspector General (OIG).

A different commenter provided an example where a transplant hospital may only receive \$20,000 from the OPO for services to maintain the cadaveric donor when an OPO harvests two lungs, two kidneys and a heart; however, the OPO charges the hospital \$70,000 for one kidney. Two commenters noted that transplant hospitals are sometimes paid by OPOs an amount far less than what their SAC payment at cost would warrant. A commenter opined that under current policy, the OPO underpayment does not negatively impact transplant hospitals because transplant hospitals must offset 100 percent of the revenue received from OPOs from allowable organ acquisition costs on the Medicare cost report. This commenter added that a transplant hospital could forego all payments from the OPO and would remain whole through its Medicare cost report filing.

Response: Our final regulation at §413.404(a)(3) would require that an IOPO that furnishes an organ to a TH bill the TH its IOPO SAC. Billing amounts in addition to the SAC would be inappropriate as the SAC is developed by incorporating all the allowable costs of procuring an organ, and is an average charge rather than the actual cost of a particular procurement. As such, there should be no billing of the SAC plus additional amounts, nor any

need to do so. As noted in a previous comment response in this section, if an IOPO experiences increased costs that the current SAC is not covering, the IOPO can ask its MAC to adjust its kidney SAC as specified in proposed § 413.404(c)(2)(iv), or the IOPO can adjust its non-renal SAC amounts if needed due to cost changes.

Additionally, an OPO is required under 42 U.S.C. 273(b)(1)(B) to have accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization. These fiscal procedures could include carefully estimating costs for the upcoming year when developing its non-renal SAC, so that the non-renal SAC is an average charge sufficient to cover procurement costs of non-renal organs. The SAC should be a reasonable estimate of average costs rather than an inflated estimate of average costs.

We believe codifying organ acquisition payment policies as we are doing in the regulation text is a step towards making our policies clearer to all stakeholders and to increasing compliance. If a MAC identifies systemic issues such as inappropriate or abusive fiscal procedures by OPOs, it can and should refer those OPOs to the OIG. We appreciate this comment about inflated SAC amounts and oversight of non-renal SACs, and are considering options for future rulemaking to strengthen policies where needed to ensure that organ acquisition costs are paid on a reasonable cost basis, and that inappropriate fiscal procedures do not impede organ procurement or transplantation.

The commenter's example appears to be a situation where a transplant hospital provided services to a cadaveric donor, but did not procure the organs; in the example, the OPO arranged for the procurement. As such, it would not be appropriate for the TH to bill the OPO its SAC, as the TH is not procuring the organ. This is discussed further in section II.C.2.1. of this final rule with comment period pertaining to donor community hospitals and transplant hospitals that incur costs for providing services to a cadaveric donor, as authorized by the OPO so that an OPO can arrange for organ procurement. In the situation

where a transplant hospital actually procures the organs and furnishes them to an IOPO, in accordance with the policy finalized at §413.404(a), the transplant hospital should bill its appropriate organ-specific SAC(s) to the IOPO, and the IOPO should pay the TH the billed SAC amount(s).

Finally, if a TH were to forego all payments from an OPO for the services the TH provides, it could affect the hospital's cash flow and could affect the OPO's year-end reconciliation of kidney acquisition costs. However, we agree with the comment that THs must offset their acquisition costs by the revenue received from OPOs, and that the reconciliation process should ensure that THs remain whole.

Comment: A commenter supported our efforts to standardize the way in which SACs for any organ are calculated. However, the commenter cautioned that inclusion of certain extraordinary expenses in SACs could result in inequitable allocation of costs among providers, including Medicare, while being a possible barrier to innovation. The commenter suggested those extraordinary expenses be identified and segregated from the expenses included in the SAC. As an example, the commenter stated that perfusion technologies, (i.e. technologies that may be used to preserve, assess and in some cases recondition organs prior to transplantation), which are new and relatively expensive, have been costs historically borne by THs, but now are costs first borne by OPOs and passed to the TH as a charge in addition to the SAC. The commenter stated that requiring OPOs to include these charges in their SAC may not be financially feasible for the OPO, and may force the OPO to eliminate its offering of these new technologies. Similarly, the commenter stated that revised allocation methods result in organs traveling greater distances to recipients, requiring OPOs to incur higher transportation expenses. If these costs are included in the SAC, the commenter believes that communities with higher rates of donation will bear an inequitable share of significant transportation costs that should instead be charged directly to the transplant hospitals incurring the cost. The commenter believed that if OPOs are required to include all costs in the SAC, regardless of the amount or



frequency of the expense, doing so could result in an inequitable yet material shift of expenses among providers and suggested CMS act to avoid that outcome.

Response: We appreciate the commenter's support for our SAC proposals. However, we do not believe that an IOPO's inclusion of allowable procurement costs in its organ acquisition costs creates inequities, including costs for expensive items such as innovations or increased procurement-related travel. Costs that an IOPO incurs to procure an organ should be recorded by the IOPO, which would allow them to be included in the IOPO's organ-specific SAC amounts, pursuant to §§ 413.402 and 413.404. The SAC calculation spreads the IOPO's total costs of procuring an organ over all the organs procured, as described in the proposed regulation at § 413.404(c). Organ acquisition costs are passed on to the TH when the IOPO procures an organ for the TH and bills the TH its organ-specific IOPO SAC. Our payment system for organ procurement is designed to cover the costs of organ acquisition on a reasonable cost basis, and we believe it incentivizes innovation. Therefore, we are not adopting this commenter's suggestion about excluding certain extraordinary expenses from the SAC calculation. Finally, we note that the finalized regulation at § 413.404(a)(3) requires the IOPO to bill the TH its SAC, not its SAC plus additional charges.

In summary, we are finalizing our proposals as proposed in §413.404 of subpart L, except for the following modifications and clarifications:

- In section II.C.2.b.(1). of this final rule, we modified the proposed registry fees and the proposed transportation costs covered as organ acquisition costs to provide expanded coverage of these costs. To conform to these final changes, we modified the SAC regulation text related to costs used to develop the living donor SAC at § 413.404(b)(3)(i)(D)(3) to refer to registry fees specified at § 413.402(b)(6), and at § 413.404(b)(3)(i)(D)(8) to refer to transportation costs of the excised organ as specified at § 413.402(b)(8)(i). Similarly, we modified the SAC regulation text related to costs used to develop the cadaveric donor SAC at § 413.404(b)(3)(ii)(C)(2) to refer to transportation costs as specified at § 413.402(b)(8).

- In § 413.404(b)(3)(i)(D)(7) and §413.404(b)(3)(ii)(C)(5), to add the word ‘organ’ to conform to the final regulation text at § 413.404(b)(5).
- In § 413.404(c)(1) to add paragraph (iii) to specify that an IOPO may adjust its non-renewal SACs during the year if necessary to account for cost changes.
- In § 413.404(a)(2), we added ‘organ acquisition’ to more clearly specify the total costs.
- In § 413.404(b)(3)(i), we added ‘organ acquisition’ to more clearly specify the average cost; and in § 413.404(b)(3)(i)(C)(1)(i), we added ‘organ acquisition’ to more clearly specify the reasonable and necessary costs.
- In § 413.404(a)(3), we removed the phrase ‘transplant hospital’ and clarified that when a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, it bills its SAC to the TH/HOPO or IOPO receiving the organs.
- In § 413.404(b)(2), we replaced ‘provides’ with ‘furnishes,’ and corrected the acronym OPO to change it to IOPO.
- In § 413.404(b)(3)(i)(C)(1), we added ‘donor’ to more clearly specify the living SAC, and in § 413.404(b)(3)(ii)(B)(2)(ii) we added ‘donor’ to more clearly specify cadaveric organs;.
- In § 413.404(b)(3)(i)(C)(2), we added ‘years’ to more clearly specify the subsequent living donor SAC, and in § 413.404(b)(3)(ii)(B)(2) we added ‘years’ to more clearly specify the subsequent cadaveric donor SAC; in § 413.404(b)(3)(i)(D)(5), to clarify what special care services are we added a parenthetical phrase that gives intensive care unit or critical care unit services as examples of special care services.
- Corrected grammatical errors in the regulation text, to ensure that parallel structure exists, that singular pronouns describe singular nouns, and that subjects and verbs agree.

#### d. Accounting for Outpatient Costs and Laboratory Services

In our proposed rule in section X.B.2.d. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25662), we explained that outpatient costs including pre-transplant

evaluation service costs were described for kidneys in ILs, as well as in the Medicare Claims Processing Manual and in a CMS Change Request.<sup>33</sup> After non-renal organs were covered for transplantation through a CMS Ruling (for heart transplants) and through NCDs (other non-renal organs),<sup>34</sup> payment policies were subsequently implemented through notice-and-comment rulemaking.<sup>35</sup>

#### (1) Outpatient Costs

Section 3102.A. of the PRM describes how to account for certain hospital outpatient costs applicable to a potential organ transplant. The TH's organ acquisition costs include donor and recipient work-ups furnished prior to admission and costs of services rendered by interns and residents not in an approved teaching program. These costs would typically be billed to Medicare Part B. However, these costs are predominantly cadaveric donor related, incurred without an identifiable beneficiary, and are included in the TH's organ acquisition cost center.

#### (2) Pre-transplant Evaluation and Laboratory Services

Section 3102.C. of the PRM specifies that pre-transplant evaluation services for recipients and donors provided by the TH, including laboratory services, are paid through the organ acquisition costs of the TH. When pre-transplant laboratory tests are performed by the TH, the TH accumulates these costs in its organ acquisition cost center. The TH also includes

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<sup>33</sup> Part A Intermediary Letter, July 01, 1973 No. 73-25 and Part B Intermediary Letter, No. 73-22; July 1973; Medicare Claims Processing Manual (IOM 100-04, chapter 3, section 90.1.1.A. (available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>); and change request 6978, available at (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2008CP.pdf>).

<sup>34</sup> See CMS Ruling 87-1, April 1987; National Coverage Determinations Manual, IOM 100-03, chapter 1, Part 4, section 260 (available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1\\_Part4.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf)).

<sup>35</sup> 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990 and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001).

the reasonable charges paid for physician tissue typing services provided to living donors and recipients.

### (3) Histocompatibility Laboratory Services

Histocompatibility laboratories are required by the statute at section 1881(b)(2)(A) of the Act to be paid on a reasonable cost basis, in accordance with section 1861(v) of the Act. Section 413.200 sets forth the payment policy for services furnished by histocompatibility laboratories in connection with kidney acquisition and transplantation. When the laboratory services are performed by a histocompatibility laboratory, the Medicare contractor establishes interim rates which are used by the laboratory in billing a TH. The contractor disseminates information on the interim rates to all THs, OPOs, and other contractors, or posts the information on its website. The TH pays the laboratory the approved interim rate. When the laboratory bills an OPO for services, the OPO is responsible for paying the interim rate. The contractor determines the final payment to the histocompatibility laboratory for kidney-related transplant tests by reconciling interim payments and reasonable costs during final settlement of the MCR. We note that in section X.B.2.m.(6). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to move revised text from §413.200(b) to §413.400, and §413.200(a), and (c) through (g), to §413.420.

Comment: A commenter stated that our proposed rule gave no consideration to the 50 separately certified freestanding Histocompatibility Laboratories (HLA). The commenter stated that these labs provide services to OPOs and Medicare-certified transplant centers for patients in all phases of the transplant process and the Coordination of Benefits process. The commenter stated there has been no discussion of how Medicare utilization is determined for final reimbursement nor has there been an analysis of the effect of the proposed regulatory change on the payments to the free-standing histocompatibility laboratories, and urged CMS to convene a working group about this.

Response: We appreciate the work of HLAs, and believe that our final policies for OPOs should not impact HLAs because OPOs and TH/HOPOs will continue to pay HLAs an interim rate that is established by the Medicare contractor for providing pre-transplant services. We did not make any proposals related to HLA operations or payment and appreciate the commenter's recommendation to convene a working group. However, we will monitor the effects of this final rule with comment period for any unintended consequences and consider changes impacting HLAs in future rulemaking.

We are finalizing the policies as set forth in section X.B.2.d. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule without any changes.

e. Accounting for the Cost of Services Provided to Living Kidney Donors

Section 1881(d) of the Act sets forth Medicare coverage for living kidney donors. Under section 1881(d) of the Act, any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of Medicare with respect to such donation. The Act requires that reimbursement for the reasonable expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and coinsurance provisions), in such manner as may be prescribed by the Secretary in regulations,<sup>36</sup> for all reasonable preparatory, operation, and post-operation recovery expenses associated with such donation. It further provides that payments for post-operation recovery expenses shall be limited to the actual period of recovery. Medicare's coverage is limited to those donor expenses that are incurred directly in connection with the kidney donation.

(1) Hospital Services to a Living Kidney Donor

When a living donor receives hospital outpatient services (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, costs of all hospital services applicable to medical evaluation are considered kidney acquisition costs. When the living donor subsequently enters the hospital for the actual excision, the hospital costs of

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<sup>36</sup> 42 CFR 409.18, 42 CFR 409.89 (Part A); 42 CFR 410.55, 42 CFR 410.163 (Part B).

services rendered to the donor will continue to be treated as kidney acquisition costs under Part A.<sup>37</sup>

The donor of a kidney for a Medicare transplant is covered for an unlimited number of days of inpatient care in connection with the organ removal operation. Days of inpatient hospital care used by the donor in connection with the organ removal operation are not charged against either party's utilization record.

Comment: A commenter objected to our use of "admitted" to describe a living kidney donor who receives a medical evaluation at the hospital in anticipation of kidney donation. The commenter stated that these pre-donation evaluations occur on an outpatient basis, therefore the patient is not "admitted."

Response: We agree with this commenter, and have revised the language in this and in the following subsection accordingly.

## (2) Physician Services to a Living Kidney Donor

When a living donor receives hospital outpatient services (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, costs of all physicians' services applicable to medical evaluation are considered kidney acquisition costs. When a living donor is admitted to a hospital for the kidney excision, physician services are no longer considered kidney acquisition costs and are not reimbursable under Part A. Under the Medicare Physician Fee Schedule, surgical excision of living donor kidneys is included in the global surgery policy, with a reasonable post-surgical follow-up defined as 90 days.<sup>38</sup> This standard 90-day post-operative period includes all services by the primary surgeon during this period unless the service is for a condition or issue unrelated to the diagnosis for which the surgery is performed or is for an added course of treatment other than normal recovery from the surgery. During the donor's inpatient stay for the excision surgery and during any subsequent

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<sup>37</sup> 42 CFR 409.18.

<sup>38</sup> See Addendum B in 59 FR 63515, for CPT code 50320, which is for living donor kidney excision.

donor inpatient stays resulting from a direct complication of the organ donation, physician services are billed under Part B. They are billed in the normal manner but under the recipient's MBI at 100 percent of the fee schedule,<sup>39</sup> with no deductible or coinsurance.<sup>40</sup>

### (3) Living Kidney Donor Follow-up

Costs incurred by the TH for routine kidney donor follow-up care are included in the TH's organ acquisition cost center. For routine follow-up care, the period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the kidney donation. Beyond the 90-day global payment period, routine follow-up services are billed to Part B using the recipient's MBI. Routine follow-up services billed to Medicare by a physician other than the operating physician for up to 3 months following donation surgery must be billed using the recipient's MBI. The Medicare Administrative Contractor will review claims for services rendered more than 3 months after kidney donation surgery. Medicare may cover routine follow-up examinations up to 6 months after the kidney donation to monitor for possible complications. In all of these situations, the kidney donor is not responsible for co-insurance or deductible amounts.<sup>41</sup>

The OPTN collects follow-up data at 6 months, 12 months, and 24 months post-donation.<sup>42</sup> Routine clinical visits to comply with the OPTN follow-up data collection are not allowable nor reportable as organ acquisition costs on the MCR and cannot be billed to Medicare. These follow-up visits are intended as a precautionary measure to provide proactive assessment of the organ function of a living donor in the near-term following removal of an organ intended for transplant. However, medical services for a living kidney donor who

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<sup>39</sup> 42 CFR 410.55 and 410.163.

<sup>40</sup> 42 CFR 410.55 and 410.163. See also the kidney policy for living donors, which is described in the Medicare Benefit Policy Manual 100-02, chapter 11, section 140.5, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf> and billing instructions in the Medicare Claims Processing Manual 100-04, chapter 3, section 90.1.1.F. and G., available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>.

<sup>41</sup> 42 CFR 410.163.

<sup>42</sup> Information from <https://optn.transplant.hrsa.gov/resources/guidance/procedures-to-collect-post-donation-follow-up-data-from-living-donors/>, accessed on March 16, 2021.

experiences a complication directly related to the kidney donation procedure can be billed under the Medicare transplant recipient's MBI. Also, as described in section II.C.2.e.(4) of this final rule with comment period, hospital services for a living non-renal organ donor who experiences complications directly related to the non-renal organ donation must be reported on the Medicare cost report as organ acquisition costs.

Comment: Several commenters interpreted our proposal as eliminating payments for living donor follow-up. A commenter requested that CMS clarify that the 90-day reference is for physician services and that there is no specified time limit for hospital services to be considered allowable organ acquisition for routine living donor follow-up. Several commenters disagreed with our assertion that the living donor follow-up visits required by the OPTN were not for meeting the medical needs of the donor, and requested that CMS allow these costs.

Response: We greatly appreciate living donors and their altruistic decision on behalf of another person. Given the confusion on our policy that was made clear in comments, we wish to clarify that payments for living donor follow-up are not being eliminated, and reiterate that we did not propose any changes to our existing policies related to living donor follow-up visits. We are also clarifying that our reference to the 90-day global payment period is referring to the surgeon's follow-up period after surgery; Medicare may cover routine follow-up examinations up to 6 months after the kidney donation to monitor for possible complications. Finally, we continue to believe that the OPTN-required living donor follow-up data collection is not primarily focused on the medical needs of individual living donors and that this data collection is primarily for collecting longer term data on the effects of living donation. While we appreciate that this data collection may benefit future living donors, we are continuing our existing policy that Medicare does not cover or pay for this OPTN-required data collection.

#### (4) Provisions Related to Living Donor Complications

In section X.B.2.e.(4). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we stated that living kidney donor complications related to the surgery to remove a kidney,



which occur after the date of discharge, are not considered kidney acquisition costs. Living kidney donor complications are statutorily authorized to be paid under Part A or Part B in section 1881(d) of the Act, with no liability for deductibles or coinsurance.<sup>43</sup> Under 42 CFR 409.18, Medicare covers costs incurred for living kidney donor complications only if they are directly related to the kidney donation. Rather than being paid as kidney acquisition costs, costs incurred for complications arising after the kidney donor's discharge date are billed under the Medicare transplant recipient's MBI, including facility costs and physician services. The contractor reviews costs for kidney donor complications billed under the transplant recipient's MBI. We proposed to codify this longstanding policy by adding 42 CFR 413.402(c) to new subpart L.

Comment: A commenter was concerned that CMS is narrowing the definition of complications by underscoring in proposed § 413.402(c)(2) the requirement that any complications be directly attributable to a kidney donation. The commenter did not find a specific basis for such a narrow scope in section 1881(d) of the Act. The commenter stated that the language in § 413.402(c) could be confusing as proposed paragraph (c)(1) notes that certain complications post-discharge are not kidney acquisition costs, which could have a “chilling effect.” The commenter suggested CMS change “directly attributable” to “reasonably related.”

Response: We proposed to codify the existing policy for living kidney donor complications in accordance with our statutory authority section 1881(d) of the Act. Section 1881(d) of the Act entitles an individual who donates a kidney for transplant surgery to Medicare benefits under parts A and B, for all reasonable preparatory, operation, and post-operation recovery expenses, limited to the actual period of recovery, associated with such donation. Prior to the enactment of section 1881 of the Act, Medicare covered post donation complications for living kidney donors, as outlined in the IL 74-23.

Regarding the commenter's opposition to our using the phrase “directly attributable” in the regulation text, we are changing the language in the final regulation at §413.402(c)(1) to

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<sup>43</sup> Section 1881(d) of the Act; 42 CFR 409.18, 409.89 for Part A costs; 42 CFR 410.55 and 410.163 for Part B costs.

replace “directly attributable” with “directly related” to match the language used in 42 CFR 409.18(b), which specifies that Medicare pays for postoperative recovery services directly related to the kidney donation. We disagree with the commenter that there is no specific basis for such a narrow scope in section 1881(d) of the Act, as we do not believe that our original language or this revised language is a stricter policy than that permitted by the statutory language, and note that the statute explicitly permits the Secretary to define how reimbursement occurs for the reasonable expenses incurred by a living donor with respect to a kidney donation in regulations.

We believe our proposed regulation text at §413.402(c)(1) that living kidney donor complications are not considered organ acquisition costs, was unclear and was misunderstood. Living kidney donor complications are organ acquisition costs, but they are not reported on the cost report or paid through the cost report as organ acquisition costs, because of the statutory authority in section 1881(d) of the Act. Instead, the costs of living kidney donor complications are billable under Medicare Part A and B using the Medicare kidney transplant recipient’s MBI as established by regulations. The costs and charges associated with the living kidney donor complications are reported on the cost report as normal patient care expenses and not organ acquisition costs or charges. Payment is made through the claims processing system. Therefore, we make a distinction about covered organ acquisition costs that are paid through the Medicare cost report as organ acquisition costs. To make this distinction clearer, we are removing language that living kidney donor complications are not considered kidney acquisition costs from the proposed regulation text at §413.402(c)(1), and specifying that costs of living kidney donor complications must not be reported as kidney acquisition costs on the Medicare cost report.

Comment: Several commenters were concerned that CMS’ proposed codification of the payment policy for living kidney donor complications only focused on kidneys and did not address living donor complications associated with non-renal organs. Commenters noted that our proposed language generally followed the language in PRM 15-1, §3105.B, but changed the

word “organ” to “kidney.” Commenters requested that CMS affirm that it will continue covering post-discharge complications related to living organ donation for all organs furnished to Medicare beneficiaries. Commenters stated that the policy given in PRM 15-1 §3105 is not specific to kidney and that if coverage of living donor complications for non-renal organs were to cease, it could limit the availability of living donor non-renal organs.

Response: We appreciate this comment and believe that covering living donor complications for all organs, renal and non-renal, more strongly supports living organ donation. As discussed in a previous comment response, we have explicit statutory authority to cover living kidney donor complications in accordance with section 1881(d) of the Act. Living kidney donor complications are separately billable under Medicare Part A and B using the Medicare kidney transplant recipient’s MBI. The payment for living kidney donor complications is made through the claims processing system, and living kidney donor complications are not reported as kidney acquisition costs on the cost report.

While we do not have a similar statutory authority to pay for living non-renal donor complications in the same manner, we do consider the hospital costs related to living non-renal donor complications to be organ acquisition costs. We recognize that there was a change to our policy manuals that resulted in this confusion on how to bill, report, or obtain payment for living non-renal donor complications.

Therefore, we are clarifying that certain costs for living non-renal donor complications are included in organ acquisition costs when the living non-renal donor complication is directly related to the living non-renal organ donation. These hospital costs for living non-renal donor complications are not separately billable to Medicare using the recipient’s MBI, but must be reported and paid through the hospital’s MCR as organ acquisition costs. We believe these clarifications in response to comments will expand our proposed codification to cover both living kidney donor complications and hospital costs related to living non-renal donor complications, but through different reporting and payment mechanisms.

