California Hospital Association

Federal Regulatory Summary

as prepared by Health Policy Alternatives, Inc.

SUMMARY OF FINAL RULE – JANUARY 2022

FFY 2022 IPPS/LTCH SUPPLEMENTAL FINAL RULE – GRADUATE MEDICAL EDUCATION AND ORGAN ACQUISITION PAYMENT PROVISIONS

Overview

On December 17, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a final rule with comment period implementing legislative changes to Medicare payments to teaching hospitals contained in the Consolidated Appropriations Act (CAA) and addressing organ acquisition payment policies through changes, clarifications, and codifications relative to organ procurement organizations (OPOs), transplant hospitals, and donor community hospitals.

The graduate medical education (GME) provisions listed below are the only issues subject to public comment:

- How CMS can incorporate a measure of care that hospitals located outside of a health professional shortage area (HPSA) are providing care to residents of a HPSA when distributing and prioritizing allocation of new medical resident slots.
- Alternatives to using HPSA scores to evaluate shortage areas.
- How to handle review of per resident amounts (PRA) and full time equivalent (FTE) resident caps for hospital cost reports that are beyond the 3-year reopening period when implementing section 131 of the CAA that allows hospitals with low PRAs and FTE caps for training a small number of residents for a short duration of time to request a reset.

The following is a comprehensive summary, prepared by Health Policy Alternatives, Inc., of the provisions in the final rule.

To Comment

Comments are due to CMS by 2 p.m. (PT) on February 25 and can be submitted electronically at https://www.regulations.gov/document/CMS_FRDOC_0001-3231.

For Additional Information

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1115 Waiver Days in the Medicaid Fraction for Medicare Disproportionate Share

Under a section