In response to public comments, we are modifying our proposal to codify living kidney donor complications and based on comments received to clarify appropriate billing, reporting and payment under §413.402(c)(1) to specify that living kidney donor complications directly related to the kidney donation, which occur after the date of the donor's discharge, must not be reported as kidney acquisition costs on the Medicare cost report. We are also codifying our proposals under §413.402(c)(1)(A) to specify that Medicare covers reasonable costs incurred for living kidney donor complications only if they are directly related to a kidney donation for a covered transplant into a Medicare beneficiary and §413.402(c)(1)(B) to specify that living kidney donor complications are paid through the claims processing system under Medicare Part A or Part B, as applicable for the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the MBI of the transplant recipient.

Based on comments received, we are also codifying a provision for living non-renal donor complications under §413.402(c)(2) to specify that hospital costs incurred for living non-renal donor complications directly related to the non-renal organ donation, which occur after the date of the donor's discharge, are not paid through the claims processing system but are reported as organ acquisition costs on the hospital's Medicare cost report. In response to comments, we are also codifying under §413.402(c)(2)(A) to specify that Medicare covers reasonable hospital costs incurred for living non-renal organ donor complications only if they are directly related to a non-renal organ donation for a covered transplant into a Medicare beneficiary and §413.402(c)(2)(B) to specify that hospital costs incurred for living non-renal organ donor complications are reported as organ acquisition costs on the hospital's Medicare cost report, and paid through the cost report on a reasonable cost basis.

We believe that finalizing these modifications to our proposed regulation text at §413.402(c) is responsive to commenters, clarifies the regulations, and supports living organ donation.

Comment: Commenters were also concerned that CMS did not specify an effective date and thus perceived the proposal to be effective retroactively. Commenters requested that CMS clarify that these policies are effective October 1, 2021.

Response: As discussed previously, the proposals being finalized in section II.C.2. of this final rule with comment period are effective for cost reporting periods beginning on or after the effective date of this final rule with comment period, unless otherwise specified. None of our proposals were proposed to be retroactive except for the codification of two statutory provisions, which were effective in accordance with their statutory effective dates and which are discussed in a response in section II.C.2.b.(1). of this final rule with comment period. We are finalizing our proposals in section II.C.2.e. of this final rule with comment period with modifications, effective for cost reporting periods beginning on or after the effective date of this final rule with comment period.

#### f. Accounting for the Cost of Services Provided to Transplant Recipients

Certain costs related to organ transplant recipients are not organ acquisition costs, but instead are billed under Part B to the transplant recipient's MBI. These costs include standard backbench preparation services; physician services for the surgeon who performs the transplant (and sometimes performs other surgical procedures at the time of the transplant) and provides 90 days of post-operative surgical care;<sup>44</sup> and/or immunosuppressant therapy management; and recipient laboratory services which occur after discharge from the hospital. See the Medicare Claims Processing Manual, IOM 100-04, chapter 12, sections 30.6.3, 40.1, and 40.4 for more details on these services.<sup>45</sup>

We received no comments on this section.

#### g. Codification of Statutory Provisions Related to Pancreata Used for Pancreatic Islet Cell Transplants

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<sup>44</sup> See Addendum B in 59 FR 63516, for CPT codes 50360 and 50365 for kidney transplantation.

<sup>45</sup> Available online at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>.

Our longstanding policies related to pancreata used for pancreatic islet cell transplants were discussed in our proposed rule. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003<sup>46</sup> (MMA) requires Medicare to pay for items and services that are reasonable and necessary routine patient care costs related to acquisition on or after October 1, 2004, and delivery of pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplants. The pancreata procured for islet cell transplants require the same quality and care to procure as pancreata procured for solid organ transplants. Therefore, as described in section II.C.2.a.(2). of this final rule with comment period, we are defining for organ acquisition payment purposes, pancreata, procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial, to be an organ. Accordingly, pancreata procured for islet cell transplants are treated as solid organs for procurement purposes, and pancreata procured for covered islet cell transplants must be assigned a full standard acquisition charge. We proposed to codify this policy by adding § 413.406 in part 413, new subpart L, in accordance with the statute. There are other clinical trials of islet cell transplants that are not funded by the National Institute of Diabetes and Digestive and Kidney Diseases, but section 733 of the MMA does not authorize Medicare coverage for those trials under title XVIII of the Act.

We received no comments on this section, and are finalizing this rule as proposed, with clarifying modifications to add the statutory effective date (for pancreata procured on or after October 1, 2004) to the regulation text at §413.406(a). We are also adding language to §413.406(b) to clarify that pancreata procured under paragraph (a) of §413.406, for covered islet

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<sup>46</sup> Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173); 42 U.S.C. 1395l.

cell transplants, must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

#### h. Calculation of Medicare's Share of Organ Acquisition Costs, Counting of Organs

##### (1) General

Medicare currently calculates its share of organ acquisition costs for THs/HOPOs by multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs (the numerator) to total usable organs (the denominator) reported on the Medicare hospital cost report.<sup>47</sup> To ensure that a TH/HOPO's organ acquisition costs are accurately allocated to the Medicare Program, THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on their MCRs.

For IOPOs, Medicare currently calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report.<sup>48</sup> Similarly, IOPOs must accurately count and report on their MCRs the number of kidneys they procure and furnish to THs or other OPOs, to ensure that kidney acquisition costs are accurately allocated to the Medicare Program.

##### (2) Medicare Usable Organs, Total Usable Organs, Medicare Usable Kidneys, and Total Usable Kidneys

Currently, Medicare reimburses THs/HOPOs for their reasonable costs incurred to acquire "Medicare usable organs." For Medicare to calculate its share of organ acquisition costs, currently the THs/HOPOs must include the following as Medicare usable organs:<sup>49</sup> (1) organs transplanted into Medicare beneficiaries; (2) organs transplanted into Medicare beneficiaries that were partially paid by a primary insurance payor in addition to Medicare; (3) organs furnished to other THs or IOPOs; (4) kidneys transplanted into Medicare Advantage (MA) beneficiaries for

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<sup>47</sup> CMS Pub. 15-2, chapter 40, section 4028.

<sup>48</sup> CMS Pub. 15-2, chapter 33, section 3312.

<sup>49</sup> In accordance with PRM § 3115.A. and CMS Pub. 15-2, chapter 40, section 4028.3.

dates of service on or after January 1, 2021;<sup>50</sup> (5) kidneys furnished to United States military renal transplant centers (MRTCs) with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor; and (6) pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the MMA, as discussed in section II.C.2.g. of this final rule with comment period.<sup>51</sup> (For counting purposes, the TH/HOPO does not count pancreata procured for islet cell transplant as a solid organ, but counts the number of Medicare beneficiaries who received these islet cell injections as the proxy for Medicare usable organs. For example, if a TH/HOPO procured pancreata for islet cell transplant and injected these islet cells into three Medicare beneficiaries and four non-Medicare patients during its cost reporting period, the TH/HOPO enters three in the Medicare usable organ count, and seven in the total usable organ count, on its Medicare hospital cost report.)

In our proposed rule, we stated that Medicare does not intend to share in the cost of acquiring organs not transplanted into Medicare beneficiaries (except those organs designated for transplant but subsequently determined to be unusable). To calculate Medicare's share, organs not transplanted into Medicare beneficiaries must be counted as total usable organs in the denominator of the fraction of Medicare usable organs to total usable organs. THs/HOPOs must include the following as total usable organs: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other THs or OPOs; (4) organs obtained from another OPO or transplant hospital and either transplanted or furnished to other THs or OPOs; (5) organs furnished to veterans' hospitals or

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<sup>50</sup> Section 17006 of the 21<sup>st</sup> Century Cures Act, (Pub. L. 114-255). Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program. The MA kidney transplants will be included in the numerator and denominator on the MCR to determine Medicare's share of kidney acquisition costs. (85 FR 33796, 33824, June 2, 2020).

<sup>51</sup> Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173); 42 U.S.C. 1395l.



organs sent outside the United States under 42 CFR 413.203; (6) organs transplanted into non-Medicare beneficiaries, under § 413.203; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) organs for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; (9) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (10) pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with the MMA<sup>52</sup>, as discussed in section II.C.2.g. of this final rule with comment period.

Medicare also currently reimburses IOPOs for their reasonable costs incurred to procure “Medicare kidneys.” Organ acquisition costs are not paid directly by Medicare to an IOPO. The IOPO is reimbursed for its services by the TH, subject to later reconciliation by Medicare for kidneys. Medicare currently calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report. For Medicare to calculate its share of Medicare kidney acquisition costs, the IOPO must include the following as Medicare kidneys: (1) kidneys furnished to THs; (2) kidneys furnished to OPOs; and (3) kidneys furnished to United States MRTCs with a reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988, and approved by the contractor. Medicare kidneys do not include kidneys furnished to VA hospitals, military hospitals, or kidneys furnished to foreign countries or transplanted into non-Medicare beneficiaries, in accordance with 42 CFR 413.202.

IOPOs must also count total usable kidneys in the denominator of the fraction of Medicare usable kidneys to total usable kidneys. IOPOs must include the following in total usable kidneys: (1) Medicare usable kidneys; (2) kidneys procured with the intention to be used for research; (3) kidneys procured and furnished to other THs or OPOs; (4) kidneys procured

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<sup>52</sup> Id.

from another OPO or transplant hospital and either transplanted or furnished to other THs or OPOs; (5) kidneys furnished to veterans' hospitals or organs sent outside the United States in accordance with 42 CFR 413.203; (6) kidneys for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; and (7) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988. Currently, organs excised by THs/HOPOs that are furnished to other THs or IOPOs, or kidneys furnished to MRTCs under an approved reciprocal sharing agreement in effect prior to March 3, 1988, are presumed to be transplanted into Medicare beneficiaries, even if they are not. Similarly, some kidneys that an IOPO procures and furnishes to other IOPOs, THs, or MRTCs under an approved reciprocal sharing agreement in effect prior to March 3, 1988, are presumed to be transplanted into Medicare beneficiaries, even if they are not. These categories do not have a distinction to determine whether the organs are actually transplanted into Medicare beneficiaries. In this regard, Medicare organ acquisition payment policy includes the presumption that some organs are transplanted into Medicare beneficiaries, despite the category name that suggests organs and kidneys are transplanted into Medicare beneficiaries: "Medicare usable organs" or "Medicare kidneys." As a result, through unintended consequences, Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries.

When Medicare added the ESRD benefit to Medicare coverage in 1972, Medicare presumed that most kidney transplant recipients would be Medicare beneficiaries receiving the ESRD benefit, and thus Medicare would pay a larger share of kidney acquisition costs.<sup>53</sup> As Medicare added benefits for transplantation of non-renal organs and included the costs to procure non-renal organs, Medicare cost reporting instructions incorporated the presumption that the ultimate transplant recipient was unknown, but likely a Medicare beneficiary. Thus, when a TH furnishes an organ to another TH or to an OPO, or when an OPO furnishes an organ to another

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<sup>53</sup> Intermediary Letter 73-25 (July 1973) and 54 FR 5619, February 6, 1989.

OPO or TH, Medicare assumed that some of the unknown transplant recipients are Medicare beneficiaries, and permits those organs to be counted as Medicare usable organs in the numerator of the fraction for Medicare usable organs to total usable organs, to be assured that Medicare is paying its share of organ acquisition costs.

However, Medicare declared its intention and a methodology to calculate its share of acquisition costs, for kidneys transplanted into Medicare beneficiaries only, in a 1978 **Federal Register** final rule with comment.<sup>54</sup> Specifically, for each kidney transplant performed on a Medicare beneficiary, the transplanting hospital shall receive a prescribed amount of reimbursement from Medicare for the pre-transplantation services of an OPA [organ procurement organization] or laboratory having such an agreement. The 1978 final rule set forth that an OPO's cost report must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the *total number of Medicare beneficiaries* for whom services were furnished by the agency or laboratory, and any other necessary data to enable the intermediary to determine the reasonable cost of covered services *to Medicare beneficiaries*. [Emphasis added.] Additionally, if the intermediary determines that the interim rate payments exceeded the reasonable cost of the services furnished, then the OPA or histocompatibility laboratory *must pay the excess amount per Medicare patient* to the intermediary. [Emphasis added.] These multiple declarations in the 1978 final rule establish Medicare's intention to pay for kidney acquisition costs incurred for kidneys transplanted into Medicare beneficiaries and were originally codified at 42 CFR 405.436 and later moved to 42 CFR 413.178 (currently reserved).

The longstanding policy that Medicare must only share in organ and kidney acquisition costs for Medicare beneficiaries is also set forth in 42 CFR 413.202 and 413.203. Section 413.202 requires OPOs to separate from Medicare allowable costs, acquisition costs for procuring kidneys furnished to foreign transplant centers and kidneys transplanted in non-

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<sup>54</sup> 43 FR 58370, December 14, 1978.

Medicare patients. Similarly, § 413.203 requires THs to separate from Medicare allowable costs, acquisition costs for procuring organs furnished to foreign transplant centers and organs transplanted in non-Medicare patients. In a 1988 proposed rule, CMS expressed belief that allowing all kidneys to be counted as Medicare kidneys was not aligned with anti-cross subsidization principles set forth in section 1861(v)(1)(A) of the Act. 53 FR 6672 at 6673 (March 2, 1988). CMS stated that the Medicare Program has always paid the total costs of OPAs [OPOs] because we assumed that all kidneys procured were for Medicare beneficiaries. However, we now realize that this assumption is incorrect and that technology has allowed a significant number of kidneys to be shipped overseas. Since the Medicare Program has been paying the cost of procuring kidneys shipped overseas or transplanted into non-Medicare beneficiaries, we believe that some action needs to be taken. We believe it is necessary to amend the regulations in order to effectuate the statutory principles embodied in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act requires that the cost of services be borne by the appropriate payor. Accordingly, the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third-party payor. Medicare is precluded from paying any costs associated with kidneys not used by Medicare beneficiaries. 53 FR 6672 at 6673 (March 2, 1988).

Medicare's decades-old presumption that most kidney transplant recipients are Medicare beneficiaries was also applied to non-renal organs because of the lack of organ tracking capabilities over the years and has led Medicare to reimburse THs and OPOs for organ acquisition costs for organs that were not actually transplanted into Medicare beneficiaries. Similar to the beliefs expressed in the 1988 proposed rule, we believe that organ tracking capabilities allow transplant hospitals and OPOs to discern organ recipients' health insurance payor information so that organ acquisition costs can be more appropriately assigned to the Medicare Program for organs transplanted into Medicare beneficiaries. The Scientific Registry

of Transplant Recipients (SRTR)<sup>55</sup> collects and maintains data from the OPTN that identifies, among other things, transplant recipients and their health insurance payors. Data obtained from SRTR show the percentage of transplants where Medicare was the recipients' payor to all transplant recipients' payors, by organ type. We compared the SRTR data for years 2017 and 2018, to the Medicare share ratio for Medicare usable organs (including kidneys) to total usable organs, for 2017 and 2018. Table 1 reflects these data. In the majority of organ types, the SRTR percentages of transplant recipients who were actual Medicare beneficiaries were lower than the Medicare share percentages for those same years. Although there is a difference in the calendar year data from SRTR and the cost reporting fiscal year data from the MCR, these data show that the majority of SRTR's percentage of Medicare transplant recipients was less than the percentages of Medicare's share compared to 2017 and 2018 submitted MCR data from the Worksheet D-4.

**TABLE 1. OVERALL ORGAN-SPECIFIC RATIOS, MEDICARE SHARE FROM COST REPORT DATA VS. SRTR MEDICARE PAYOR RATIO, 2017 AND 2018\***

<b>Organ Type</b>	<b>2017 Medicare Ratio (Medicare Usable Organs/Total Usable Organs)</b>	<b>2017 SRTR Ratio of Actual Transplants with Medicare as Payor</b>	<b>2018 Medicare Ratio (Medicare Usable Organs/Total Usable Organs)</b>	<b>2018 SRTR Ratio of Actual Transplants with Medicare as Payor</b>
<b>Kidney</b>	68.2%	58.9%	67.8%	58.6%
<b>Heart</b>	42.0%	31.6%	42.8%	33.0%
<b>Liver</b>	39.1%	28.4%	38.6%	29.2%
<b>Lung</b>	44.2%	43.9%	46.6%	45.7%
<b>Pancreas</b>	61.6%	49.1%	58.0%	45.8%
<b>Intestine</b>	18.1%	14.7%	14.9%	15.4%

\*Scientific Registry of Transplant Recipients. Request for Information. Requested on 01/29/2021.

<sup>55</sup> Section 373 of the Public Health Service (PHS) Act requires the operation of Scientific Registry of Transplant Recipients (SRTR) to support ongoing evaluation of the scientific and clinical status of solid organ transplantation. The U.S. Congress passed the National Organ Transplant Act (NOTA; Pub. L. 98-507) in 1984.

Data from the OPTN also show the percentage of organs transplanted in 2018, by organ type, that were paid by Medicare, including Medicare Fee-For-Service and Medicare Choice, and other non-Medicare payor categories. These data are reflected in Table 2.

**TABLE 2. OVERALL ORGAN-SPECIFIC PAYOR RATIOS INCLUDING NON-MEDICARE PAYORS', FROM OPTN 2018<sup>^</sup>**

<b>Organ Type</b>	<b>Private Insurance</b>	<b>Medicaid/CHIP</b>	<b>Medicare Choice</b>	<b>Medicare FFS</b>	<b>Other*</b>	<b>Total</b>
<b>Kidney</b>	30.2%	7.1%	14.0%	42.7%	6.0%	100.00%
<b>Liver</b>	48.2%	18.4%	10.7%	18.6%	4.2%	100.00%
<b>Pancreas</b>	9.8%	4.2%	1.1%	3.3%	81.6%**	100.00%
<b>Heart</b>	44.7%	18.2%	15.0%	17.9%	4.1%	100.00%
<b>Lung</b>	41.5%	9.3%	22.4%	23.3%	3.5%	100.00%
<b>Intestine</b>	40.4%	37.5%	7.7%	7.7%	6.7%	100.00%

<sup>^</sup> Organ Procurement and Transplantation Network. Accessed on 09/13/2021.

Note: Combination transplants (heart/lung, kidney/pancreas) are included under each affected organ type.

\*Other includes transplants covered by donations, foreign governments, free care, Veteran's Administration, other government, self-pay, or unknown.

\*\*This percentage is due to 833 kidney/pancreas transplants that were in the OPTN database with "unknown" as the payor type.

We believe that the capability exists to track the location and disposition of organs, from the time organs are excised from donors until they are transplanted into recipients. Organ tracking capability may allow THs and OPOs the ability to know the identity of all organ transplant recipients and the donor from whom the recipient's transplanted organ was excised. Knowing the identity of all organ transplant recipients, and the donor from whom the recipient's transplanted organ was excised, allows THs and OPOs the ability to also know whether a transplant recipient is a Medicare beneficiary. OPTN policy provides that OPOs use organ tracking capability<sup>56</sup>, and some THs also optionally use organ tracking capability. Per OPTN policies, THs and OPOs report information to the OPTN on the identity of transplant recipients and donors.<sup>57</sup> Additionally, the OPTN data collection forms show what data elements are currently being collected.<sup>58</sup> The Data System for Organ Procurement and Transplantation

<sup>56</sup> OPTN Policy 16, [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf)

<sup>57</sup> OPTN Policy 18, [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf)

<sup>58</sup> <https://unos.org/data/data-collection/>

Network<sup>59</sup>, (OMB form No. 0915-0157, expiration August 31, 2023), collects the recipient's and payor's information for the transplant. The identity of the recipient and the recipient's payor is required to be reported. THs, histocompatibility laboratories, and organ procurement organizations submit required information to the OPTN's organ matching system that links all 57 OPOs, 254 THs and 150 histocompatibility labs to list patients for transplant, and matches patients with available donor organs.<sup>60</sup>

By way of knowing the identity of the recipient, the providers can further discern whether a recipient is a Medicare beneficiary by contacting the recipient TH or OPO to discern such payor information. Therefore, we believe it is possible for THs and OPOs to report, on their respective MCRs, the number of organs and kidneys transplanted into Medicare beneficiaries, eliminating the reason for Medicare organ acquisition payment policy to presume that some organs and kidneys are transplanted into Medicare beneficiaries, when they are not.

We believe it is necessary to update Medicare organ acquisition payment policy to recognize organ tracking capabilities and the ability for OPOs and THs/HOPOs to discern the identity of the recipient into whom the excised organ is transplanted, and whether that recipient is a Medicare beneficiary. Doing so will result in Medicare more accurately paying its share of organ acquisition costs. We believe it is necessary to require that THs and OPOs report on their cost reports only organs and kidneys transplanted into Medicare beneficiaries as Medicare usable organs and Medicare kidneys, respectively. Doing so will also help safeguard the Medicare Trust Fund and ensure that Medicare appropriately pays only its share of organ acquisition costs, and that acquisition costs for organs not transplanted into Medicare beneficiaries are not borne by Medicare. The Medicare reasonable cost principles, upon which Medicare organ acquisition payment policy is based, and the prohibition of cross-subsidization articulated in section 1861(v) of the Act require the cost of services be borne by the appropriate payor.

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<sup>59</sup> <https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0915-0157#>

<sup>60</sup> <https://optn.transplant.hrsa.gov/members/>

While all OPOs, and some THs, use an organ tracking capability, we believe that THs that do not use an organ tracking capability can also ascertain the exact recipient, and thus recipient's payor, when an organ is excised in their hospital and furnished to another TH or OPO. We understand that some THs that do not use an organ tracking capability still track organs they furnish to other THs or OPOs by using manual, written methodologies. In this regard, THs can determine the organ recipient from their records and by verifying the insurance payor of the recipient with the transplant recipient's hospital. Additionally, THs can contact the OPO to which they furnished the organ, and because the OPTN directs OPOs to use an organ tracking system, the OPO can relay the recipient's information and recipient's payor to the TH. Likewise, Medicare contractors, who review MCRs submitted by THs and OPOs, can confirm Medicare usable organs and Medicare usable kidneys reported by THs and OPOs with supporting documentation from provider's records.

Medicare kidneys include, for cost reporting statistical purposes and counting, kidneys procured by an OPO and furnished to a MRTC for transplant, in accordance with certain longstanding arrangements that existed before March 3, 1988, approved by the contractor. However, due to organ tracking capability, and to achieve equitable treatment among all OPOs (for OPOs that do not have long-standing arrangements with military THs), and to also achieve appropriate Medicare expenditures for kidney acquisition costs, we no longer believe it is appropriate to allow such kidneys to be designated as Medicare kidneys under such arrangements. Because organ tracking capability permits OPOs the ability to know a donor's transplant recipient, and thus their payor's identity, it is no longer necessary for Medicare to continue to apply its longstanding policy to deem and count all kidneys an OPO excises at, or furnishes to, a MRTC as Medicare kidneys for purposes of apportioning Medicare's share of the kidney acquisition costs.

In the proposed rule we proposed to add § 413.408(a) to new subpart L to specify that THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on



their Medicare hospital cost reports to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare for services provided to Medicare beneficiaries. We also proposed to add § 413.408(b) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, Medicare usable organs include only organs transplanted into Medicare beneficiaries (including kidneys for MA beneficiaries with dates of service after January 1, 2021), organs for which Medicare has a secondary payer liability<sup>61</sup> for the organ transplant, and pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

We also proposed to add § 413.408(c) to new Subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, total usable organs include: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other transplant hospitals or OPOs; (4) organs obtained from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs; (5) organs furnished to veterans' hospitals or organs sent outside the United States; (6) organs transplanted into non-Medicare beneficiaries; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) organs for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; (9) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (10) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

We also proposed to remove § 413.203, and add § 413.408(d) to new subpart L, so that all organ acquisition policies are housed together, to specify that a TH's total costs for all organs are reduced by the costs associated with procuring organs that are furnished to foreign transplant

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<sup>61</sup> Medicare secondary payer is governed by section 1862(b)(2) of the Act and 42 CFR 411.20 through 411.39.

centers or transplanted in patients other than Medicare beneficiaries; and to specify that THs must separate costs for procuring organs that are furnished to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in proposed § 413.408(e).

We also proposed to add § 413.408(e) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, Medicare's share of organ acquisition costs for a TH/HOPO is calculated by multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs transplanted into Medicare beneficiaries, as specified in proposed § 413.408(b), to total usable organs, as specified in proposed § 413.408(c).

For rules pertaining to counting kidneys and calculating Medicare's share of kidney acquisition costs for IOPOs, in the proposed rule, we proposed to add § 413.410(a) to new subpart L to specify that IOPOs must accurately count and report Medicare usable kidneys and total usable kidneys on their Medicare IOPO cost reports to ensure that costs to acquire Medicare usable kidneys are accurately allocated to Medicare. We also proposed to add § 413.410(b) to new subpart L to specify that, for cost reporting periods beginning on or after October 1, 2021, for IOPOs, Medicare kidneys include only kidneys transplanted into Medicare beneficiaries.

We also proposed to add § 413.410(c) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for IOPOs, total usable kidneys include: (1) Medicare usable kidneys; (2) kidneys procured with the intention to be used for research; (3) kidneys procured and furnished to other transplant hospitals or OPOs; (4) kidneys procured from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs; (5) kidneys furnished to veterans' hospitals or organs sent outside the United States; (6) kidneys for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; and (7) kidneys furnished to United States MRTCs with or without a

contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988.

We proposed to remove § 413.202 and add § 413.410(d) to new subpart L, to specify that an IOPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys furnished to foreign transplant centers or transplanted in patients other than Medicare beneficiaries; and to specify that IOPOs must separate costs for procuring kidneys furnished to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in proposed § 413.410(e).

We also proposed to add § 413.410(e) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, Medicare's share of kidney acquisition costs is calculated by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys, as specified in proposed § 413.410(b), to total kidneys, as specified in proposed § 413.410(c).

Comment: Commenters overall were not supportive of CMS' proposals for THs and OPOs to count only organs and kidneys transplanted into Medicare beneficiaries as Medicare usable organs and Medicare usable kidneys, to calculate Medicare's share of organ acquisition costs for THs and kidney acquisition costs for OPOs. Many commenters, including children's hospitals, stated they would experience a loss of revenue. Some commenters opined that this proposal would shift costs to others within the organ acquisition and transplantation ecosystem, and have the effect of raising procurement costs, although details on specifically how or which costs would increase, or how a shift in cost would occur were not provided. A commenter suggested that the policy proposal will inappropriately transfer organ acquisition costs for some Medicare beneficiaries from Medicare to the transplant hospitals that excise organs and furnish them to other THs or OPOs.

Response: We appreciate the lifesaving contributions that THs and OPOs make within the transplant community and we understand commenters' concerns over the potential loss of revenue they may experience stemming from our proposal to limit Medicare's organ acquisition costs to costs incurred for organs actually transplanted into Medicare beneficiaries. After consideration of the public comments we received, we believe these concerns warrant further review; therefore, we are not finalizing our proposed policy with respect to counting organs for determination of Medicare's share of organ acquisition costs as proposed at §§413.408 and 413.410, but may consider this policy in future rulemaking.

Commenters did not provide substantive information or data to explain how or why they believe costs to acquire organs would increase under our proposed policy and it is not clear to us how such costs would increase absent revenue from Medicare for organ acquisition costs for organs not transplanted into Medicare beneficiaries. We do not believe that the proposed policy would inappropriately transfer organ acquisition costs for some Medicare beneficiaries from Medicare to the transplant hospitals that excise organs and furnish them to other THs or OPOs.

When a TH excises and furnishes an organ to another TH or OPO, or when an OPO furnishes an organ to a TH or another OPO, the TH or OPO furnishing the organ currently receives revenue from the recipient TH to which the organ was furnished; the recipient TH is in turn reimbursed by the transplant recipient's payor. Even when the transplant recipient is not a Medicare beneficiary, the TH that excises and furnishes the organ to the recipient TH receives an additional payment from Medicare, because the current Medicare organ counting policy allows that organ to be counted as a Medicare usable organ and assumes that the organ is transplanted into a Medicare beneficiary. (If the organ is a kidney, the OPO receives a reconciliation payment from Medicare based on the assumption that the kidney was transplanted into a Medicare beneficiary.) If a TH incurs costs to provide services to maintain a cadaveric donor after declaration of death and consent to donate is given, then the TH accumulates and enters those charges as organ acquisition costs on the TH's cost report, charges the OPO for the services

rendered, and offsets the revenue received from the OPO for the organ acquisition costs associated with organs furnished to Medicare beneficiaries. In this regard, the TH receives revenue for its costs incurred in exchange for providing the services to the cadaveric donor, either from the OPO to which the organ was furnished, or as an amount included in its acquisition costs on its cost report.

If all payors within the transplant ecosystem are paying their share of organ acquisition costs for organs acquired for transplant into their insured recipients or Medicare beneficiaries, then there should not be an increase of an amount of unreimbursed acquisition costs.

We understand commenters' views that this proposal would result in organ acquisition costs that have been historically paid by Medicare to no longer be paid by Medicare if the organs were not transplanted into Medicare beneficiaries and that THs and OPOs will need to modify their organ tracking and billing processes in order to recoup any loss of revenue they may experience. We also acknowledge commenters' pointing out that children's hospitals may experience a loss of revenue because they traditionally have very low Medicare utilization. Specifically, we acknowledge that they noted that under the proposal, children's hospitals would experience a loss of revenue because they will only be able to count organs actually transplanted into Medicare beneficiaries, which occurs rarely with pediatric organs transplanted into adults.

In response to this proposal to count only organs transplanted into Medicare beneficiaries as Medicare usable organs, we have heard stakeholders' concerns that the process of tracking organs, to report only organs transplanted into Medicare beneficiaries on the Medicare cost report, is perceived to be burdensome. We have also heard stakeholders' concerns regarding the financial impacts from the loss of revenue from Medicare stemming from this policy proposal and the value of studying impacts to patients. We are not finalizing this proposal at this time to allow more time to better understand these and other concerns that commenters have raised, including those related to organ tracking processes, as we continue our efforts to ensure

Medicare more accurately pays its share of organ acquisition costs as well as adhere to the statutory prohibition of cross-subsidization articulated in section 1861(v) of the Act.

Comment: Many commenters suggested either a withdrawal of the proposal or a delayed implementation date to allow THs additional time to re-negotiate contracts with other payors to make up for the decreased revenue they may experience stemming from the proposal. Some commenters requested that CMS delay implementation to conduct a study on the financial impact upon the transplant community as a result of the proposal. Some commenters believed that Medicare's impact estimate was underestimated and imprecise when using SRTR data reflecting organs transplanted into Medicare beneficiaries; in this regard, commenters believed the SRTR data to be underreported with recipients' payor information from transplanting THs. A commenter suggested that CMS calculate and use an "in-house" Medicare ratio for THs, as a proxy to apply to the number of organs the TH/HOPO furnishes to other hospitals or OPOs which are transplanted into Medicare beneficiaries. Other commenters requested that Medicare study and publish a hospital specific impact analysis resulting from these proposals.

Response: We thank commenters for sharing their concerns and requests for a delayed implementation of the proposed policy so that stakeholders may renegotiate their contracts with other payors, or conduct further analyses of their financial impacts. We agree that additional time may be needed for stakeholders to renegotiate their contracts and update their tracking and billing processes; therefore, we are not finalizing our policies proposed at §§413.408 and 413.410 at this time in order to further consider the public comments and financial impacts as a consequence of those proposed policies.

In response to comments about the impact analysis included in the proposed rule, we note that our impact estimate in the proposed rule was projected as a savings to the Medicare Program and was based on data collected by the OPTN and reported by the SRTR that categorizes transplant recipients by payor. THs and OPOs are required to submit information to the OPTN that are used to match donors and recipients, including the recipient's primary payor information

at the time of the recipient's registration. The OPTN requires the organ recipient's payor information be updated by the transplanting hospital at the time of transplant. The SRTR derives its data from the OPTN database and we believe that these data were the best available data and a reasonable proxy for Medicare's share of organ acquisition costs for organs a TH excises and furnishes to other THs or OPOs. (See the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25665).) We also acknowledge commenters' suggestions that we could estimate the percent of organs a TH furnishes to other THs or OPOs that are transplanted into Medicare beneficiaries, by using a TH's data to calculate an in-house ratio of organs transplanted into Medicare beneficiaries within the TH's own hospital, and by applying that in-house Medicare ratio, as a proxy, to the organs a transplant hospital furnishes to other THs or OPOs.

In response to commenters' requests that CMS conduct additional analyses, we will conduct additional analyses of impacts upon THs, children's hospitals, and OPOs before we consider revising this policy in future rulemaking on counting organs as proposed at §§413.408 and 413.410.

Comment: Some commenters stated that Medicare's current organ acquisition payment policy was intentionally devised decades ago to ensure that Medicare provided an incentive to hospitals to participate in organ transplantation. A few commenters provided copies of a 1995 letter authored by CMS personnel that explained cost reporting instructions and audit adjustments for recording organs procured by hospitals and HOPOs, (and kidneys procured by OPOs), that were furnished to other hospitals and OPOs as Medicare usable organs and Medicare usable kidneys. Commenters opined that the methodologies discussed in the 1995 letter were an incentive for hospitals and OPOs to procure organs.

Response: We appreciate commenters bringing to our attention a 1995 letter authored by CMS personnel, however, we believe this letter explains the Medicare usable organ and Medicare usable kidney acquisition policies as they existed when the letter was authored. The 1995 letter explains that a TH or OPO that excises kidneys and furnishes them to other THs and

OPOs do not have control over the disposition of the kidneys, and do not know whether these kidneys are actually transplanted, and if they are transplanted, whether they are transplanted into Medicare beneficiaries. We understand that commenters may perceive the policies outlined in the 1995 letter as providing a financial incentive for OPOs and THs to excise and furnish organs to other THs and OPOs. This was not the intention. Medicare has allowed THs and OPOs to count all organs and kidneys excised and furnished to other THs and OPOs as Medicare usable organs or Medicare usable kidneys and required the offset of revenue; however, when revenue did not reflect the actual costs incurred, Medicare likely paid for more than its share. As we discussed in the preamble to the proposed rule, capability now exists to track the location and disposition of organs, from the time organs are excised from donors until they are transplanted into recipients. As such, we no longer believe the methodology outlined in the 1995 letter aligns with Medicare's anti-cross subsidization principles, as well as reasonable cost principles upon which Medicare's organ acquisition cost reimbursement policies are based. As stewards of the Medicare Trust Fund, it is important to establish and maintain policies that align with Medicare's anti-cross subsidization principles to ensure that Medicare pays for costs incurred for the care of Medicare beneficiaries. Other payors that may be responsible for organ acquisition costs for organs transplanted into their patients must likewise bear the cost of organ acquisition costs for their patients. Although we no longer believe the methodology outlined in the 1995 letter aligns with Medicare's anti-cross subsidization principles, or reasonable cost principles upon which Medicare's organ acquisition cost reimbursement policies are based, we understand stakeholders' concerns regarding loss of revenue and the perceived burdens to implement this proposal warrant further consideration and thus we are not finalizing the organ counting proposal. We may revisit this proposal in future rulemaking.

Comment: Many commenters expressed appreciation for the clarification and codification of organ acquisition payment policies and CMS's goal to make more precise payments for organ acquisition costs from the Medicare Trust Fund. A commenter who



supported the proposal stated that the current Medicare usable organ counting policy was adopted 35 years ago when most organ donors were trauma patients at a transplant center but stated today less than a third of donors are trauma patients. It seems the commenter was suggesting that organs are procured from trauma patients at a transplant center less frequently today and more organs are being procured from other hospitals or by OPOs and sent to THs or OPOs for transplant elsewhere.

Response: We appreciate commenters' support of our intention to clarify and codify organ acquisition payment policies and our goal to make more precise payments for organ acquisition costs from the Medicare Trust Fund. We agree that over the past 35 years, the transplant ecosystem and circumstances have changed, such that more organs today are excised at one location and transported elsewhere for transplant.

Comment: Many commenters expressed concern with THs and OPOs having to track organs and report on the Medicare cost report only organs transplanted into Medicare beneficiaries, as Medicare usable organs. Some commenters stated that their administrative costs would increase under the proposed policy. Some commenters suggested that CMS develop a centralized organ tracking system and other commenters suggested that the OPTN allow all THs and OPOs access to a centralized database with updated recipients' payor information. Some commenters stated that THs were not required to update OPTN data with recipients' payor information at the time of transplant, resulting in outdated OPTN payor data for transplant recipients and likely underreporting Medicare as a payor. Some commenters opined that a TH that excised and furnished organs to other THs or OPOs would be unable to have access to organ recipients' payor data in the OPTN database. Other commenters suggested that the OPTN require THs to update their OPTN data with their transplant recipients' payor information at the time of transplant to avoid having outdated payor information if a recipient's payor status changed at the time of transplant. Some commenters opined that a TH that excises and furnishes organs to other THs or OPOs would be unable to have access to organ recipients' payor data in

the OPTN database. Some commenters stated that a recipient's insurance information is entered into the OPTN database when the recipient is first placed on a waiting list for an organ, but the recipient's insurance status may change over time and not be updated in the OPTN database, remaining the same as when the recipient was first placed on the waiting list. A commenter suggested that the Medicare contractor provide verification as to whether a Medicare usable organ recorded on the cost report was actually transplanted into a beneficiary. Another commenter suggested that the Medicare contractor routinely provide beneficiary insurance status to the OPOs, instead of the OPOs contacting the transplant center to which they furnished the organ to discern whether the organ recipient was a Medicare beneficiary.

Response: We appreciate commenters' concerns regarding the burden in implementing this policy and accordingly have decided not to issue a final rule on counting of organs as proposed at §§413.408 and 413.410 at this time.

Although we are not finalizing our proposals at §§413.408 and 413.410, we are aware that OPOs have access to the OPTN database and to the identity of the recipients of each organ procured by that OPO. We also understand that all THs know the correct up-to-date primary payor of each of their transplant recipients (and the Medicare beneficiary status) at the time of transplant as this information is necessary for the TH to accurately submit its claim for reimbursement for the procedure. We note that OPOs, donor hospitals, and THs rely on a close collaborative relationship involving information sharing to ensure that organs are successfully procured and appropriately placed with transplant recipients. Many OPO commenters acknowledged that they are in contact with recipient transplant hospitals to which the organ was furnished. We believe that during these communications, collaborations and encounters, when OPOs and THs coordinate the organ acquisition and transportation between the OPO and the TH, the OPO could reasonably determine whether the organ recipient is a Medicare beneficiary.

OPTN rules require that THs update their OPTN data with their transplant recipients' payor information at the time of hospital discharge but no later than six weeks after the

recipient's transplant. Under 42 CFR 121.11(b)(2), OPOs and THs are required to submit to the OPTN, and the Scientific Registry, as appropriate, and to the Secretary information regarding transplant candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Additionally, the OPTN Policy 18 sets forth data submission requirements regarding transplant recipients that THs must submit, with accuracy, to the OPTN following the organ transplant. The Data System for Organ Procurement and Transplantation Network<sup>62</sup>, (OMB 0915-0157, expiration August 31, 2023), collects information on recipients and recipients' payors for the organ transplant. The OPTN data collection system contains data entry fields to capture a recipient's primary payor information. We understand that an OPO or TH that excises and furnish organs to a recipient TH or OPO, may not have access to the OPTN data for the organ recipient in order to determine the primary payor and realize that more work may be needed to ensure that the excising TH or OPO have access to this OPTN data in the future to discern the organ recipient's payor identity.

We do not believe it is the role of the Medicare contractors to provide verification or payor information for a TH or OPO to discern whether an organ may be considered a Medicare usable organ and recorded as such on the Medicare cost report. A framework to discern a recipient's payor status already exists within the OPTN database. We note that 42 CFR 413.20 sets forth requirements that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare Program and must furnish such information to the contractor as necessary to assure proper payment from Medicare.

We acknowledge the concerns raised by commenters warrant further consideration and thus we are not finalizing the organ counting proposal and may revisit this proposal in future rulemaking.

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<sup>62</sup> <https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0915-0157#>

Comment: A commenter indicated that the proposal was contrary to 42 CFR 412.113(d), which sets forth that payment for organ acquisition costs incurred by hospitals with approved transplant centers are made on a reasonable cost basis.

Response: We do not believe our proposals are contrary to § 412.113(d), which describes other payments made to hospitals under the prospective payment systems, and sets forth that payment for organ acquisition costs incurred by hospitals with approved transplant centers are made on a reasonable cost basis. Under the proposal, costs incurred by hospitals with approved transplant centers will continue to be paid by Medicare on a reasonable cost basis for the acquisition of organs transplanted into Medicare beneficiaries.

Comment: A commenter requested that CMS make a policy declaration with respect to revenue offsets under this proposal for organs that a TH/HOPO excises and furnishes to other THs or OPOs, or kidneys that an IOPO furnishes to THs or other OPOs, that would not be counted as Medicare usable organs. This commenter pointed out that there would be an underpayment of the organ acquisition costs attributable to Medicare beneficiaries if a revenue offset were required for organs that are not transplanted into Medicare beneficiaries. Under the current policy, because organs that a TH/HOPO excises and furnishes to other THs or OPOs are deemed or assumed to be Medicare usable organs, the revenue the excising TH/HOPO or OPO receives from the OPO or TH to which the organ is furnished must be offset from the excising TH/HOPO's organ acquisition costs. However, if an organ is not a Medicare usable organ, the revenue the excising TH/HOPO or IOPO receives must not be offset or deducted from the excising TH/HOPO's or the IOPO's organ acquisition costs.

Response: We agree with the commenter's concerns regarding revenue offsets that are not required for organs that are not transplanted into Medicare beneficiaries. Current Medicare hospital and IOPO cost reporting instructions require a TH that excises and furnishes, or an IOPO that furnishes, organs to other OPOs or THs, to offset or reduce its organ acquisition costs by the amount of revenue received from the TH or OPO, to which the organ was furnished when

the organ is a Medicare usable organ.<sup>63</sup> Although we are not finalizing the organ counting policies as proposed in §§413.408 and 413.410, Medicare still requires these revenue offsets in the Medicare cost report. Doing so will accurately account for the organ acquisition costs attributable to Medicare.

Comment: Some commenters stated that the proposed policy presented privacy or Health Insurance Portability and Accountability Act of 1996 (HIPAA) concerns with THs and OPOs disclosing or receiving the payor status of an organ recipient.

Response: Although we are not finalizing our proposed rule at §§413.408 and 413.410 at this time, we do not believe there should be uncertainties regarding information sharing, privacy, or HIPAA concerns, especially considering the numerous consent forms patients sign as a matter of course for medical treatment. The HIPAA Privacy Rule permits disclosure of information, without an individual's authorization, for payment related operations. Medicare is seeking to make more accurate payments for organ acquisition costs by proposing to pay acquisition costs for organs that are actually transplanted into Medicare beneficiaries. We believe that a patient's disclosure of their payor information is consistent with Medicare's payment goals and is the minimum necessary information required to ensure accurate payment from Medicare. We believe that disclosure that an organ recipient is a Medicare beneficiary is permissible under the HIPAA Rule. Additionally, patient consent forms should allow for OPOs or THs to discern whether a recipient was a Medicare beneficiary without invoking HIPAA Privacy Rule violations because the patient has provided consent for such disclosure. Under regulations at 45 CFR 164.501 that set forth the privacy of individually identifiable health information, the definition of payment means activities undertaken by a health care provider to obtain or provide reimbursement for the provision of health care. Thus, the disclosure of the organ recipient's payor status falls within this scope of payment, such that there would be no HIPAA Privacy Rule

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<sup>63</sup> For Medicare hospital cost reports, see CMS Pub. 15-2, chapter 40, section 4028.3. For IOPO cost reports, see CMS Pub. 15-2, chapter 33, sections 3309 and 3311.

violations for a TH or OPO to disclose a recipient's payor information to another TH or OPO. We believe that any information sharing, privacy or HIPAA regulatory concerns can be abated with amendments to existing financial consent forms, if necessary, whereby organ transplant recipients can consent to have their health insurance payor information released.

Comment: Some commenters questioned how they could determine whether Medicare has a secondary payer liability to count an organ as a Medicare usable organ. Several commenters disagreed with the proposal they perceived as requiring a TH that excises and furnishes organs to another TH or OPO to count those organs as Medicare usable organs when Medicare has a secondary payer liability.

Response: We appreciate commenters' concerns. Although we are not finalizing the organ counting proposals in proposed §§413.408 and 413.410 in this final rule with comment period, we wish to clarify for commenters that our proposals to codify, at §413.414, our longstanding manual provisions with respect to organ acquisition costs and counting organs when Medicare is a secondary payer pertains only to a TH that performs the transplant. In this regard, a TH that excises and furnishes an organ to another TH or OPO does not have a possibility of a secondary payer payment from Medicare because the excising TH did not perform the transplant and receive the DRG payment. Thus, the transplanting TH, not the excising TH that furnishes organs to others, needs to compare the total cost of the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer to determine if there is a secondary payer liability from Medicare for the transplanting TH's organ acquisition costs. The Medicare secondary payer provisions with respect to how the TH would determine whether Medicare has secondary payer liability for organ acquisition costs are discussed in II.C.2.j. of this final rule with comment period.

Comment: A commenter suggested that the proposals could lead to more widespread use of organ recovery centers. Stakeholder sentiment is that the current policy has served as a disincentive to transport deceased donors from THs to organ recovery centers. This is because a

TH cannot include on its Medicare cost report organs excised at an ORC from a cadaveric donor that was transported from the TH to the ORC for removal of the organs in the ORC. A commenter misconstrued the proposal as permitting THs to count as Medicare usable organs, those organs transplanted into Medicare beneficiaries that had been recovered in an OPO's organ recovery center from a cadaveric donor that had been transported from the TH to the OPO's organ recovery center. A commenter requested that CMS finalize a policy that allows THs to include as Medicare usable organs, any organs recovered in an OPO's organ recovery center from cadaveric donors that were transported from the TH to the organ recovery center.

Response: We appreciate commenters' concerns. However, an OPO's operation of an organ recovery center is outside of the scope of our proposals.

Comment: Some commenters suggested that the proposal to count only organs transplanted into Medicare beneficiaries as Medicare usable organs will increase wait times, waitlist mortality and morbidity for ESRD-eligible Medicare beneficiaries. Many commenters opined that the proposal would decrease organ supply and limit the number of organs that can be procured or procured "in a financially sustainable" manner.

Response: We appreciate commenters' concerns. Although we are not finalizing the organ counting proposal at this time and may further consider in future rulemaking, our proposal was intended to ensure that Medicare pays its share of organ acquisition costs for organs procured and transplanted into Medicare beneficiaries, protect the Medicare Trust Fund, and not impede organ supply or transplantation. Commenters did not provide specific details to support their assertion that these policy proposals would increase wait times, waitlist mortality and morbidity for ESRD-eligible Medicare beneficiaries and decrease organ supply. However, we interpret the comments to mean that THs and OPOs may be less likely to procure organs as a result of any decrease in revenue they may experience from the proposal to count as Medicare usable organs only organs transplanted into Medicare beneficiaries, even when organs are furnished to transplant recipients for whom financial responsibility rests with other payors. We

note that OPOs have existing statutory duties, under 42 U.S.C 273, to conduct and participate in systematic efforts to acquire all useable organs from potential donors. OPOs also must meet the CfCs under 42 CFR 486.344 that require them to have written protocols for donor evaluation and management and organ placement and recovery that must meet current standards of practice and that are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

On December 2, 2020, CMS published a final rule that finalized two new outcome measures for OPOs, the organ donation rate and transplantation rate measures, with the goal of increasing the supply of organs available for transplants (85 FR 77898). We believe that these outcome measures will incentivize OPOs to recover more organs that will ultimately be available for transplantation. However, if an OPO's performance on the outcome measures does not improve sufficiently, CMS will open the designated service area (DSA) and allow other high performing OPOs to compete for the open DSA.

We also note that pursuant to the finalized SAC policy at §413.404, THs establish SACs by organ type prior to their first transplant.<sup>64</sup> If the TH believes their SACs are insufficient, they have the ability to increase their SACs<sup>65</sup> or negotiate with other payors to avoid cost reimbursement disparities.

Comment: A few commenters opined that our proposal was “to only reimburse kidney transplants for MA patients starting January 1, 2021” and opined that CMS proposed retroactive policy provisions at proposed §§ 413.408(b)(1) and (c)(8) and 413.410(b) and (c)(6) without explanation. The commenters seemed to question why only kidneys, and not all organs, transplanted into MA beneficiaries were included in the calculation of Medicare's share of organ acquisition costs for THs and OPOs.

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<sup>64</sup> See 413.404(b)(3)(i)(C)(1) and 413.404(b)(3)(ii)(B)(1).

<sup>65</sup> See 413.404(b)(3)(i)(C)(2) and 413.404(b)(3)(ii)(B)(2).



Response: Although we are not finalizing our proposed rule at §§413.408 and 413.410 at this time, we wish to clarify that we did not propose in a retroactive manner, to include kidneys transplanted into MA beneficiaries as Medicare usable kidneys for purposes of calculating Medicare's share of kidney acquisition costs. In the preamble to the proposed rule, we proposed to codify, (at proposed §§ 413.408(b)(1) and (c)(8) and 413.410(b) and (c)(6)), the statutory provision that requires Medicare to pay for kidney acquisition costs for MA beneficiaries on a reasonable cost basis for dates of service starting on January 1, 2021.<sup>66</sup>

The provisions of the 21<sup>st</sup> Century Cures Act, passed in 2016 (Pub. L. 114-255), changed Medicare's reimbursement methodology for the acquisition costs of kidneys transplanted into MA beneficiaries. In the preamble to the FY 2022 IPPS/LTCH PPS proposed rule, we explained in a footnote the genesis for this statutory provision (see 86 FR 25664). Section 17006(c) of Pub. L. 114-255 amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. As such, effective January 1, 2021, in accordance with the statutory provisions these costs are covered under the original Medicare FFS program and paid on a reasonable cost basis. (For more information, see the June 2, 2020 final rule (85 FR 33824). Kidneys procured for MA beneficiaries are included as Medicare usable kidneys, and are included in the numerator and denominator on the MCR to determine Medicare's share of kidney acquisition costs, despite our not finalizing §§413.408 or 413.410 at this time. Procurement costs for non-renal organs and transplants continue to follow existing reimbursement methodologies through MA for MA beneficiaries.

Comment: A commenter suggested that proposed § 413.408(d) may lead to doubling the estimated non-Medicare organ and kidney acquisition costs because the proposed regulation at § 413.408(d) proposes to reduce the costs associated with procuring organs furnished to foreign transplant centers or costs associated with transplanting organs in patients other than Medicare

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<sup>66</sup> See 86 FR 25664, and 25702, and 25703.

beneficiaries, and the Medicare ratio that is applied to total costs already removes these non-Medicare costs. The commenters suggested removing proposed § 413.408(d), as it appears to be unnecessary since the calculation of Medicare allowable costs is achieved through proposed § 413.408(b), (c), and (e).

Response: We appreciate commenters' concerns and note this comment also applies to proposed § 413.410(d) pertaining to Medicare's share of kidney acquisition costs. We are not finalizing the proposed counting policy in §§ 413.408 and 413.410, we may further consider this issue as we consider additional rulemaking.

i. Provisions Related to Intent to Transplant, and Counting En Bloc, Research, and Discarded Organs

In the FY 2022 IPP/LTCH PPS proposed rule, we set forth our policy, pertaining to intent to transplant, counting en bloc organs, research organs, and discarded organs for THs and OPOs (86 FR 25667 through 25668). These policies provide for the proper calculation of Medicare's share of organ acquisition costs that are used for the appropriate allocation of organ acquisition costs on the MCR. The calculation of Medicare's share of organ acquisition costs is discussed in section II.C.2.h.(1). of this final rule with comment period. The methodology of counting organs to calculate Medicare's share of organ acquisition costs is used for the allocation of organ acquisition costs on the MCR and differs from Medicare's organ counting policy to assess OPOs' performance, which is set forth under the OPO CfCs, 42 CFR part 486, subpart G. To calculate Medicare's share of organ acquisition costs, when organ procurement is attempted, but no organ is actually retrieved (or the organ is instead discarded), proper counting of the organ must occur to ensure that overhead costs are appropriately allocated to Medicare and non-

Medicare payors. However, cost allocation is not a factor when counting organs for evaluating an OPO's performance under the CfCs.

(1) Principle of Intent to Transplant

Medicare presumes that THs and OPOs intend to procure all donor organs that are medically suitable for transplant.<sup>67</sup> We proposed to add § 413.412(a)(1) to new subpart L, to specify, for organ acquisition payment purposes, an organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s). Regardless of whether the OPO or TH procures organs for transplant, it incurred cost in attempting to procure organs.<sup>68</sup> We proposed to add § 413.412(a)(2) to new subpart L, to specify, OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type.

Comment: A commenter appreciated CMS clarifying and codifying long-standing CMS policy regarding intent to transplant, counting en bloc, research and discarded organs because it will help ensure more accurate reporting of total usable organs, Medicare usable organs, and organ statistics on the MCR.

Response: We appreciate the commenter's support for our clarifications of the policy regarding intent to transplant, counting en bloc, research and discarded organs. For additional clarity, we also note that an OPO or TH can demonstrate that it did not intend to procure a particular organ, if an instance such as one of the following occurs: the donor does not meet the criteria for eligible death as specified by the OPTN; the organ has been eliminated for eligibility because of donor information; the organ has been ruled out by laboratory data prior to the donor entering the operating room for excision of organs; the family does not provide consent to donate

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<sup>67</sup> 86 FR 25668.

<sup>68</sup> 86 FR 25668.

the organ or the donor is not a registered organ donor; or the search for a recipient for that particular organ has ended unsuccessfully prior to the donor's entrance into the operating room.

After consideration of the public comments we received, we are finalizing our proposals regarding intent to transplant under § 413.412(a).

## (2) Counting and Cost Allocation of En Bloc Organs

In the proposed rule, we set forth our policy for counting en bloc organs for cost allocation purposes (86 FR 25668). We proposed to add § 413.412(b) to new subpart L, to specify our policy for counting en bloc organs for Medicare cost allocation purposes and to specify that en bloc organs can be en bloc lungs or en bloc kidneys.

We proposed to add § 413.412(b)(1) to new subpart L to specify that OPOs and THs count en bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

We proposed to add § 413.412(b)(2) to new subpart L to specify that OPOs and THs count en bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

Comment: A commenter suggested CMS' proposals relative to counting en bloc organs does not take into consideration added costs of procuring and transplanting multiple organs. This commenter perceived our proposal to codify our longstanding policy for counting en bloc organs procured for transplant as a change in policy. The commenter further indicated that this policy will reduce Medicare reimbursement and is inconsistent with Congressional intent to ensure Medicare payment policies expand access to transplantation-related services.

Response: We did not propose changes to Medicare's policy for counting en bloc organs for organ acquisition payment purposes. Our proposals are intended to codify our longstanding policy for counting en bloc organs procured for transplant as was previously set forth in manual

provisions. In this regard, we did not propose changes that would change or affect how Medicare's share of costs is calculated to acquire en bloc organs for transplant. Our intent is to ensure that Medicare pays only its fair share of en bloc organ acquisition costs.

After consideration of the public comments we received, we are finalizing our proposals regarding counting of en bloc organs under § 413.412(b), with modification to remove the references to § 413.408(b) and § 413.410(b) because those provisions are not being finalized.

### (3) Research Organs

In the proposed rule, we set forth our policy regarding counting of organs excised and used for research for Medicare cost allocation purposes (86 FR 25668). We proposed to clarify that for organ acquisition cost allocation purposes, a "research organ" is an organ procured and used for research regardless of whether it is transplanted as part of clinical care (with the exception of pancreata previously discussed in section II.C.2.h.(2). of this final rule with comment period). We proposed to add § 413.412(c) to new subpart L to specify that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata previously discussed in section II.C.2.h.(2). of this final rule with comment period). We also proposed to clarify that Medicare shares in the costs of organs that are designated for transplant prior to the time the donor entered the hospital's operating room, but subsequently determined to be unusable and donated to research. The costs incurred are allocated among all remaining usable organs.

We proposed to add § 413.412(c)(1)(i) to new subpart L to specify that OPOs and THs do not count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organs. We proposed to add § 413.412(c)(1)(ii) to specify that OPOs and THs count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs, as total usable organs.

We proposed to add § 413.412(c)(2) to new subpart L to specify that OPOs and THs do not count organs designated for transplant prior to the time the donor entered the hospital's operating room for surgical removal of the organs but subsequently determined to be unusable and donated to research, as Medicare usable organs or total usable organs.

Comment: Overall, commenters disagreed with CMS' proposal relative to counting organs intended for research (excluding certain pancreata procured to acquire pancreatic islet cells for transplantation under proposed § 413.408) and suggested our proposal reflects a change in CMS' current policy. Several of these commenters requested we exclude organs designated for research from the count of total usable organs for the purpose of allocating costs.

A few commenters noted that the instructions in the IOPO MCR manual would need to be updated if our proposal was finalized because currently IOPOs are instructed to exclude organs intended for research from total organs and offset the revenue received from these organs against allowable cost. A commenter suggested that including organs intended for research in total usable organs results in a duplicative removal of costs for these organs because of the current MCR instructions. This commenter questioned whether CMS intended to include research organs in the allocation of all organ costs (hospital related organ procurement costs, organ acquisition overhead costs, and Medicare's share of total organ costs); and suggested the proposed rule would lower the costs reimbursed by Medicare, resulting in higher acquisition fees for research organs.

Several commenters requested clarification on the application of our proposed policy relative to organs intended for research. One such commenter requested examples of factual scenarios, similar to those CMS provided in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25669 through 25673) for accounting of kidney paired donation.

Response: We acknowledge commenters' concerns with our proposal for counting organs including research organs. Our proposal was intended to clarify the current policy for counting research organs to ensure that Medicare pays its fair share of organ acquisition costs

and does not fund non-reimbursable activities such as research. Under 42 CFR 413.90(a), costs incurred for research purposes, over and above usual patient care, are not includable as Medicare allowable costs.

After consideration of the public comments received, we are not finalizing our proposed policy with respect to counting research organs in total usable organs, as proposed under § 413.412(c)(1) and (2), and may consider it in future rulemaking. However, we are finalizing at § 413.412(c) that the only research organs that may be included as Medicare usable organs are pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Comment: Many commenters disagreed with the impact our proposal would have on Medicare's share of organ acquisition costs. These commenters indicated under the current policy Medicare covers certain donor-related costs such as testing, hospitalization, or operating room costs. These commenters claimed CMS's proposal would shift donor-related expenses and organ acquisition costs to research organizations and would negatively impact the affordability and availability of research organs and the advancement of clinical research. Several commenters also suggested our proposed policy stands at direct odds with the Biden Administration's commitment to advance clinical research.

Several commenters requested CMS not finalize the policy because of the financial impact and the impact on the availability of organs for research. Commenters suggested an impact analysis is needed on the potential negative effects of the proposed changes. A few commenters requested we delay the implementation of this proposal by one year, so as not to hinder medical research and to allow OPOs time to reappportion this significant shift in acquisition costs for research organs and medical research institutions to attempt to redirect financial resources to cover this additional cost.

Response: We acknowledge the commenters' concerns. Our proposals were not intended to impact the affordability and availability of organs used for research. However, we recognize that our proposals may impact the cost researchers and other institutions face for research organs, and may require them to pursue other methods of funding. In accordance with 42 CFR 413.90(b)(1), funds for research activities are provided under many Federal programs and by other tax supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research.

We appreciate the commenters' concerns that our proposals relative to counting organs intended for research for cost allocation purposes may impede the continuation of research or clinical advancement. CMS supports efforts to advance clinical research and understands that providing organs for research supports researchers in discovering new treatments. We note that OPOs are required to conduct and participate in systemic efforts, including professional education, to acquire all usable organs from potential donors. (42 U.S.C. § 273(b)(3)(B)). CMS's recent regulatory amendments for OPOs is aimed at increasing organ supply and transplantations.

We acknowledge the commenters' requests not to finalize the policy because of the financial impact and the impact on the availability of organs for research. We also acknowledge commenters' requests that we delay the implementation of this proposal by one-year and allow OPOs time to redirect financial resources to cover the costs associated with research organs.

After consideration of the public comments received, we are not finalizing our proposed policy at § 413.412(c)(1) and (2) with respect to THs or OPOs counting organs used for research, as Medicare usable organs or total usable organs, depending upon whether the organs were originally designated for research or designated for transplant. Additionally, as discussed in section II.C.2.h. of this final rule with comment period, we are not finalizing our proposal at § 413.408(c)(2) to require TH/HOPOs to include organs excised with the intention to be used for



research in total usable organs. We are also not finalizing our proposal at § 413.410(c)(2) to require OPOs to include organs excised with the intention to be used for research in total usable organs. We may consider these issues further as we consider future rulemaking.

In this final rule with comment period, we are finalizing our proposal under § 413.412(c) to require that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)) and kidneys used for research are not counted as Medicare usable kidneys in Medicare's share of kidney acquisition costs.

Comment: A commenter questioned whether the collection for umbilical cords (currently, not classified as human organs) for research is impacted by our proposal.

Response: Our proposal was specific to organs defined in § 413.400 of this final rule with comment period, which does not include umbilical cords. Accordingly, this comment is outside of the scope of this rule.

Comment: A commenter requested CMS clarify that organs intended for research will not count towards its denominator in the donation rate and transplantation rate measures. This commenter requested CMS explain how OPOs would know whether patients that are participating in the "two kidney trials" would continue to be reimbursed by Medicare.

Response: Comments on donation and transplantation rate measures relate to CfCs and are outside of the scope of this rule. Our proposals, which we are not finalizing, were related to counting organs to determine Medicare's share of organ acquisition costs and differ from counting organs for evaluating an OPO's performance under the outcome measures at § 486.318. We are unclear to which "two kidney trials" the commenter is referring. Currently, as required under section 733 of the MMA, Medicare pays for the cost to acquire pancreatic islet cells for transplantation into Medicare beneficiaries participating in a NIDDK clinical trial.

(4) Counting and Cost Allocation of Discarded/Unusable Organs

In the proposed rule, we set forth our policy regarding counting of discarded/unusable organs for Medicare cost allocation purposes (86 FR 25668). In the proposed rule, we proposed to add § 413.412(d) to new subpart L, to specify that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded. This includes organs that are determined to be unusable and subsequently donated to research as previously described in section II.C.2.i.(3). of this final rule with comment period.

Comment: A commenter suggested that the proposed policy requires unrecovered organs be counted in the denominator of the Medicare fraction, which results in allocation of all related costs to non-Medicare payors; however, organs that are recovered but determined to be unusable or discarded are excluded from the denominator. This commenter suggested that both unrecovered organs, and unusable or discarded organs should be excluded from the denominator of the Medicare fraction and the costs should be treated as overhead costs of the Program and allocated pro rata between Medicare and other payors. Another commenter requested we count organs intended for transplant at the time of entry into the operating room and subsequently determined to be unusable and donated for research as Medicare usable organs. A commenter also questioned whether allowable costs for obtaining organs that are discarded without being used for research will be paid or if such costs can be included in our MCR or SAC calculations.

Response: We thank the commenters for their comments and appreciate their recommendations. We are clarifying our longstanding policy that organs determined to be unusable or discarded are not included in the count of Medicare usable or total usable organs. The cost of unrecovered organs, and unusable or discarded organs must be included in the appropriate organ cost center on the Medicare cost report. In addition, the costs associated with unusable or discarded organs are equitably allocated amongst the remaining usable organs and included in the SAC calculation set forth in § 413.404.

In light of the numerous comments received surrounding the treatment of research organs, we are finalizing our proposal under § 413.412(d) with modification to require that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded and removing the language relative to organs that are determined to be unusable and subsequently donated to research. We may consider addressing organs subsequently donated to research in future rulemaking.

Comment: A commenter suggested that the proposed changes to the calculation of Medicare's share of organ acquisition costs discourages the procurement of marginal organs that may end up being unusable organs.

Response: We disagree with the commenter. Our longstanding policy requires THs and OPOs to exclude unusable organs or organs procured and subsequently determined unusable from the numerator and the denominator of the Medicare share calculation. Excluding these organs from the count allows the costs to be included and spread out amongst all the remaining transplantable organs and shared by all payors. We acknowledge that this policy was not clear in the treatment of organs determined unusable and subsequently donated to research; however, our proposal was to treat these organs the same way we treat unusable organs. We received numerous comments on the treatment of research organs in general, and on the counting of research organs and; therefore, decided not to finalize this portion of our proposal. As such, we are finalizing our proposal under § 413.412(d) with modification to remove the language relative to organs that are determined to be unusable and subsequently donated to research. We may consider addressing organs subsequently donated to research in future rulemaking.

Comment: A commenter noted IOPOs have always been required to report organs intended for research or transplant but discarded on the appropriate MCR worksheets for cost

allocation purposes. This commenter requested we revise the IOPO cost report (CMS-216) accordingly.

Response: We acknowledge the commenter's request; however, because we are not finalizing our policy as proposed, we are not revising the Medicare cost report, (CMS-216) as the commenter suggested. We are finalizing our proposal under § 413.412(d) with modification to require that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded, and removed the language relative to organs that are determined to be unusable and subsequently donated to research. We may consider addressing organs subsequently donated to research in future rulemaking.

#### j. Provisions Related to Medicare as Secondary Payer - Organ Acquisition Costs and Medicare Organ Count

If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer in certain instances. Medicare prohibits secondary payment if the provider is either obligated to accept, or voluntarily accepts, as payment in full, a primary payment that is less than its charges. See 42 CFR 411.32(b). When a provider or supplier is obligated to accept as full payment an amount less than its charges, Medicare considers that lower amount to be the provider's charges. (For more information see the October 11, 1989, final rule (54 FR 41728)). In this final rule, we are codifying into the regulations the organ acquisition cost reimbursement policy with regard to Medicare secondary payer policy.

To determine whether the provider is contractually obligated to accept the primary insurer's payment as payment in full, and thus whether Medicare has zero liability as a secondary payer, it is necessary to review the provider or supplier's agreement with the primary insurer. If

the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not counted as a Medicare usable organ.

When the primary insurer's agreement does not require the provider to accept the payment from the primary insurer as payment in full and the payment the provider receives from the primary insurer for the transplant and the organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability for the organ acquisition costs. To determine whether Medicare has a secondary payer liability, it is necessary for the provider to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer. The provider's Medicare remittance advice may or may not show that Medicare has a liability because the remittance advice only reflects the transplant portion of the payment. Thus, the provider will need to compare the total Medicare cost (the transplant DRG and the organ acquisition costs) to the payment from the primary payer to determine whether Medicare has a liability for the organ acquisition costs. If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the organ must not be counted as a Medicare usable organ. If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and the organ is counted as a Medicare usable organ. In this circumstance, the payment from the primary payer is pro-rated between the transplant DRG payment and the organ acquisition payment. If the organ is counted as Medicare usable, the organ acquisition portion of the primary payment must be included on the appropriate line as a revenue offset on the TH's MCR (currently Form CMS-2552). This is consistent with the cost reporting instructions in CMS Pub. 15-2, (PRM-2) chapter 40, section 4028.

Consider the following example as an illustration of Medicare's payment of organ acquisition costs as a secondary payer. A TH transplants a patient that has private health insurance and Medicare. The private health insurance is primary and Medicare is secondary. The private health insurance pays the TH \$70,000 for the transplant and the organ acquisition costs; there is no requirement in the primary insurer's agreement with the provider for the TH to accept this payment as payment in full. If Medicare was the primary payer, the combined payment to the TH would have been \$100,000 (\$60,000 for the transplant and \$40,000 for the organ acquisition costs). The TH compares the primary payer payment to the total amount Medicare would have paid if it had been primary (the transplant DRG and organ acquisition costs). The TH prorates the primary payer's payment of \$70,000 between a portion of the transplant DRG and a portion of the organ acquisition costs. The TH determines the primary payer amount for the transplant DRG payment is \$42,000 ( $\$70,000 \text{ payment from the primary payer} \times [\$60,000 \text{ for the transplant portion from Medicare} / \$100,000 \text{ combined Medicare payment}]$ ) and for organ acquisition costs is \$28,000 ( $\$70,000 \text{ payment from the primary payer} \times [\$40,000 \text{ for the organ acquisition portion from Medicare} / \$100,000 \text{ combined Medicare payment}]$ ). The TH counts the organ as a Medicare usable organ on its MCR and offsets the primary payment amount (\$28,000) as revenue received, thereby reducing Medicare's liability.

In the proposed rule, we proposed to add § 413.414(a) to new subpart L to set forth the general principle that if a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer in certain instances. To determine whether Medicare has liability as a secondary payer for organ acquisition costs, it is necessary to review the TH's agreement with the primary insurer. In the proposed rule, we also proposed to add § 413.414(b) to new subpart L to set forth the circumstances when Medicare has no secondary payer liability for organ acquisition costs. If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment

in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ. We also proposed to add § 413.414(c) to new subpart L to set forth the policy for when Medicare may have a secondary payer liability for organ acquisition costs, which is based upon the provider's agreement with the primary insurer that does not require the provider to accept the payment from the primary insurer as payment in full, and the payment from the primary payer for the transplant and the organ acquisition costs is less than the provider's costs for the transplant and the organ acquisition costs. When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full and the payment the TH receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability for the organ acquisition costs. To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer. If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the organ cannot be counted as a Medicare usable organ. If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and the organ is counted as a Medicare usable organ. In this circumstance, the payment from the primary payer is pro-rated between the transplant DRG payment and the organ acquisition payment and the portion of the payment applicable to organ acquisition will be used on the cost report to reduce the Medicare organ acquisition costs.

Comment: A commenter suggested that when Medicare is required to pay for medical services furnished in connection with a kidney donation for a Medicare beneficiary with ESRD,

the kidney should also be counted as a Medicare usable organ, regardless of whether the provider is “either obligated to accept, or voluntarily accepts, as payment in full, a primary payment that is less than its charges.” This commenter suggested that the proposal to codify the Medicare secondary payer provisions with respect to organ transplants is inconsistent with the statute or Congressional intent. This commenter stated that many commercial payers make no separate payment, nor identify a prorated amount, for organ acquisition costs outside of a DRG, and suggested that when Medicare pro-rates the primary payer’s reimbursement between the transplant DRG and the organ acquisition payment, Medicare reduces its responsibility for organ acquisition cost. The commenter disagreed with this approach and believes it is arbitrary and capricious to allow third-party payers to dictate the level of liability Medicare has for organ acquisition costs.

Response: We appreciate the commenter’s perspective; however, we note that the Medicare secondary payer policy is well established in statute at section 1862(b) of the Act and in the regulations at § 411.32, and applies to many aspects of Medicare reimbursement outside of transplant and organ acquisition cost reimbursement. We note that Medicare secondary payer policy is independent of commercial payers’ approach to organ acquisition costs. As discussed in the proposed rule, § 411.32 sets forth the basis for Medicare secondary payments, and establishes that Medicare prohibits secondary payment if the provider is either obligated to accept, or voluntarily accepts, as payment in full, a primary payment that is less than its charges. In the proposed rule, we proposed to codify Medicare’s longstanding policy with respect to Medicare secondary payer and organ acquisition costs so that THs that perform transplants can discern whether Medicare has a secondary payer liability for organ acquisition costs incurred by the transplanting hospital.

In section II.C.2.h.(2). of this final rule with comment period, we also addressed comments received pertaining to counting organs as Medicare usable organs when Medicare has secondary payer liability, in which we explained that only the transplant hospital that performs



the transplant counts as a Medicare usable organ, an organ transplanted for which Medicare has a secondary payer liability for the organ transplant.

After consideration of the public comments we received, we are codifying the provisions related to Medicare as secondary payer for organ acquisition costs and counting Medicare usable organs as proposed at § 413.414 in new subpart L, with modifications at § 413.414(c)(3)(ii) to clarify that only the TH that performs the transplant counts the organ as a Medicare usable organ when there is a Medicare secondary payer liability.

#### k. Proposed Organ Acquisition Charges for Kidney Paired Exchanges

In a directed living kidney donation, the donor names a specific recipient who will receive the donor's kidney.<sup>69</sup> Because the donor and recipient are known prior to the organ excision and transplantation, the organ acquisition costs can be appropriately and accurately matched to the recipient's account. In a non-directed donation, the donor does not name a specific recipient for the kidney and instead, the donor is matched with a recipient in need.<sup>70</sup> Kidney paired exchanges are similar to directed living donations; however, when the living donor and recipient do not match, they can consent to participate in a kidney paired exchange program. Kidney paired exchanges can occur when two or more living donor/recipient pairs match each other and the donated kidneys from two or more donors are exchanged so each recipient receives a compatible kidney for transplantation.

In a kidney paired exchange, the living donor and matched recipient may have their procedures performed at different THs. When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all. The Medicare organ acquisition payment policy for kidney paired donations is currently set forth

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<sup>69</sup> <https://www.kidney.org/transplantation/livingdonors/general-information-living-donation>

<sup>70</sup> Id.

at PRM section 3106. In the proposed rule, we proposed to codify Medicare's organ acquisition payment policy with respect to KPD transactions to ensure that the kidney acquisition costs in a kidney paired exchange are documented so that the kidney acquisition costs are appropriately and accurately assigned to the transplant recipient's account, and appropriate organ acquisition payment outcomes are achieved, consistent with a directed donation.

The costs of all hospital and physician services for pre-transplant living donor and recipient evaluations become acquisition costs and are included in the MCR of the recipient's TH, regardless of whether the recipient is a Medicare beneficiary. Additionally, all total usable kidneys and all Medicare usable kidneys are recorded by the transplant hospital on its MCR so that Medicare's share of kidney acquisition costs can be computed; this is true regardless of whether the transplant results from a KPD or from a directed donation. In a kidney paired exchange, once the donor and recipient are matched, any additional tests requested by the recipient's TH, and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's MCR, regardless of whether an actual donation occurs, and regardless of whether the recipient is a Medicare beneficiary. When a donor's TH procures and furnishes a kidney to a recipient's TH, the donor's TH bills the recipient's TH the donor TH's kidney SAC, or alternatively, its standard departmental charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney. The donor's TH records these costs on its MCR as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs. The recipient's TH records as part of its kidney acquisition costs, the amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ, as well as any additional testing performed and billed by the donor's TH.

In the scenario where a donor's TH does not procure a kidney, and instead the donor travels to the recipient's TH and the recipient's TH procures the organ from the donor, the

reasonable costs associated with the organ procurement are included on the MCR of the recipient's TH. As discussed in section II.C.2.b.(3). of this final rule with comment period, transportation and travel expenses of the living donor are not allowable Medicare costs. Programs outside of Medicare, such as that of the National Living Donor Assistance Center<sup>71</sup>, may pay for transportation costs for living donors.

Example. The following is an example of the accounting of organ acquisition costs in a kidney paired exchange for Medicare cost reporting purposes.

(Step 1), the Participants. There are 4 THs: TH A, TH B, TH C, and TH D. Each TH has a potential transplant recipient in need of a kidney and each recipient has a willing, but poorly matched, donor; thus, all donors and recipients enter into a kidney paired exchange. Each recipient and donor pair have been evaluated at their respective TH.

- TH A. Recipient A is a patient of TH A. TH A evaluates three potential living donors for Recipient A before a donor, Donor A, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH A's cost report. Recipient A and Donor A do not match each other but both agree to participate in a KPD exchange.

- TH B. Recipient B is a patient of TH B. TH B evaluates two potential living donors for Recipient B before a donor, Donor B, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH B's cost report. Recipient B and Donor B do not match each other but both agree to participate in a KPD exchange.

- TH C. Recipient C is a patient of TH C. TH C evaluates three potential living donors for Recipient C before a donor, Donor C, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH C's cost report. Recipient C and Donor C do not match each other but both agree to participate in a KPD exchange.

- TH D. Recipient D is a patient of TH D. TH D evaluates three potential living donors for Recipient D before a donor, Donor D, is identified. The costs of these evaluations are

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<sup>71</sup> <https://www.livingdonorassistance.org/>; accessed on November 30, 2021.

reported as kidney acquisition costs on TH D's cost report. Recipient D and Donor D do not match each other but both agree to participate in a KPD exchange.

(Step 2), the KPD Match. Through the KPD exchange it is determined that Recipient A matches Donor C; Recipient B matches Donor D; Recipient C matches Donor A; and Recipient D matches Donor B.

(Step 3), After the KPD Match.

- Recipient C's TH requests Donor A's TH perform an additional test that was not included in Donor A's initial evaluation. Donor A's TH performs the additional test and bills Recipient's C's TH, charges reduced to cost, for the additional tests of Donor A. The amounts billed by TH A to TH C are included in TH C's MCR as organ acquisition costs for Recipient C.

- Donor B elects to travel to TH D for the procurement and any additional testing.

(Note: The cost of travel for a living donor is not an allowable organ acquisition cost.)

- Donor A, Donor C, and Donor D remain at their original intended recipients' THs (TH A, TH C and TH D, respectively) where they were evaluated and where their organ procurement will occur.

(Step 4), Procuring, Packaging and Transporting the Kidneys.

- TH A procures Donor A's kidney and packages and transports it to TH C for Recipient C. TH A bills TH C, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by TH C that was not included in the initial evaluation of Donor A. Donor A's TH records these costs on its MCR as kidney acquisition costs and offsets any payments received from TH C against its kidney acquisitions costs.

- TH B does not procure a kidney. Donor B elects to travel to TH D for the procurement. TH D procures Donor B's kidney and records these costs on its cost report as kidney acquisition costs. TH B receives a kidney from TH D for transplant into recipient B. TH B records the amounts it pays to TH D on TH B's MCR as kidney acquisition costs.

- TH C procures Donor C’s kidney and packages and transports it to TH A for Recipient A. TH C bills TH A, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by TH A that was not included in the initial evaluation of Donor C. Donor C’s TH records these costs on its MCR as kidney acquisition costs and records any payments received from TH A on TH C’s MCR to offset its kidney acquisitions costs.

- TH D procures Donor D’s kidney and packages and transports it to TH B for recipient B. TH D bills TH B, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney, as well as any additional testing requested by TH B that was not included in the initial evaluation of Donor D. Donor D’s TH records these costs on its MCR as kidney acquisition costs and records any payments received from TH B on TH D’s MCR to offset its kidney acquisitions costs. TH B records the amounts it pays to TH D for Donor D’s kidney on TH B’s MCR as kidney acquisition costs.

The following tables summarize the KPD exchange described previously.

**TABLE 3. SUMMARY OF KIDNEY PAIRED DONATION EXCHANGE EXAMPLE**

	<b>TH A</b>	<b>TH B</b>	<b>TH C</b>	<b>TH D</b>
<b>Recipient</b>	<b>Recipient A</b>	<b>Recipient B</b>	<b>Recipient C</b>	<b>Recipient D</b>
Number of evaluations	Evaluates 3 potential donors before Donor A is identified.	Evaluates 2 potential donors before Donor B is identified.	Evaluates 3 potential donors before Donor C is identified.	Evaluates 3 potential donors before Donor D is identified.
Donor	Donor A	Donor B	Donor C	Donor D
	Recipient A and Donor A do not match each other but agree to a KPD exchange.	Recipient B and Donor B do not match each other but agree to a KPD exchange.	Recipient C and Donor C do not match each other but agree to a KPD exchange.	Recipient D and Donor D do not match each other but agree to a KPD exchange.
KPD match	Recipient A matches with Donor C.	Recipient B matches with Donor D.	Recipient C matches with Donor A.	Recipient D matches with Donor B.
After the match	TH A performs additional tests and procures kidney from Donor A for TH C.	TH B does not procure kidney from Donor B for TH D. Donor B travels to TH D.	TH C procures kidney from Donor C for TH A.	TH D procures kidney from Donor D for TH B. Donor B travels to TH D for the kidney procurement.

**TABLE 4. SUMMARY OF ACCOUNTING FOR KIDNEY PAIR DONATION  
EXAMPLE**

<b>Accounting</b>				
Cost of evaluations	\$12,000 incurred by TH A	\$9,000 incurred by TH B	\$15,000 incurred by TH C	\$20,000 incurred by TH D
Counting Medicare usable kidneys	2 Medicare usable kidneys: 1 kidney procured/ furnished and 1 kidney received/ transplanted.	1 Medicare usable kidney: 1 kidney received/transplanted.	2 Medicare usable kidneys: 1 organ procured/furnished and 1 kidney received/transplanted.	2 Medicare usable kidneys: 1 kidney procured/furnished and 1 kidney procured/transplanted.
Donor costs associated with procuring, packaging and transporting the kidney to the recipient TH s	TH A bills TH C \$18,000 for costs incurred to procure Donor A's kidney.	No bills sent to TH D.	TH C bills TH A \$10,000 for costs incurred to procure Donor C's kidney.	TH D bills TH B \$14,000 for costs incurred to procure Donor D's kidney.
Recipient costs associated with procuring, packaging and transporting the kidney bill by Donor THs	TH A receives a bill from TH C for \$10,000 for costs incurred to procure Donor C's kidney.	TH B receives a bill from TH D for \$14,000 for costs incurred to procure Donor D's kidney.	TH C receives a bill from TH A for \$18,000 for costs incurred to procure Donor A's kidney.	No bills received from TH B. TH D claims all costs after initial evaluation for Donor B.
Kidney acquisition costs recorded on MCR	\$12,000 evaluation costs of TH A  \$18,000 for costs billed to TH C  \$10,000 billed from TH C  \$40,000	\$9,000 evaluation costs of TH B    \$14,000 billed from TH D	\$15,000 evaluation costs of TH C  \$10,000 for costs billed to TH A  \$18,000 billed from TH A  \$43,000	\$20,000 evaluation costs of TH D  \$14,000 for costs billed to TH B  \$8,000 for costs incurred to procure Donor B's kidney at TH D.
Subtotal		\$23,000		\$42,000
Offset on MCR amounts received from recipient TH. Amounts in ( ) denote a negative number.	(\$18,000) received from TH C	No payment received from TH D	(\$10,000) received from TH A	(\$14,000) received from TH B
<b>Net cost recorded on MCR</b>	<b>\$22,000</b>	<b>\$23,000</b>	<b>\$33,000</b>	<b>\$28,000</b>

In the proposed rule, we proposed to codify into the regulations the Medicare organ acquisition payment policy for kidney paired exchanges, as set forth in PRM section 3106. Consistent with this provision, we also proposed to add § 413.416(a) to new subpart L to specify that when a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all. We also proposed to add § 413.416(b) to new subpart L to specify that in a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's MCR. We also proposed to add § 413.416(c) to new subpart L to specify that

in a kidney paired exchange, when a donor's TH procures and furnishes a kidney to a recipient's TH, all costs must be reasonable and necessary and (1) the donor's TH bills the recipient's TH the donor TH's charges reduced to cost or the TH's applicable SAC for the reasonable costs associated with procuring, packaging and transporting the kidney; (2) the donor's TH records these costs associated with procuring, packaging and transporting the kidney on its MCR as kidney acquisition costs and offsets any payments received from the recipient's TH against these kidney acquisition costs; and (3) the recipient's TH records as part of its kidney acquisition costs, the amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ as well as any additional testing performed and billed by the donor's TH. We also proposed to add § 413.416(d) to new subpart L to specify that, in a kidney paired exchange--(1) when a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the MCR of the recipient's TH; and (2) travel expenses of the living donor are not allowable Medicare costs. In section II.C.2.c.(2). of this final rule with comment period, we finalized the proposal to add § 413.404(b)(2) to specify that when a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

We did not receive comments on the proposal to codify Medicare's organ acquisition payment policy with respect to KPD transactions and as such, we are finalizing these provisions as proposed in § 413.416.

#### 1. Provisions Requiring Donor Community Hospitals to Charge OPOs Reasonable Costs, Charges Reduced to Cost

Medicare-certified hospitals that are not THs but collaborate with OPOs to procure organs from cadaveric donors for transplantation are hereinafter referred to as "donor community hospitals". To participate in the Medicare Program, donor community hospitals and THs have organ procurement responsibilities and must have an agreement with a designated OPO to timely

notify the OPO of individuals whose death is imminent or who have died in the hospital (42 CFR 482.45(a)(1)). The OPO then implements its donation protocol and, when appropriate (after declaration of death and consent to donate), will arrange for the procurement of all medically suitable cadaveric donor organs for transplant, at the donor community hospital or TH. In this regard, donor community hospitals and THs may incur costs for services provided to cadaveric organ donors following declaration of death and consent to donate through the procurement of the organs (for example, use of the hospitals operating room, staff, and ventilators to maintain the viability of the cadaveric donor organs).

Currently, when a donor community hospital incurs costs for services provided to the cadaveric donor, as authorized by the OPO following the declaration of death and consent to donate, it bills the OPO its customary charges (not reduced to cost) or a negotiated rate. (PRM-1 section 3107). Donor community hospital billing procedures are described in IL 74-23, published July 1, 1974, which provides, “where the excising hospital is not a TH, it will bill its customary charges for those services used in excising the cadaver kidney.” Thereafter, the OPO includes the charges from the donor community hospital on its cost report as part of the OPO’s organ acquisition costs. At the end of its accounting period, the TH/HOPO uses these amounts to calculate its renal and non-renal SAC amounts for the following year, and the IOPO uses these amounts to calculate its non-renal SAC amounts for the following year. Medicare contractor’s also use these amounts to calculate the IOPO’s kidney SAC for the following year.

When the IOPO furnishes an organ to a TH (or other OPO), the IOPO bills the TH (or other OPO) the IOPO’s SAC for the specific organ type. Currently, when a TH/HOPO furnishes an organ to another TH or OPO, it must bill its SAC or its standard departmental charges reduced to cost. The OPO’s SAC is a charge which reflects an average of the total actual costs the OPO incurs to furnish an organ and reflects amounts the OPO is charged by the donor community hospital for services the donor community hospital provides to cadaveric donors. THs then include these SACs they have paid to OPOs to procure organs as allowable acquisition costs in



their bills to Medicare, which Medicare pays. Therefore, because the OPO's incurred costs are passed on to and paid by the TH, and because the TH then includes these amounts as organ acquisition costs on its cost report, this chain of incurred costs results in Medicare paying these donor hospital charges (that are not reduced to cost) when it reconciles the organ acquisition costs on the TH cost report.

Stakeholders have made CMS aware that some donor community hospitals are charging OPOs amounts that are in excess of reasonable costs for services provided to cadaveric organ donors, resulting in Medicare paying more than reasonable costs for the acquisition of cadaveric donor organs for transplant. In one instance, an OPO identified a donor community hospital in its designated service area that billed amounts in excess of reasonable costs. CMS reviewed the donor community hospital's bills to the OPO and the donor community hospital's MCR information to evaluate the costs associated with those charges. CMS computed, using the hospitals cost-to-charge ratios (CCR), that the charges billed by the donor community hospital in the amount of \$194,000, equated to a cost of \$11,000. Thus, the donor community hospital's actual costs were approximately 6 percent of their billed charges.

Organ acquisition costs are reimbursed under Medicare's principles of reasonable cost established under section 1861(v) of the Act. Donor community hospitals (and THs) are Medicare-certified hospitals and must follow Medicare's reasonable cost principles under section 1861(v) of the Act. Because the services donor community hospitals provide to cadaveric donors, and thus charge to OPOs, are included as organ acquisition costs on OPOs' cost reports, these charges are also subject to Medicare's principles of reasonable cost established under section 1861(v) of the Act, and 42 CFR 413.5 and 413.9.

In a 1978 final rule with comment, CMS similarly noted that THs have no basis for determining the reasonableness of the charges made by the OPO.<sup>72</sup> CMS observed that services furnished by OPOs, if they are not part of the transplant hospital, are billed to transplant

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<sup>72</sup> 43 FR 58370 (December 14, 1978)

hospitals, which pay the charges shown on the bill. The charges then become allowable costs of the hospitals.<sup>73</sup> When donor community hospitals charge OPOs amounts not reduced to costs, and the OPOs pay the charges shown on the bill, those charges become incorporated as organ acquisition costs to the TH and are subsequently shared by Medicare; thus, Medicare's reasonable cost principles applicable to organ acquisition costs are not observed. We note that organs recovered from donor community hospitals comprised 62 percent of all transplanted organs in 2017 and 2018.<sup>74</sup> We recognize that because THs bill the OPOs' charges to Medicare, Medicare is paying more than reasonable costs for these services that become organ acquisition costs.

Because these charges become allowable organ acquisition costs of the TH, we believe that donor community hospitals should be required to reduce their charges to cost for services provided to cadaveric donors and billed to OPOs, in accordance with reasonable cost principles given in section 1861(v) of the Act and in our regulations at 42 CFR 413.5 and 413.9. Doing so will result in conformance to Medicare reasonable cost principles, and result in reduced costs to the OPOs, subsequently reducing cadaveric donor SACs billed to THs or OPOs, which may benefit other payors, as well as Medicare. Donor community hospitals are reimbursed either a DRG payment by Medicare (if the patient is a Medicare beneficiary), or a payment from other payors, for services provided to a potential organ donor prior to declaration of death and consent to donate. For services provided after declaration of death and consent to donate, if our provision is implemented, donor hospitals will be reimbursed by OPOs for their reasonable costs in accordance with Medicare's principles of reimbursement. Therefore, a donor community hospital would see a reduction in reimbursement from OPOs, because the donor hospital was previously permitted to bill the OPO its customary charges or negotiated rates. However, donor community hospitals would still have their reasonable costs reimbursed.

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<sup>73</sup> Id.

<sup>74</sup> Scientific Registry of Transplant Recipients. Request for Information. Requested on 02/08/2021.

We believe that an equitable and accurate methodology to reduce a donor community hospital's charges to cost would be to use the most recently available hospital-specific CCR. Using the hospital-specific CCR would be unique to each donor community hospital and would more accurately compensate them for services provided to cadaveric organ donors, as opposed to using an alternative like the statewide CCR. Because contractors recalculate each hospital's specific CCR on an ongoing basis, whenever more recent cost report data is available, the hospital's specific CCR is arguably more accurate and more closely aligned with creating a uniform charge to cost structure.

One methodology we considered to reduce a donor community hospital's charges to cost was to require the donor community hospital to use its statewide average operating CCR and apply this statewide average CCR to its charges. The statewide average operating CCR is updated annually in the FY IPPS/LTCH rule and is a transparent source of data. We note that the statewide average operating CCR published in the FY 2021 IPPS/LTCH final rule was 0.272 for urban hospitals and 0.336 for rural hospitals. Using a statewide average CCR would even out any instances in which a hospital's operating costs fall above or below established parameters. However, because it is an average, it would not accurately represent the variability in actual hospital specific CCRs. Therefore, using a statewide CCR may not adequately serve the purpose of reducing charges to cost.

Stakeholders have suggested that some donor community hospitals are improperly billing OPOs for services provided to cadaveric donors *prior* to the declaration of death and consent to donate. This would be inappropriate because hospital services provided prior to declaration of death and consent to donate are billable to the donor's insurance in the same manner hospital services are billable to an individual receiving services, regardless of whether the payor is Medicare. We reiterate that when a donor community hospital or TH incurs costs for providing services to a cadaveric donor, as authorized by the OPO, only those costs incurred after the declaration of the donor's death and consent to donate are permitted to be billed to the OPO.

The OPO must accept bills from donor community hospitals and THs for costs only incurred after the declaration of death and consent to donate. Contractors will review OPO cost reports to ensure that donor community hospitals and THs charge OPOs for cadaveric donor costs incurred after declaration of death and consent to donate.

We proposed to add § 413.418(a) in new subpart L, to specify that a donor community hospital (a Medicare-certified non-transplant hospital) incurs organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate.

We proposed to add § 413.418(b) in new subpart L, to specify that for cost reporting periods beginning on or after October 1, 2021, when a donor community hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered.

Comment: A few commenters suggested that if Medicare does not cover expenses prior to a donor's death, there would be uncompensated donor testing which may become the responsibility of the donor's family or other third-party payers.

Response: OPOs and THs are responsible for all costs for donor evaluation and medical management once declaration of death and consent for donation occurs. Generally, Medicare does not cover costs of services incurred for a potential organ donation as organ acquisition costs unless those costs occur after the declaration of death and consent to donate is obtained.

Therefore, costs of services incurred for a potential organ donor prior to declaration of death and consent to donate must not be included on the OPO cost report.

Comment: A commenter supported our proposal and noted when entities continue to engage in improper billing they violate CMS reasonable cost principles, and drive up the overall cost of organ donation and procurement. Several commenters appreciated our concerns that some donor community hospitals bill OPOs more than cost for services provided to cadaveric

donors and generally supported our proposal to require donor community hospitals to bill the OPO its customary charges reduced to cost for such services. However, some of these supporters that were OPOs indicated they have successfully negotiated competitive “per-case” rates with donor hospitals and stated there may be instances where OPOs have negotiated lower “per-case” rates than charges reduced to cost. These commenters suggested that our policy, if finalized as proposed, would unintentionally interfere with longstanding arrangements many OPOs have with donor community hospitals. Some supporters of our proposal underscored the importance of considering stakeholder input to create evidence-based policy.

Response: We appreciate the commenter’s support for our proposal. We agree that when entities continue to engage in improper billing they violate CMS reasonable cost principles, and drive up the overall cost of organ donation and procurement. Our proposal was not intended to interfere with longstanding arrangements whereby OPOs and donor community hospitals have negotiated per-case rates that align with Medicare’s reasonable cost principles. We agree that flexibility should be afforded to OPOs and donor community hospitals by allowing for alternative charge arrangements like per-case rates currently in place between some OPOs and donor community hospitals, however, as long as the amount is less than customary charges adjusted to cost.

Comment: Several commenters disagreed with our proposal and claimed it would increase administrative burden, which could delay payment. A commenter suggested to reduce donor community hospital administrative burden, donor community hospitals could continue normal billing practices, and either the OPOs or CMS could apply a cost to charge calculation using the public CCRs found in the IPPS Impact Files.

Response: We disagree with commenters' assertions that our proposal would increase administrative burden. We also disagree with the suggestion that OPOs or CMS should apply the CCR on behalf of the donor community hospitals. The current policy allows donor community hospitals to bill customary charges (or negotiated rates) to OPOs for services

provided to the cadaveric donor; therefore, these hospitals have established billing practices in place and will not incur added burden as a result of our proposal. In addition, 42 CFR 413.24(f) requires all Medicare-certified donor community hospitals to file an MCR on an annual basis. Therefore, the information required to reduce charges to cost is readily available to donor community hospitals.

Comment: Some commenters claimed limiting amounts paid to donor community hospitals would limit the number of organs available for transplant. Another commenter stated when donor community hospitals charge, and OPOs pay amounts greater than cost, the policy provides a clear financial benefit to these hospitals. Another commenter stated because donor community hospitals are not reimbursed for organ acquisition-related costs on the MCR they will have no incentive to support the costs associated with a deceased donor.

Several commenters suggested concern that some donor community hospitals may not work cooperatively with OPOs as a result of this proposal. One of these commenters acknowledged reports of some donor community hospitals billing “outlandishly high charges” for costs associated with organ recovery, but indicated their experience with donor community hospitals works because of negotiated acquisition fees in place. This commenter acknowledged that Medicare’s CoPs require cooperation between hospital staff and OPOs, but questioned whether enforcement of those cooperation requirements is a priority.

Response: We appreciate commenters’ concerns that the proposal would limit amounts paid to donor community hospitals. We acknowledge that when donor community hospitals bill, and OPOs pay, amounts greater than cost, the donor community hospital benefits financially. In the proposed rule, we noted that a donor community hospital would see a reduction in reimbursement from OPOs, because the donor community hospital was previously permitted to bill the OPO its customary charges or negotiated rates. However, donor community hospitals will still be paid for their services provided to potential donors, at amounts that recognize Medicare’s reasonable cost principles.

In addition, donor community hospitals must work with OPOs per the Medicare requirements for CoPs at 42 CFR 482.45. These regulations require that donor community hospitals notify OPOs, in a timely manner, of individuals whose death is imminent or who have died in the hospital to assure that the OPO can determine medical suitability for organ donation. The regulations also require that the hospital work cooperatively with its designated OPO to educate staff on donation issues and maintain potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place. Our proposal to require donor community hospitals to charge OPOs amounts that are reduced to its cost does not impede hospitals' compliance with Medicare CoPs. Hospitals will still be paid for their services provided to potential donors, at amounts that recognize Medicare's reasonable cost principles. As such, we believe that our proposal should not impact the number of organs available for transplant or cooperation between OPOs and donor community hospitals because OPOs and donor community hospitals must continue to work together, as required under Medicare CoPs, to procure all available organs for transplant.

Comment: Many commenters suggested alternatives to our proposal to require donor community hospitals to bill OPOs charges reduced to cost. These commenters suggested that CMS require donor community hospitals to bill OPOs an amount no more than customary charges adjusted to cost, but allow for alternative charge arrangements like per-case rates currently in place between some OPOs and donor community hospitals, as long as the amount is less than customary charges adjusted to cost. A few commenters suggested CMS establish a maximum price ceiling instead of a universal price so that these per-case rates, often perceived to be more competitive, can remain in place. A commenter requested we temporarily withdraw the proposal and develop a donor community hospital SAC methodology that would permit such hospitals to charge (and OPOs to pay) rates above actual, reasonable cost. A few commenters suggested CMS work with stakeholders to develop a model to account for the cost of delayed or canceled operating room procedures and use this model when an OPO and a donor community

hospital do not have a negotiated a standard acquisition charge. Finally, several commenters requested our proposals be delayed to allow time for an impact analysis.

Response: We appreciate commenters' suggestions to withdraw the proposed policy and develop a SAC for donor community hospitals that would permit OPOs to pay charges greater than cost, but respectfully disagree. The SAC generally represents the average of the total actual costs associated with procuring either cadaveric donor organs or living donor organs and is based on Medicare's reasonable cost principles, which do not allow for payment of amounts greater than reasonable cost. We believe that flexibility should be afforded to OPOs and donor community hospitals and THs by allowing for alternative charge arrangements like per-case rates currently in place between some OPOs and donor community hospitals, as long as the amount is less than customary charges adjusted to cost. Because of this flexibility, we do not believe that we need to develop a model, as commenters suggest, to account for the cost of delayed or canceled operating room procedures and to use this model when an OPO and a donor community hospital do not have a negotiated standard acquisition charge. We also do not believe that our proposals should be delayed so that an impact analysis can be conducted. As we discussed in the proposed rule, we believe the impact is not estimable because we do not have information to calculate the effects on revenue and costs to donor community hospitals, OPOs, or transplant hospitals.

Comment: A few commenters suggested that CMS should specify that the proposal to require that donor community hospitals bill OPOs customary charges that are reduced to cost should not apply only to donor community hospitals, but also to THs that bill OPOs for services provided to cadaveric donors. A commenter claimed our proposal is inconsistent with past position on hospitals maintaining uniform and customary charge structures that apply universally to all payers and requested we withdraw our proposal.

Response: We agree that THs provide services to cadaveric donors, placing them in a similar situation as donor community hospitals when billing amounts to OPOs for services



provided to cadaveric donors following the declaration of death and consent to donate, as authorized by the OPO. We believe that a TH must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital-specific CCR for the period in which the service was rendered, or a negotiated rate. We note that charges for services provided to cadaveric donors become organ acquisition costs, and payment for such aligns with Medicare's reasonable cost principles under which organ acquisition costs are paid and does not run afoul of CMS requirements for hospitals to maintain uniform and customary charge structures. As such, we do not believe it is necessary to withdraw our proposal.

Comment: Some commenters suggested CMS institute an oversight mechanism for enforcing our proposal, as they perceive no requirement for donor community hospitals to negotiate rates with OPOs.

Response: Providers under the Medicare program are required to submit Medicare cost reports on an annual basis 42 CFR 413.24(f). We believe that Medicare contractors' review and audit of hospitals' submitted cost reports serve as an existing oversight mechanism for enforcing our proposal.

Comment: Some commenters requested specific instructions be issued to hospitals for the appropriate billing of their charges reduced to cost, and questioned which hospital CCRs should be used in the calculation, and whether it should be based on final cost reports or on interim cost reports. Other commenters questioned whether OPOs will be required to validate the CCRs used by hospitals, where CMS will publish the hospital specific files, or if hospitals will be required to furnish their hospital specific CCR in cases where they have case rates or flat rates with the OPO. A commenter stated that use of the most recently available MCR could understate costs due to increasing healthcare costs. A commenter suggested, when the most recently available MCR is used, an update factor should be applied to ensure the cost represents the costs for the period in which the service was actually provided. Another commenter questioned whether hospitals should bill OPOs for physician professional fees at cost, or whether

OPOs should pay physician charges based on the Medicare physician fee schedule to ensure that OPOs are not overpaying hospitals for physician services.

Response: We are clarifying that a donor community hospital must use the most recently available hospital specific CCR, included in the provider-specific file published on the CMS website<sup>75</sup>, for the period in which the service was rendered. The hospital-specific CCR is the same CCR that is used in the IPPS outlier calculation. A donor community hospital must provide, upon request from the OPO or TH, its hospital-specific CCR for review, or comparison in cases where they have case rates or flat rates with the OPO. If the donor community hospital or TH believes its most recently available CCR does not convert charges to reflect its actual cost, we believe instead of applying an update factor, it would be reasonable for the hospital to follow the procedures outlined in the Medicare Claims Processing Manual, (CMS Pub. 100-04), chapter 3, section 20.1.2.1. for use of an alternative CCR. Finally, we appreciate the commenters' concern about OPOs overpaying hospitals for physician services; however, we believe that OPOs either employ or contract with physicians to provide services in a donor community hospital. In addition, our proposal only addressed charges as they relate to hospital services provided to cadaveric donors.

After consideration of the public comments we received, we are finalizing our proposal with modifications based on comments received to specify at § 413.418(a) in new subpart L, that a donor community hospital (a Medicare-certified non-transplant hospital) and a transplant hospital incur organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate. We are also finalizing our proposal with modifications, to specify at § 413.418(b) that for cost reporting periods beginning on or after the effective date of this final rule with comment period, when a donor community hospital or a transplant hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital or transplant hospital must bill the OPO the lesser of its

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<sup>75</sup> [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspectivePaymentSystem/psf\\_text](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspectivePaymentSystem/psf_text)

customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

m. Revisions, Technical Corrections, and Conforming Changes to 42 CFR Part 412, Subparts A, E, G, and H and to Part 413, Subparts A, C, and H

(1) Conforming Changes to Terminology in 42 CFR Parts 412 and 413

In section X.B.2.a.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule and in section II.C.2.a.(1). of this final rule with comment period, we noted terminology differences in the use of “transplantation center”, where the regulations in 42 CFR part 412, subparts A, E, G, and H and in Part 413, subparts A, C, and H use the term to mean an organ-specific transplantation program that is within a TH. We proposed to conform the language in the regulation text to the terminology used in the CoPs at § 482.70 by replacing the term “transplantation center” and its various permutations with the term “transplant program” and its various permutations. We proposed to make this conforming change in the text of the following regulations: §§ 412.1(a)(1)(ii), 412.2(e)(4), 412.71(b)(3), 412.90(d), 412.100 (in the title and in the text at §§ 412.100(a)(1)), 412.113(d), 412.116(c), and 413.40(a)(3). We also proposed to update the terminology to replace “organ procurement agency” and its various permutations with “organ procurement organization” and its various permutations. Further, we proposed to replace the acronym “OPAs” with “OPOs”. We proposed to make these terminology changes to the regulation text at §§ 412.100(b) and 413.1(a)(2)(v) to conform to the terminology used in the CoPs found in 42 CFR part 482. Finally, we proposed to change “renal” to “kidney” in §§ 412.71(b)(3), 412.90(d), in the title and paragraph (a) of § 412.100, and in § 412.116(c), to conform to the terminology used in the CoPs at § 482.104.

We did not receive comments on these proposals and are finalizing these provisions as proposed.

(2) Revisions, Technical Corrections, and Conforming Changes to § 412.100

In the proposed rule, we proposed to revise the text currently found in § 412.100(a) and (b) to change “expenses” to “costs” and to remove the word “estimated” from § 412.100(a)(1). We also proposed to make a technical correction to remove from § 412.100(a)(1) cross-references to CoPs which no longer exist, and replace them with § 482.104, and proposed to add language to clarify that CMS adjusts inpatient prospective payment system (IPPS) rates for inpatient operating costs. We proposed to revise § 412.100(a)(1) to state that CMS adjusts the inpatient prospective payment system (IPPS) rates for inpatient operating costs determined under subparts D and E of this part for hospitals with approved kidney transplant programs (discussed at § 482.104) to remove the net costs associated with kidney acquisition.

Additionally, we proposed to revise § 412.100(a)(2) to clarify the language, and to specify that Medicare payment for kidney acquisition costs includes only those costs for kidneys transplanted into Medicare beneficiaries. We proposed to revise § 412.100(a)(2) to specify the following:

- Payment for Medicare kidney acquisition costs, as set forth in subpart L of part 413 of this chapter, is made on a reasonable cost basis apart from the prospective payment rate for inpatient operating costs.
- IPPS payment to the hospital is adjusted in each cost reporting period to reflect an amount necessary to compensate the hospital for reasonable costs of Medicare kidney acquisition.

In section X.B.2.b.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to revise § 412.100(b) by revising and relocating the list of organ acquisition costs given in that paragraph and adding the list as paragraph (b) in proposed § 413.402 of new subpart L. Further, we proposed to revise § 412.100(b) to make it clearer that kidney acquisition costs must be incurred. Finally, we proposed to revise § 412.100(b) to add language that the items and services covered as kidney acquisition costs are specified in § 413.402(b).

We did not receive comments on the proposals made in section X.B.2.m.(2). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, and are finalizing our provisions as proposed.

(3) Revisions and Conforming Changes to 42 CFR 412.113(d)

In addition to the conforming change discussed in section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to revise the regulation text at § 412.113(d) to reference the organ acquisition policies given in new subpart L of part 413, rather than to maintain the existing cross-reference to the definition of organ given in § 486.302.

We did not receive comments on this proposal and are finalizing the provision as proposed.

(4) Technical Corrections and Conforming Changes to § 413.1

In addition to the conforming change discussed in section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we revised the text in § 413.1(d)(2)(i) to put it into list form. We also proposed to revise the text related to kidney acquisition costs to refer to organ acquisition costs as specified in part 413 subpart L.

We did not receive comments on this proposal and are finalizing the provision as proposed.

(5) Revisions to 42 CFR 413.40(a)(3)

In addition to the proposed conforming changes discussed in section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we set forth a technical correction and a revision to paragraph (a)(3) of § 413.40. We proposed to revise the regulation text that references heart, kidney, and liver acquisition costs to refer to organ acquisition costs as specified in part 413 subpart L so that the language reflects all solid organs for which Medicare covers organ acquisition costs and directs readers to the organ acquisition cost regulations in part 413, subpart L.

We did not receive comments on this proposal and are finalizing the provision as proposed.

(6) Regulatory Changes to § 413.200

We proposed to remove the regulation found at 42 CFR 413.200 specifying payment of independent organ procurement organizations and histocompatibility laboratories. We proposed to add § 413.400 to contain revised text from § 413.200(b), and to add § 413.420 to contain the remaining regulation text from § 413.200 (a) and (c) through (g), along with a revised title, so that the content of § 413.200, with revisions, is located with other regulations specific to organ acquisition in part 413, new subpart L. We proposed to make a technical correction or revisions to two of the three definitions found in § 413.200(b), as described in section II.C.2.a.(2). of this final rule with comment period. We proposed to add these definitions to proposed § 413.400, as described in section II.C.2.a.(2). of this final rule with comment period.

We proposed to relocate and revise the regulation title and regulation text currently existing in § 413.200 in paragraphs (a), and (c) through (g), by adding § 413.420 to specify payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs and by adding paragraphs (a), and (c) through (g) with the text from those same paragraphs in § 413.200. We proposed to make conforming changes to the regulation text in § 413.420(a), and (c) through (g), to distinguish independent OPOs (IOPOs) from all OPOs where appropriate, in accordance with the proposed definition of IOPO in § 413.400. We also proposed to add paragraph (b) to § 413.420 to provide a cross-reference to the definitions in § 413.400 of new subpart L. Therefore, the proposed new § 413.420 would maintain the same paragraph structure as the existing § 413.200. Finally, we proposed minor revisions to clarify the regulation text, including changing language from passive to active tense, changing verbs from future tense to present tense, and editing to improve readability.

We did not receive comments on these proposals and are finalizing the provisions as proposed.

### 3. Solicitation of Comments Regarding Surgeon Fees for Cadaveric Donor Excisions

Since 1987, we have limited the amount an OPO may reimburse a physician for cadaveric kidney donor retrieval services. Chapters 27 and 31 of the PRM limit the physician payment for cadaveric kidney retrieval to \$1,250 per donor (one or two kidneys). The history behind the limitation on physician payment may be based on a July 1974 \$400 physician services limitation on excising kidneys in community hospitals that do not participate in Medicare, which was noted in a Part A Intermediary Letter (IL No. 74-23, July 1974); it may also be based in part on the 1983 median cost paid by OPOs for surgical excision of cadaveric kidneys, which was approximately \$800.<sup>76</sup> Although the payments made to physicians for organ retrieval services associated with other types of organ transplants have increased, cadaveric kidney retrieval rates have remained capped at \$1,250. We have received several requests to change the amount we pay for cadaveric kidney retrievals. In the CY 2009 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009 (hereafter, Physician's Fee) proposed rule (73 FR 38580 and 38581), we solicited public comments and data that are reflective of organ retrieval service costs for all types of organs. At that time, we did not have data upon which to base a change in payment. We stated that we may use this information to determine the extent to which a recalculation of the payment for cadaveric organ retrieval services performed by a physician is warranted and to inform any future rulemaking on this subject. We received four timely public comments in response to our request for information and data for use in updating the organ retrieval physician payment amount included in organ acquisition costs, which were discussed in detail in the CY 2009 Physicians Fee Schedule final rule (73 FR 69864). However, we did not receive any data that would be useful in evaluating the appropriateness of the \$1,250 per donor surgeon fee limit for cadaveric kidney retrievals.

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<sup>76</sup> Organ Transplants: Hearings before the Subcommittee on Investigations and Oversight, of the House Committee on Science and Technology. 98<sup>th</sup> Cong. 43 (1983) (testimony ofCarolyn K. Davis, PhD, Administrator, Health Care Financing Administration).

For this final rule, we used 2017 cost report data from 48 OPOs to calculate a surgeon fee cost per local kidney for each provider, by dividing the kidney surgeon fee costs reported on Worksheet A-2, line 13, column 3 of the MCR by the number of local kidneys reported on Worksheet S-1, Part 1, Line 1, column 1 of the MCR. Excluding three providers with extremely low surgeon fees per local kidney (ranging from \$0 to \$231), the average surgeon fee cost per local kidney was \$745. These provider-reported data suggest that the \$1,250 limit on surgeon fees for cadaveric donor kidney retrievals is sufficient and allows for some higher cost excisions. However, we have received comments suggesting that this limit needs to be reconsidered.

While we did not propose to change the physician payment limit for cadaveric kidney retrieval, we solicited information on the physician effort and resources required to procure a cadaveric kidney for transplantation. Specifically, we solicited data or other information on surgical time, dry runs (number and percentage of retrievals in which an organ is not recovered), travel and wait times, as well as the incremental time required for extended criteria donors and donors after cardiac death. Additionally, we solicited resource information to determine the difference in procuring one kidney or a pair of kidneys from a single donor. We indicated in the proposed rule that the comments we received may inform development of future proposals related to surgeon fee payment for organ retrieval from cadaveric donors.

Comment: Commenters were generally appreciative of this comment solicitation. A commenter did not support increasing surgeon fees for cadaveric kidney removal, and stated that CMS should consider whether an increase to surgeon fees and the additional cost burden to the Medicare Trust Fund would result in an increase in the number of kidneys available for transplant. This commenter stated that many existing OPO practices already maximize kidney donation within the current payment limit and without incurring additional costs, and those practices should not be disrupted.

Some commenters supported increasing surgeon fees. Most of these commenters stated that the current limit of \$1,250 is inadequate relative to the surgical, travel, dry run, and wait



times. Some commenters cited increased travel costs resulting from new kidney allocation policies, and medical and technological advancements in donor management which have added to the cost of surgical procurement. A commenter noted that procuring marginal kidneys increases the complexity of organ recovery and the frequency of intra-operative findings that result in the abandonment of the effort. Some commenters added that DCD procurements add complexity to the procurement process and require surgeons to learn new skills. A commenter stated that the entire vasculature (including the aorta and vena cava) and en-bloc kidneys are dissected out and removed from the donor body, and then separated outside.

A commenter stated that an OPO sometimes pays more than \$1,250 to ensure surgeons are readily available to excise kidneys; the commenter stated amounts over \$1,250 are not reimbursable and must be absorbed by other non-renal or tissue revenue, with this cost shift increasing SAC fees for non-renal organs, or, when covered by tissue revenue, requiring the OPO to pay for costs that are a result of services provided to a Medicare beneficiary. This commenter encouraged CMS to ensure that the costs attributable to Medicare beneficiaries are appropriately covered.

A commenter questioned if the cadaveric kidney retrieval cap of \$1,250 also applies to the transplant hospitals, and if so, how the retrieval cap applies when multiple organs are excised. This commenter also questioned if CMS has an established cap on surgeon fees for the excision of other organs.

Another commenter stated that CMS' use of 2017 cost report data is flawed, as most OPOs only contract and pay their kidney surgeons \$1,250 per donor (due to Medicare's limitation), so the cost report worksheet A-2 data would only reflect the limitation on surgeon fees as cost, and the average kidney surgeon fee cost per kidney should be around \$1,250.

A few commenters suggested that CMS formally survey transplant programs to collect the data necessary to rebase payments for this service. Another suggested CMS establish an annual process to solicit stakeholder input to update pricing. A commenter recommended that

CMS apply at least an inflationary increase to the historical \$1,250 rate while continuing to collect community data to support an updated fee. Another commenter welcomed additional opportunities for OPOs to collect and provide relevant data beyond this 60-day comment window.

Response: We appreciate these comments, and may consider them if we undertake future rulemaking related to surgeon fees for recovering cadaveric kidneys.

### **III. Collection of Information Requirements**

#### **A. Statutory Requirement for Solicitation of Comments**

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2022 IPPS/LTCH PPS proposed rule, we solicited public comment on the following provision of this final rule comment period that contain information collection requirements (ICRs).

As discussed in section II.B.3. of this final rule with comment period, teaching hospitals would be able to submit electronic applications to CMS for resident slot increase requests. The burden associated with these requests is captured in an information collection request currently

available for public review and comment. The 60-day notice published on October 22, 2021 (86 FR 58664). We note that the application included in this information collection has yet to be approved. Comments can be submitted as part of October 22, 2021 60-day notice or as part of the subsequent 30-day **Federal Register** notice. We will review and respond to any comments received on either notice.

#### **IV. Regulatory Impact Analysis**

##### A. Statement of Need

###### 1. Changes to the IME and Direct GME Payments

This final rule with comment period is necessary in order to make Medicare payment and policy changes to the statutory methodology for determining payments to hospitals for the direct costs of approved GME programs and the IME adjustment under the IPPS for hospitals that have residents in an approved GME program, as described in more detail in section IV.C. of this final rule with comment period. The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

In this final rule with comment period, we are finalizing policies to implement sections 126, 127, and 131 of the CAA of 2021. Section 126 makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in FY 2023, with priority given to hospitals in 4 statutorily-specified categories. Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track, and to the 3-year rolling average used to calculate payments for these hospitals. Section 131 of the CAA makes statutory changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals

that hosted a small number of residents for a short duration. We expect these changes will make appropriate Medicare GME payments to hospitals for Medicare's share of the direct costs to operate the hospital's approved medical residency program, and for IPPS hospitals the indirect costs associated with residency programs that may result in higher patient care costs, consistent with the law.

We expect that these changes will ensure that the outcomes of these Medicare payment policies are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

## 2. Changes to the Organ Acquisition Payment Policies

In the FY 2022 IPPS/LTCH/PPS proposed rule, we proposed Medicare payment and policy changes to the methodology for counting Medicare organs by transplant hospitals, and Medicare kidneys by OPOs, for calculation of Medicare's share of organ acquisition costs, however, in this final rule with comment period, we are not finalizing the proposed organ counting policy, and may revisit the policy in future rulemaking. Therefore, the Medicare organ counting policy is not addressed in the regulatory impact analysis of this final rule with comment period.

In this final rule with comment period, we are finalizing certain longstanding organ acquisition payment policies to better support organ availability and transplantation. We are finalizing a policy related to amounts billed to OPOs for organ acquisition costs when a donor community hospital or transplant hospital incurs costs for services furnished to a cadaveric donor, to ensure that billing is in accord with reasonable cost principles. We are also finalizing existing payment policies to clarify and codify definitions, organ acquisition costs, and examples of items or services that are not organ acquisition costs; to allow certain additional registry fees and transportation costs; to codify existing policies related to living organ donor complications and clarify accounting and payment methods; to codify existing policies related to standard acquisition charges, acquisition of pancreata for islet cell transplants, Medicare as a secondary

payor, kidney-paired donations, and payment to independent OPOs and histocompatibility laboratories for kidney acquisition costs. We expect these codifications will provide greater understanding of organ acquisition payment policies to the organ procurement and transplant community, and that our allowing certain additional costs will support organ transplantation and improve health equity. We expect these changes will result in clarity and consistency with Medicare's reasonable cost principles.

## B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action(s) and/or with economically significant effects (\$100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is "economically significant" as measured by the \$100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

The analysis in this RIA, in conjunction with the remainder of this document, demonstrates that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule with comment period would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this final rule with comment period.

### C. Detailed Economic Analysis

#### 1. Effects of the Changes to IME and Direct GME Payments

The CAA of 2021 contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals. Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions, with 200 slots to be distributed in 5 rounds over 5 years starting in FY 2023, with priority given to hospitals in 4 categories. Section 127 of the CAA, effective for cost reporting periods beginning on or after October 1, 2022, makes changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track, and the application of the 3-year rolling average to the payment calculation of these hospitals. Section

131 of the CAA makes changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration, based on new programs started on or after enactment (December 27, 2020) and 5 years after (December 26, 2025). We provided details for implementing these 3 GME CAA provisions in section II.B. of this final rule with comment period. Following is a table showing the estimated cost of implementation of these 3 GME CAA provisions:

**TABLE 5. COST IMPACT OF CAA 2021 GME PROVISIONS (in \$millions)**

<b>FY</b>	<b>Section 126</b>	<b>Section 127</b>	<b>Section 131</b>
2021	0	0	10
2022	0	0	30
2023	10	0	60
2024	60	10	90
2025	120	10	130
2026	180	10	150
2027	240	20	170
2028	290	20	180
2029	300	20	180
2030	310	20	190
2031	320	20	190

In summary, the Office of the Actuary estimates an increase of \$10 million in Medicare payments to teaching hospitals for FY 2021, an increase in Medicare payments to teaching hospitals of \$860 million for FYs 2022 through 2026 (over 5 years). In total, for FYs 2021 through 2031, Medicare payments to teaching hospitals are estimated to increase by \$3.30 billion.

## 2. Effects of the Organ Acquisition Payment Policy

In section X.C.2. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to codify into the Medicare regulations some longstanding Medicare organ acquisition payment policies, with clarifications where necessary, and to codify some new organ acquisition payment policies. In section II.C.2.a of this final rule with comment period, we discuss clarifications and codification of longstanding definitions related to organ acquisition. These final policies are not expected to have an impact on expenditures because the finalized policies

pertain to changes to definitions and usage of consistent terminology. In section II.C.2.b of this final rule with comment period, we discuss the revisions to and codification of longstanding policies related to items or services that are organ acquisition costs, which we are modifying to allow certain additional organ recipient registry fees and cadaveric donor transportation costs. To the extent that these provisions have an impact on expenditures, that impact is not estimable because we do not have information to calculate the change in registry fee costs or transportation costs. In sections II.C.2.c. and II.C.2.d. of this final rule with comment period, we discuss our final policies related to standard acquisition charges and outpatient costs and laboratory services related to organ acquisition, however, these final policies are not expected to have an impact on expenditures.

In section II.C.2.e. this final rule with comment period, we also discuss revisions to and codification of longstanding policies related to Medicare coverage of living donor complications. To the extent that these provisions have an impact on expenditures, that impact is not estimable because we do not have cost data pertaining to non-renal living donors to calculate the increase in cost from codifying policies specifying reporting and payment of costs for non-renal living donor complications. In sections II.C.2.f. and II.C.2.g. of this final rule with comment period, we discuss final policies related to services to transplant recipients and the codification of a statutory policy related to pancreatic islet cell transplants, which are not expected to have an impact on expenditures.

In section II.C.2.h. of this final rule with comment period, we discuss the organ counting policy, however, we are not finalizing our proposed policy and as such, there are no impacts on expenditures. In section II.C.2.i. of this final rule with comment period, we discuss final policies related to intent to transplant, and counting en bloc, research, and discarded organs which are not expected to have an impact on expenditures. In sections II.C.2.j. and II.C.2.k. of this final rule with comment period, we discuss the codification of longstanding organ acquisition policies



related to Medicare as a secondary payor and accounting for kidney-paired donations, respectively, which are not expected to have an impact on expenditures.

Additionally, in section II.C.2.l. of this final rule with comment period, we discuss finalized policy codifications for donor community hospitals' (Medicare-certified non-transplant hospitals) and THs' charges for services provided to cadaveric donors. To the extent that these provisions have an impact on expenditures, that impact is not estimable because we do not have information, such as the cost of services and number of cadaveric donors to whom services are provided to calculate the effects on donor community hospitals, or transplant hospitals for services provided to organ procurement organizations. Based on the Scientific Registry of Transplant Recipient (SRTR) data, we recognize that organs recovered from donor community hospitals comprised 62 percent of all transplanted organs in 2017 and 2018.<sup>77</sup> Under the current policy, donor community hospitals bill customary charges or negotiated rates and not charges reduced to cost. Because our final policy requires donor community hospitals and THs to bill the lesser of charges reduced to cost or a negotiated rate, we anticipate a cost savings to the Medicare Trust Fund.

In section II.C.2.m. of this final rule with comment period, we finalized technical corrections, clarifications, conforming changes, and redesignations in the regulations, which are not expected to have an impact on expenditures. Finally, in section II.C.3. of this final rule with comment period, we solicited comments on the existing cap on surgeon fees for cadaveric kidney excisions and provided a summary of the comments received; there is no expected impact of the comment solicitation.

Comment: With regard to the organ counting proposal, some commenters believed that Medicare's impact estimate was underestimated and imprecise when using SRTR payor data to estimate organs transplanted into Medicare beneficiaries. One commenter suggested we calculate and use an "in-house" Medicare ratio for TH/HOPOs, as a proxy to apply to the

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<sup>77</sup> Scientific Registry of Transplant Recipients. Request for Information. Requested on 02/08/2021.

number of organs the TH/HOPO furnishes to other hospitals or OPOs which are transplanted into Medicare beneficiaries. Other commenters requested that Medicare study and publish a hospital specific impact analysis resulting from these proposals. Some commenters also raised concerns about the effects of this proposal on children's transplant hospitals.

Response: We thank commenters for bringing to our attention the need for additional analyses to better understand the effects of the Medicare usable organ and kidney counting proposal. Our proposed rule impact estimation methodology determined Medicare organ acquisition costs using 2018 cost data by organ type, by multiplying total acquisition costs by the SRTR payor data ratio for Medicare as the payor. We summed these organ-specific Medicare organ acquisition costs, and compared that total with the total Medicare organ acquisition costs calculated using the same methodology, but using the Medicare ratio from the cost report data rather than the SRTR ratio; the difference between the two Medicare organ acquisition cost amounts was the estimated savings for a single year.

After consideration of the public comments we received, we are not finalizing our organ counting proposals, and may revisit this proposal in future rulemaking.

#### D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We

welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought public comments on this assumption. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$114.24 per hour, including overhead and fringe benefits [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm) . Assuming an average reading speed, we estimate that it would take approximately 4.16 hours for the staff to review half of this final rule with comment period. For each entity that reviews the rule, the estimated cost is \$475.24 (4.16 hours x \$114.24). Therefore, we estimate that the total cost of reviewing this rule is \$270,886.80 (\$475.24 x 570).

#### E. Alternatives Considered

This final rule with comment period contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

##### 1. Alternatives Considered for Distribution of Additional Residency Positions Under the Provisions of Section 126 of the CAA

Section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) of the Act requiring the distribution of additional residency positions to qualifying hospitals. Section 1886(h)(9)(A) of the Act requires that for FY 2023, and for each succeeding fiscal year until the aggregate number of FTE residency positions distributed is equal to 1,000, the Secretary shall initiate separate rounds of applications from hospitals for these additional residency positions.

After consideration of public comments, we are finalizing our proposal with modifications, that applicant hospitals are eligible for distribution of residency positions under section 126 if they meet the definition of any one or more of the statutory categories, Category One, Category Two, Category Three, or Category Four, as described in section II.B.3. of this final rule with comment period. Based on the residency training program for which the hospital is applying, the hospital will choose, if applicable, either a geographic or population HPSA where residents spend at least 50 percent of their training time. Hospitals will attest to meeting this 50 percent training criterion.

The HPSA scores associated with the geographic or population HPSAs chosen by hospitals that qualify under the aforementioned criteria will be ranked from highest to lowest and the 200 residency positions available for each FY will be prioritized in this manner, with each applicant hospital receiving up to 5.0 FTEs based on the length of the program associated with the hospital's application.

We considered alternative approaches for distribution of additional residency positions under the provisions of section 126 of the CAA. An alternative we considered was to distribute 200 additional residency positions for FY 2023 entirely among hospitals that qualify in Category One, Category Two, Category Three, and/or Category Four, with higher priority given to applications from hospitals that qualify in more categories. We would distribute 1.0 FTE to each hospital that qualified under all four categories, prorating only in the event that the number of hospitals that qualified under all four categories exceeds 200. However, given that we believe the additional residency positions distributed under section 126 of the CAA should be consistent with the Administration's goal of advancing health equity in underserved communities, we believe prioritizing applications based on HPSA scores is a feasible means to achieve this goal. Therefore, we are not finalizing our proposed alternative.

## 2. Alternatives Considered for Counting Organs used to Determine Medicare's Share of Organ Acquisition Costs

After consideration of public comments, we considered two alternatives for counting organs used to determine Medicare's share of organ acquisition costs: (1) withdrawing the proposal; or (2) finalizing the proposal but with a delay or a delay with a transition. Although we believe our proposed organ counting policy is appropriate and consistent with Medicare's anti cross-subsidization principles at section 1861(v) of the Act, and our regulations at 42 CFR 413.5, which do not permit the Medicare program to bear the costs of non-Medicare patients, we have decided to not finalize the proposal to allow more time to better understand concerns that commenters have raised. We would like more time to thoroughly evaluate some of the concerns raised by commenters, such as those related to tracking the payor status of the organ recipients, to ensure that the policy can be operationalized by all OPOs and THs without a disruption to the transplantation ecosystem. We also recognize commenters' concerns about other changes occurring in the transplantation ecosystem which compete for time and resources, such as adapting to the new organ allocation system and initiatives to increase kidney transplantation. Therefore, we decided we are not finalizing our proposal at this time, and may revisit this proposal in future rulemaking.

### F. Accounting Statement and Table

As required by OMB Circular A-4 (available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), we have prepared an accounting statement in Table 6 showing the classification of the impact associated with the provisions of this final rule with comment period as they relate to Medicare GME payments to hospitals from FY 2021 to FY 2031. Table 6 provides our best estimate of the change in Medicare payments to providers as a result of the changes to the Medicare GME payments presented in this final rule with comment period. All expenditures are classified as transfers to Medicare providers.

**TABLE 6.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM FY 2021 TO FY 2031**

<b>Category</b>	<b>7% Discount Rate</b>	<b>3% Discount Rate</b>
Annualized Monetized Transfers	\$245.25 Million	\$277.30 Million
From Whom to Whom?	Federal Government to Medicare Providers (Teaching Hospitals)	

G. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business. Table 7 details the size standards for those industries that may be affected by this rule, though we expect that General Medical and Surgical Hospitals would be most affected.

**TABLE 7.--SIZE STANDARDS BY AFFECTED INDUSTRY**

<b>NAICS Code</b>	<b>NAICS Industry Description</b>	<b>Size Standard (in millions)</b>
622110	General Medical and Surgical Hospitals	\$ 41.5
622210	Psychiatric and Substance Abuse Hospitals	\$ 41.5
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	\$ 41.5

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule with comment period are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS’s practice in interpreting the RFA’s reference to a “significant economic impact on a substantial number of small entities” is to consider effects economically "significant” if greater than 5 percent of small providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. Based on our analysis described in section IV.C. this final rule with comment period,

we believe that the overall impact on hospitals as a whole, and thus on small entities specifically, of the provisions of this final rule with comment period will not exceed the 3 to 5 percent threshold discussed previously. Therefore, the Secretary has determined that this final rule with comment period will not have significant economic impact on a substantial number of small entities. We note that for some hospitals, these estimates may represent the total expected impact on their inpatient hospital revenue; for other hospitals, this represents only a portion of the total expected impact, as much of their revenue comes from non-Medicare cases. We estimate that hospitals will experience a net benefit resulting from the GME provisions of this final rule with comment period, as such we do not expect small entities to incur significant costs.

This final rule with comment period contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the policies, and presents rationales for our decisions and, where relevant, alternatives that were considered, including those alternatives discussed in section IV.E. of this final rule with comment period. The analyses discussed in this RIA and throughout the preamble of this final rule with comment period constitutes our regulatory flexibility analysis. We solicited public comments on our estimates and analysis of the impact of our policies on small entities. We received no public comments on those estimates and analysis other than the comments noted in section IV.C.1. and IV.C.2. of this final rule with comment period. As discussed in section IV.C.2. of this final rule with comment period, there is no impact on hospitals or OPOs in FY 2022 from the final organ acquisition policies discussed in this final rule with comment period. Also, as discussed previously, in this final rule with comment period we are finalizing policies to implement section 126 of the CAA of 2021, which makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in FY 2023. A separate round of applications from hospitals will be initiated for these additional residency positions, and hospitals must be notified of the number of positions distributed to them by January 31 of the fiscal year, effective beginning July 1 of that fiscal year.

Teaching hospitals that apply timely and are awarded FTE residency positions will experience an increase in their Medicare GME payments once the hospital fills the positions. However, until hospitals submit applications requesting the FTE residency positions and submit documentation demonstrating they meet the eligibility criteria and other requirements, we do not know which hospitals or what types of hospitals will receive additional FTE residency positions under this provision. To the extent that small rural hospitals apply for and receive FTE residency positions under this provision, they will experience an increase in their GME payments. Therefore, the Secretary has certified that this final rule with comment period will have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As explained previously, to the extent that small rural hospitals apply for and receive FTE residency positions, they will experience an increase in their GME payments. Therefore, the Secretary has certified that this final rule with comment period will have a significant impact on the operations of a substantial number of small rural hospitals.

However, we note that the organ acquisition policies for transplant hospitals will not have a significant impact, as no certified transplant hospitals are small rural hospitals. Additionally, while some donor community hospitals may be small rural hospitals, we are making changes to their billing practices which should not affect hospital operations as donor community hospitals will be paid the lesser of their reasonable cost or a negotiated rate.

We assume that the costs for reviewing this rule is the same for small entities as it is for larger entities. For each entity that reviews the rule, the estimated cost is \$475.24 (4.16 hours x



\$114.24). Therefore, we estimate that the total cost of reviewing this rule is \$270,886.80 (\$475.24 x 570).

#### H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately \$158 million. This final rule with comment period would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$158 million in any 1 year.

#### I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule with comment period) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on state or local governments, preempt states, or otherwise have a Federalism implication.

This final rule with comment period is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

#### **V. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

*Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 14, 2021.*

## **List of Subjects**

### **42 CFR Part 412**

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements

### **42 CFR Part 413**

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services is amending 42 CFR Chapter IV as set forth below:

**PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES**

1. The authority citation for Part 412 continues to read as follows:

**Authority:** 42 U.S.C. 1302 and 1395hh.

2. Section 412.1 is amended by revising paragraph (a)(1)(ii) to read as follows:

**§ 412.1 Scope of part.**

(a) \* \* \*

(1) \* \* \*

(ii) Payment for other costs related to inpatient hospital services is made on a reasonable cost basis as follows:

(A) Organ acquisition costs incurred by hospitals with approved organ transplant programs.

(B) The costs of qualified nonphysician anesthetist's services, as described in § 412.113(c).

(C) Direct costs of approved nursing and allied health educational programs.

(D) Costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant as described in § 412.113(e).

\* \* \* \* \*

3. Section 412.2 is amended by revising paragraph (e)(4) to read as follows:

**§ 412.2 Basis of payment.**

\* \* \* \* \*

(e) \* \* \*

(4) The acquisition costs of hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved transplant programs.

\* \* \* \* \*

4. Section 412.71 is amended by revising paragraph (b)(3) to read as follows:

**§412.71 Determination of base-year inpatient operating costs.**

\* \* \* \* \*

(b) \* \* \*

(3) Kidney acquisition costs incurred by hospitals with approved kidney transplant programs as described in § 412.100. Kidney acquisition costs in the base year are determined by multiplying the hospital's average kidney acquisition cost per kidney times the number of kidney transplants covered by Medicare Part A during the base period.

\* \* \* \* \*

5. Section 412.90 is amended by revising paragraph (d) to read as follows:

**§ 412.90 General rules.**

\* \* \* \* \*

(d) *Kidney acquisition costs incurred by hospitals with approved kidney transplant programs.* CMS pays for kidney acquisition costs incurred by kidney transplant programs on a reasonable cost basis. The criteria for this special payment provision are set forth in §412.100.

\* \* \* \* \*

6. Section 412.100 is revised to read as follows:

**§ 412.100 Special treatment: Kidney transplant programs.**

(a) *Adjustments for kidney transplant programs.* (1) CMS adjusts the inpatient prospective payment system (IPPS) rates for inpatient operating costs determined under subparts D and E of this part for hospitals with approved kidney transplant programs (discussed at § 482.104 of this chapter) to remove the net costs associated with kidney acquisition.

(2)(i) Payment for Medicare kidney acquisition costs, as set forth in subpart L of part 413 of this chapter, is made on a reasonable cost basis apart from the prospective payment rate for inpatient operating costs.

(ii) IPPS payment to the hospital is adjusted in each cost reporting period to reflect an amount necessary to compensate the hospital for reasonable costs of Medicare kidney acquisition.

(b) *Costs of kidney acquisition.* Kidney acquisition costs include costs incurred in the acquisition of a kidney from a living or a cadaveric donor, by the hospital or an organ procurement organization, as appropriate. These costs are listed in § 413.402(b) of this chapter.

7. Section 412.105 is amended by:

a. Revising paragraph (a)(1)(i);

b. Adding paragraph (f)(1)(iv)(C)(3); and

c. Revising paragraphs (f)(1)(v)(F), (f)(1)(vii), and (f)(1)(x).

The addition and revisions read as follows:

**§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.**

(a) \* \* \*

(1) \* \* \*

(i) Except for the special circumstances for Medicare GME affiliated groups, emergency Medicare GME affiliated groups, and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, and for Rural Track Programs within their 5-year cap building period described in paragraph (f)(1)(x)(B) in cost reporting periods beginning on or after October 1, 2022, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

\* \* \* \*

(f) \* \* \*

(1) \* \* \*

(iv) \* \* \*

(C) \* \* \*

(3) Effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in § 413.79(p) of this subchapter are met.

\* \* \* \*

(v) \* \* \*

(F)(I) Subject to the provisions of paragraph (f)(1)(x) of this section, effective for cost reporting periods beginning on or after April 1, 2000, and beginning before October 1, 2022, full-time equivalent residents at an urban hospital in a rural track program are included in the urban hospital's rolling average calculation described in paragraph (f)(1)(v)(B) of this section.

(2) Subject to the provisions of paragraph (f)(1)(x) of this section, for cost reporting periods beginning on or after October 1, 2022, full-time equivalent residents at an urban hospital or rural hospital in a Rural Track Program are excluded from the rolling average calculation described in paragraph (f)(1)(v)(B) of this section during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

\* \* \* \*

(vii)(A) If a hospital establishes a new medical residency training program, as defined in § 413.79(l) of this subchapter, the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of § 413.79(e) of this subchapter.

(B)(I) A hospital that, as of December 27, 2020, has a full-time equivalent cap of less than 1.0 FTE based on a cost reporting period beginning before October 1, 1997, that begins

training residents in a new medical residency training program, as defined at § 413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains at least 1.0 FTE in such new medical residency training program(s), to be calculated in accordance with § 413.79(e) of this subchapter.

(2) A hospital that has a full-time equivalent cap of no more than 3.0 FTEs based on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, that begins training residents in a new medical residency training program, as defined at § 413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains more than 3.0 FTE in such new medical residency training program(s), to be calculated in accordance with the provisions of § 413.79(e) of this subchapter.

\* \* \* \* \*

(x)(A) For rural track programs started in a cost reporting period beginning before October 1, 2022, an urban hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter), or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks in accordance with the applicable provisions of § 413.79(k) of this subchapter.

(B) For cost reporting periods beginning on or after October 1, 2022, an urban hospital or rural hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter) that is a Rural Track Program (as defined at § 413.75(b) of this subchapter), or adds an additional site to a Rural Track Program, may include in its FTE count residents in the Rural Track Program in accordance with the applicable provisions of § 413.79(k) of this subchapter.

\* \* \* \* \*

8. Section 412.113 is amended by revising paragraph (d) to read as follows:

**§ 412.113 Other payments.**

\* \* \* \* \*

(d) *Organ acquisition.* Payment for organ acquisition costs as specified in part 413, subpart L, incurred by hospitals with approved transplant programs is made on a reasonable cost basis.

\* \* \* \* \*

8. Section 412.116 is amended by revising paragraph (c) to read as follows:

**§ 412.116 Method of payment.**

\* \* \* \* \*

(c) *Special interim payments for certain costs.* For capital-related costs for cost-reporting periods beginning before October 1, 1991, and the direct costs of medical education, which are not included in prospective payments but are reimbursed as specified in §§ 413.130 and 413.85 of this chapter, respectively, interim payments are made subject to final cost settlement. Interim payments for capital-related items for cost-reporting periods beginning before October 1, 1991, and the estimated cost of approved medical education programs (applicable to inpatient costs payable under Medicare Part A and for kidney acquisition costs in hospitals with approved kidney transplant programs) are determined by estimating the reimbursable amount for the year based on the previous year's experience and on substantiated information for the current year and divided into 26 equal biweekly payments. Each payment is made 2 weeks after the end of a biweekly period of services, as described in § 413.64(h)(5) of this subchapter. The interim payments are reviewed by the intermediary at least twice during the reporting period and adjusted if necessary.

\* \* \* \* \*

**PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES**

9. The authority citation for part 413 continues to read as follows:



**Authority:** 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

10. Section 413.1 is amended by revising paragraphs (a)(2)(v) and (d)(2)(i) to read as follows:

**§413.1 Introduction.**

(a) \* \* \*

(2) \* \* \*

(v) Organ procurement organizations (OPOs) and histocompatibility laboratories.

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(i) Payment for the following is described in § 412.113 of this chapter:

(A) Capital related costs for cost reporting periods beginning before October 1991.

(B) Medical education costs.

(C) Organ acquisition costs as specified in part 413, subpart L.

(D) The costs of certain anesthesia services.

\* \* \* \* \*

11. Section 413.40 is amended by revising paragraph (a)(3) to read as follows:

**§413.40 Ceiling on the rate of increase in hospital inpatient costs.**

(a) \* \* \*

(3) *Net inpatient operating costs* include the costs of certain preadmission services as specified in paragraph (c)(2) of this section, the costs of routine services, ancillary services, and intensive care services (as defined in §413.53(b)) incurred by a hospital in furnishing covered inpatient services to Medicare beneficiaries. Net inpatient operating costs exclude capital-related costs as described in § 413.130, the costs of approved medical education programs as described in §§ 413.75 through 413.83 and 413.85, and organ acquisition costs as specified in subpart L of

this part incurred by approved transplant programs. These costs are identified and excluded from inpatient operating costs before the application of the ceiling.

\* \* \* \* \*

12. In § 413.75 amend paragraph (b) by:

a. In the definition of “Rural track FTE limitation”, by removing the phrase “urban hospital may include in its” and adding in its place the phrase “urban hospital or rural hospital may include in its”;

b. Revising the definition of “Rural track or integrated rural track”;

c. Adding in alphabetical order the definition of “Rural Track Program”.

The addition and revision read as follows:

**§ 413.75 Direct GME payments: General requirements.**

\*\*\*\*\*

(b) \*\*\*

*Rural track or integrated rural track* means, for programs started in cost reporting periods prior to October 1, 2022, an approved medical residency training program established by an urban hospital in which residents train for a portion of the program at the urban hospital and then rotate for a portion of the program to a rural hospital(s) or a rural nonhospital site(s).

*Rural Track Program* means, effective for cost reporting periods beginning on or after October 1, 2022, an ACGME-accredited program in which residents/fellows gain both urban and rural experience with more than half of the education and training for a resident/fellow taking place in a rural area as defined at 42 CFR 412.62(f)(iii).

\*\*\*\*\*

13. Section 413.77 is amended by revising paragraph (e)(1)(iii) and adding paragraphs (e)(1)(iv) and (v) to read as follows:

**§ 413.77 Direct GME payments: Determination of per resident amounts.**

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

(iii) If, under paragraph (e)(1)(ii)(A) or (B) or (e)(1)(iv)(B) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

(iv) A hospital that, as of December 27, 2020, has a per resident amount based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997, may choose to receive a recalculated per resident amount either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost reporting period beginning after [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. A hospital that, as of December 27, 2020, has a per resident amount based on no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, may choose to receive a recalculated per resident amount either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning after [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. In either case, residents need not be on duty during the first month of the cost reporting period. The recalculated per resident amount is based on the lower of--

(A) The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's base year cost reporting period, which is, for hospitals with a per resident amount previously based on less than 1.0 FTE, either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after

December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost reporting period beginning after [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]; and for hospitals with a per resident amount previously based on not more than 3.0 FTEs, either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning after [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]; or

(B) The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(v) Effective for a cost reporting periods beginning on or after December 27, 2020, a per resident amount must be established if a hospital trains less than 1.0 FTE resident and this training results from the hospital's participation in a Medicare GME affiliation agreement under § 413.79(f). Effective for a cost reporting period beginning on or after December 27, 2020, a per resident amount must only be established when the hospital trains at least 1.0 FTE and does not participate in a Medicare GME affiliation agreement under § 413.79(f) for that training.

Residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.

\* \* \* \* \*

14. Section 413.78 is amended by revising paragraph (b) to reads as follows:

**§ 413.78 Direct GME payments: Determination of the total number of FTE residents**

\* \* \* \* \*

(b)(1) No individual resident may be counted as more than one FTE based on the total time spent in training at all sites. A hospital cannot claim the time spent by residents training at another hospital, except as provided in paragraph (i) of this section. Except as provided in

paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a non-provider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

(2) Effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if it does not participate in a Medicare GME affiliation agreement (as defined under § 413.75(b)), and the hospital trains at least 1.0 FTE in an approved program or programs, or, if the hospital trains less than 1.0 FTE residents in an approved program or programs and this training results from the hospital's participation in a Medicare GME affiliation agreement (as defined under §413.75(b)).

\* \* \* \* \*

15. Section 413.79 is amended by—

- a. Revising paragraph (c)(2) introductory text;
- b. Revising paragraph (d)(7);
- c. Adding paragraphs (e)(1)(vi), (e)(6), and (f)(8);
- d. Revising paragraphs (k) introductory text, (k)(1), (k)(2) introductory text, (k)(2)(i), and (k)(3);
- e. Adding paragraph (k)(4)(i)(C);
- f. Revising paragraph (k)(4)(ii) introductory text;
- g. Adding (k)(4)(ii)(C);
- h. In paragraph (k)(5)(i), removing the phrase “An urban hospital may not include in its rural track FTE limitation or (assuming the urban hospital's FTE” and adding in its place the phrase “A hospital may not include in its rural track FTE limitation or (assuming the hospital's FTE”;

- i. In paragraph (k)(5)(ii), removing the phrase “The hospital” and adding in its place the phrase “Each hospital”; and
- j. Adding paragraphs (k)(5)(iv) and (p).

The revisions and additions read as follows:

**§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.**

\* \* \* \* \*

(c) \* \* \*

(2) *Determination of the FTE resident cap.* Subject to the provisions of paragraphs (c)(3) through (6) and (m) through (p) of this section and § 413.81, for purposes of determining direct GME payment—

\*\*\*\*\*

(d) \* \* \*

(7)(i) Subject to the provisions under paragraph (k) of this section, effective for cost reporting periods beginning on or after April 1, 2000 and before cost reporting periods beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital are included in the urban hospital's rolling average calculation described in this paragraph (d).

(ii) Subject to the provisions under paragraph (k) of this section, effective for rural track programs started in a cost reporting period beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital or rural hospital are excluded from rolling average calculation described in this paragraph (d) during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

(e) \* \* \*

(1) \* \* \*

(vi) In the case of a hospital that, as of December 27, 2020, has a FTE cap based on the training of less than 1.0 FTE in any cost reporting period beginning before October 1, 1997; or

based on the training of no more than 3.0 FTEs in on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, if such a hospital begins training residents in a new approved program (as defined under § 413.79(l)) in a program year beginning on or after December 27, 2020 and before December 26, 2025, the hospital with a previous FTE cap of less than 1.0 FTE may receive an adjusted FTE cap when it begins to train at least 1.0 FTE in a new program(s); and the hospital with a previous FTE cap of no more than 3.0 FTEs may receive an adjusted FTE cap when it begins to train more than 3.0 FTEs in a new program(s). The adjusted FTE cap is equal to the sum of the original FTE cap and the products of the following three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence started in a program year beginning on or after December 27, 2020 and before December 26, 2025, at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

\* \* \* \* \*

(6) Effective for a cost reporting period beginning on or after December 27, 2020, FTE resident caps must be established when the hospital trains 1.0 or more FTE residents in a new medical residency program (as defined under paragraph (l) of this section).

(f) \* \* \*

(8) FTE resident cap slots added under section 126 of Pub. L. 116-260 may be used in a Medicare GME affiliation agreement beginning in the fifth year after the effective date of those FTE resident cap slots.

\* \* \* \* \*

(k) *Residents training in rural track programs.* Subject to the provisions of § 413.81, an urban hospital that establishes a new residency program, or has an existing residency program, with a rural track (or an integrated rural track) may add the rotations of the residents in those rural tracks to its FTE cap specified under paragraph (c) of this section. An urban hospital (or, effective for a cost reporting period beginning on or after October 1, 2022, a rural hospital) with a Rural Track Program (as defined at section 413.75(b) of this subchapter) may count residents in those Rural Track Programs up to a rural track FTE limitation if the hospital complies with the conditions specified in paragraphs (k)(2) through (7) of this section.

(1) If an urban hospital rotates residents to a separately accredited rural track program at a rural hospital(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and before October 1, 2022, the urban hospital may include those residents in its FTE count for the time the rural track residents spend at the urban hospital, not to exceed its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if an urban hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural hospital(s) for more than one-half of the duration of the program, both the urban and the rural hospital may include those residents in their FTE counts for the time the rural track residents spend at the urban and rural hospital, respectively, not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost



reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For cost reporting periods beginning on or after October 1, 2022, , before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012 and before October 1, 2022, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section. For Rural Track Programs started on or after October 1, 2022, beginning with the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonprovider site(s) for two-thirds of the duration of the program for cost reporting periods

beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g). For cost reporting periods beginning on or after October 1, 2022, if an urban or rural hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural nonprovider site for more than one-half of the duration of the program, the urban or rural hospital may include those residents in its FTE count, subject to which hospital meets the requirements under § 413.78(g), not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s). For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s). For Rural Track Programs prior to the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each respective hospital will be the actual number of FTE residents training in the Rural Track Program at the hospital and, subject to the requirements under § 413.78(g), in the rural nonprovider site(s).

\* \* \* \* \*

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration

of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(4) \* \* \*

(i) \* \* \*

(C) For programs started in a cost reporting period beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(ii) For rural track programs started on or after October 1, 2012 and prior to October 1, 2022, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(g). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

\* \* \* \* \*

(C) For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(5) \* \* \*

(iv) Effective for cost reporting periods beginning on or after October 1, 2022, in order for an urban or rural hospital to receive a rural track FTE limitation, greater than 50 percent of the program must occur in a rural area.

\* \* \* \* \*

(p) *Determination of an increase in the otherwise applicable resident cap under section 126 of the Consolidated Appropriations Act (Pub. L. 116-260).* For portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

#### **Subpart H—Payment for End-Stage Renal Disease (ESRD) Services**

16. The subpart heading for Subpart H is revised to read as set forth above.

#### **§§ 413.200 [Removed and Reserved]**

17. Section 413.200 is removed and reserved.

18. Subpart L is added to read as follows:

#### **Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals, Organ**

#### **Procurement Organizations, and Histocompatibility Laboratories**

Sec.

413.400 Definitions.

413.402 Organ acquisition costs.

413.404 Standard acquisition charge.

413.406 Acquisition of pancreata for islet cell transplant.

413.408 [Reserved]

413.410 [Reserved]

413.412 Intent to transplant, and counting en bloc, research, and discarded organs.

- 413.414 Medicare secondary payer and organ acquisition costs.
- 413.416 Organ acquisition charges for kidney-paired exchanges.
- 413.418 Amounts billed to organ procurement organizations by donor community hospitals and transplant hospitals for hospital services provided to cadaveric donors in the hospital and included as organ acquisition costs.
- 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

**Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals. Organ Procurement Organizations, and Histocompatibility Laboratories**

**§ 413.400 Definitions.**

As used in this subpart:

*Histocompatibility laboratory* means a laboratory meeting the requirements set forth in § 493.1227 of this chapter and providing the services for the acquisition of kidneys or other organs for transplantation.

*Hospital-based organ procurement organization (HOPO)* means an organ procurement organization that is considered a department of the transplant hospital and reports organ acquisition costs it incurs on the transplant hospital's Medicare cost report.

*Independent organ procurement organization (IOPO)* means an organ procurement organization that files a Medicare cost report separate from a hospital and meets all of the following:

- (1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees.
- (2) Is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).
- (3) Reports organ acquisition costs it incurs on the IOPO Medicare cost report.

*Organ*, for Medicare organ acquisition payment purposes, means:

- (1) A human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

(2) Pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

*Organ procurement organization (OPO)* means an organization defined in §486.302 of this chapter. OPOs can be independent or hospital based.

*Standard acquisition charge (SAC)* means a charge as defined in §413.404 of this chapter.

*Transplant hospital* means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

*Transplant hospital/HOPO (TH/HOPO)* refers to a transplant hospital, or a transplant hospital that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the transplant hospital's Medicare cost report.

*Transplant program* means an organ-specific transplant program within a transplant hospital (as defined in this section).

#### **§ 413.402 Organ acquisition costs.**

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are costs incurred in the acquisition of organs from a living donor or a cadaveric donor, by the hospital or an organ procurement organization, as appropriate. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.

(b) *Types of costs.* Organ acquisition costs are as follows:

- (1) Tissue typing, including tissue typing furnished by independent laboratories.
- (2) Donor and beneficiary evaluation.

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or cadaveric donor.

(4) Operating room and other inpatient ancillary services applicable to the living or cadaveric donor.

(5) Organ preservation and perfusion costs.

(6) Organ Procurement and Transplantation Network registration fees, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.

(7) Surgeons' fees for excising cadaveric organs (currently limited to \$1,250 for kidneys).

(8) Transportation of the:

(i) Excised organ to the transplant hospital; and

(ii) Cadaveric donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

(9) Costs of organs acquired from other hospitals or organ procurement organizations.

(10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission).

(11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs.

(12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and the costs of physicians' services.

(c) *Living donor complications.* (1) *Living kidney donor complications.* Living kidney donor complications directly related to the kidney donation, which occur after the date of the donor's discharge, must not be reported as kidney acquisition costs on the Medicare cost report.

(A) Medicare covers reasonable costs incurred for living kidney donor complications only if they are directly related to a kidney donation for a covered transplant into a Medicare beneficiary.

(B) Living kidney donor complications are paid through the claims processing system under Medicare Part A or Part B, as applicable for the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the Medicare Beneficiary Identifier of the transplant recipient.

(2) *Living non-renal donor complications.* Hospital costs incurred for living non-renal donor complications directly related to the non-renal organ donation, which occur after the date of the donor's discharge are not paid through the claims processing system but are reported as organ acquisition costs on the hospital's Medicare cost report.

(A) Medicare covers reasonable hospital costs incurred for living non-renal organ donor complications only if they are directly related to a non-renal organ donation for a covered transplant into a Medicare beneficiary.

(B) Hospital costs incurred for living non-renal organ donor complications are reported as organ acquisition costs on the Medicare cost report, and paid through the cost report on a reasonable cost basis.

(d) *Costs not related to organ acquisition.* (1) Items or services that are not related or reasonable to acquire an organ for transplantation, non-allowable administrative and general costs, or costs that are not related to patient care, are not considered organ acquisition costs.

(2) Examples of items or services that are not organ acquisition costs include, but are not limited to: the following:

(i) Donor burial and funeral expenses.

(ii) Transportation costs of the cadaveric donor after organ procurement for funeral services or for burial.

(iii) Transportation costs for a living donor.



(iv) Fees or in-center payments for donor referrals.

(v) Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at §486.326(b)).

(vi) Unreasonable costs incurred for administrator's duties associated with professional organizations.

**§ 413.404 Standard acquisition charge.**

(a) *General.* (1) Procuring an organ is not a covered service when performed independent of a Medicare covered transplant, however, the reasonable costs to procure an organ are reimbursable when billed in connection with a Medicare covered transplant.

(2) The SAC represents the average of the total organ acquisition costs associated with procuring either cadaveric donor organs or living donor organs, by organ type.

(3) When a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, it bills its SAC to the TH/HOPO or IOPO receiving the organ.

(b) *THs/HOPOs SACs.* (1) A TH/HOPO must develop a SAC for each organ type (for example heart, liver, or lung).

(2) When a TH/HOPO furnishes an organ to another transplant hospital or IOPO, it must bill the receiving transplant hospital or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A transplant hospital must establish SACs for living donor organs. A TH/HOPO must establish SACs for cadaveric donor organs.

(i) *Living donor SAC for transplant hospitals—(A) Definition.* The living donor SAC is an average organ acquisition cost that a transplant hospital incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A transplant hospital must establish a living donor SAC (living SAC) before the transplant hospital bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC—(1) Initial living donor SAC.* A transplant hospital calculates its initial living donor SAC for each living organ type as follows:

(i) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.

(ii) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(1)(i) of this section by the projected number of usable living donor organs to be procured by the transplant hospital during the transplant hospital's cost reporting period.

(2) *Subsequent living donor SAC.* A transplant hospital calculates its subsequent years' living donor SAC for each living organ type as follows:

(i) By using the transplant hospital's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(ii) Dividing the costs in paragraph (b)(3)(i)(C)(2)(i) of this section by the actual number of usable living donor organs procured by the transplant hospital during that prior cost reporting period.

(D) *Costs used to develop the living donor SAC.* Costs that may be used to develop the living donor SAC include, but are not limited to the following:

(1) Costs of tissue typing services, including those furnished by independent laboratories.

(2) Costs of physician pre-admission transplant evaluation services.

(3) Registry fees as specified at § 413.402(b)(6) of this subpart.

(4) Costs for donor and recipient evaluations and workups furnished prior to admission for transplantation.

(5) Other costs associated with procurement, for example, general routine and special care services (for example, intensive care unit or critical care unit services), related to the donor.

(6) Costs of operating room and other inpatient ancillary services related to the donor.

(7) Organ preservation and perfusion costs.

(8) Transportation costs of the excised organ as specified in § 413.402(b)(8)(i) of this subpart.

(ii) *Cadaveric donor SAC for THs/HOPOs—(A) Definition.* The cadaveric donor SAC is an average cost that a TH/HOPO incurs to procure a cadaveric donor organ.

(B) *Calculating the cadaveric SAC—(1) Initial cadaveric donor SAC.* A TH/HOPO calculates its initial cadaveric SAC for each cadaveric organ type as follows:

(i) By estimating the reasonable and necessary costs it expects to incur to procure cadaveric organs, combined with the expected costs of acquiring cadaveric organs from OPOs or other transplant hospitals.

(ii) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(1)(i) of this section by the projected number of usable cadaveric organs to be procured by the TH/HOPO within the transplant hospital's cost reporting period.

(2) *Subsequent cadaveric donor SAC.* A TH/HOPO calculates its subsequent years' cadaveric donor SAC for each cadaveric organ type as follows:

(i) By using the transplant hospital's actual organ acquisition costs for the cadaveric donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(ii) By dividing the costs in paragraph (b)(3)(ii)(B)(2)(i) of this section by the actual number of usable cadaveric donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the cadaveric donor SAC.* Costs that may be used to develop the cadaveric donor SAC include, but are not limited to the following:

- (1) Costs of organs acquired from other transplant hospitals or OPOs.
  - (2) Costs of transportation as specified in §413.402(b)(8) of this subpart.
  - (3) Surgeons' fees for excising cadaveric organs (currently limited to \$1,250 for kidneys).
  - (4) Costs of tissue typing services, including those furnished by independent laboratories.
  - (5) Organ preservation and perfusion costs.
  - (6) General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).
  - (7) Operating room and other inpatient ancillary service costs.
- (c) *Independent OPO SACs*—(1) *Non-renal SAC.* An IOPO establishes non-renal SACs based on its costs of procuring non-renal organs for each organ type, by—
- (i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure cadaveric donor non-renal organs during the IOPO's cost reporting period; and
  - (ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of cadaveric donor non-renal organs the IOPO expects to procure within its cost reporting period.
  - (iii) An IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

(2) *Kidney SAC.* (i) *General.* An IOPO's Medicare contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure cadaveric kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable cadaveric kidneys the IOPO expects to procure.

(ii) *Initial year.* The Medicare contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years.* The kidney SAC for subsequent years is computed using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable cadaveric kidneys procured during that cost reporting period. The SAC is the basis for the interim payments by the transplant hospital to the IOPO, as set forth in § 413.420(d).

(iv) The IOPO's Medicare contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

(v) The IOPO cannot use or change its kidney SAC without the contractor's approval.

(3) *Billing SACs for organs generally.* When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type and not the procuring IOPO's SAC when billing the transplant hospital receiving the organ.

#### **§ 413.406 Acquisition of pancreata for islet cell transplant.**

(a) Medicare only covers and pays for reasonable costs of acquisition on or after October 1, 2004, of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

(b) Pancreata procured under paragraph (a), for covered islet cell transplants must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

**413.408 [Reserved]**

**413.410 [Reserved]**

**§ 413.412 Intent to transplant, and counting en bloc, research, and discarded organs and kidneys.**

(a) *Principle of intent to transplant for organ acquisition payment purposes.* (1) An organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s).

(2) OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type.

(b) *Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and THs count—

(1) En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

(2) En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

(c) *Research organs.* For Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)) and kidneys used for research are not counted as Medicare usable kidneys in Medicare's share of kidney acquisition costs.

(d) *Counting of discarded/unusable organs.* An organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or

after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded.

**§413.414 Medicare secondary payer and organ acquisition costs.**

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer to the transplant hospital that performs the transplant in certain instances. To determine whether Medicare has liability to the transplant hospital that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the transplant hospital that performs the transplant to review the transplant hospital's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the transplant hospital to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the transplant hospital that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the transplant hospital receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability to the transplant hospital that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the transplant hospital that performs the transplant to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the transplant hospital must not count the organ as a Medicare usable organ.

(3) If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and all of the following must occur:

(i) The transplant hospital must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the transplant hospital that performs the transplant counts the organ as a Medicare usable organ.

(iii) The portion of the payment applicable to organ acquisition is used on the cost report to reduce the Medicare organ acquisition costs.

#### **§ 413.416 Organ acquisition charges for kidney-paired exchanges.**

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's transplant hospital, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's transplant hospital and performed by the donor's transplant hospital, are billed to the recipient's transplant hospital as charges reduced to cost (using the donor's transplant hospital's cost to charge ratio) and included as acquisition costs on the recipient transplant hospital's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's transplant hospital procures and furnishes a kidney to a recipient's transplant hospital all of the following are applicable:



(1) All costs must be reasonable and necessary.

(2)(i) The donor's transplant hospital bills the recipient's transplant hospital.

(ii) The donor's transplant hospital bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's transplant hospital records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's transplant hospital against its kidney acquisition costs.

(4) The recipient's transplant hospital records as part of its kidney acquisition costs—

(i) The amounts billed by the donor's transplant hospital for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's transplant hospital.

(d) *Donor's procurement occurs at recipient transplant hospital.* In a kidney-paired exchange—

(1) When a donor's transplant hospital does not procure a kidney, but the donor travels to the recipient's transplant hospital for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's transplant hospital; and

(2) The travel expenses of the living donor are not allowable Medicare costs.

**§ 413.418 Amounts billed to organ procurement organizations by donor community hospitals and transplant hospitals for hospital services provided to cadaveric donors in the hospital and included as organ acquisition costs.**

(a) *General.* A donor community hospital (a Medicare-certified non-transplant hospital) and a transplant hospital incur organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate.

(b) *Amounts billed for organ acquisition costs.* For cost reporting periods beginning on or after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], when a donor community hospital or a transplant hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital or transplant hospital must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

**§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.**

(a) *Principle.* (1) Covered services furnished after September 30, 1978, by OPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the transplant hospital using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by HOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* Definitions relevant to this section can be found in § 413.400.

(c) *Agreements with IOPOs and laboratories.* (1) Any IOPO or histocompatibility laboratory that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or laboratory agrees to do all of the following:

(i) To file a cost report in accordance with § 413.24(f) within 5 months following the close of the period covered by the report.

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate payable by the transplant hospitals for services provided by the IOPO or laboratory and to determine the reasonable cost based upon the cost report filed by the IOPO or laboratory.

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.

(iv) To pay to CMS amounts that have been paid by CMS to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an IOPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c)(1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Transplant hospitals with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is based on a kidney SAC or contractor established rates, associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the Medicare contractor determines it according to the IOPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by transplant hospitals on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all transplant hospitals and contractors.

(e) *Retroactive adjustment*—(1) *Cost reports*. Information provided in cost reports by IOPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in §413.24. These cost reports must provide the following:

(i) A complete accounting of the cost incurred by the IOPO or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services.

(ii) Any other data necessary to enable the contractor to determine the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment*. A cost report submitted by an IOPO or histocompatibility laboratory is reviewed by the contractor and a new interim reimbursement rate for kidney acquisition costs for the subsequent fiscal year is established based upon this review.

(i) A retroactive adjustment in the amount paid under the interim rate is made in accordance with §413.64(f).

(ii) If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

(f) *Payment requirements*. For services furnished on or after April 1, 1988, no payment may be made for services furnished by an IOPO that does not meet the requirements of part 486, subpart G, of this chapter.

(g) *Appeals*. If the amount in controversy is \$1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, in accordance with the procedures set forth in §§ 405.1811 through 405.1833 of this chapter.

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**Xavier Becerra,**

Secretary,

Department of Health and Human Services.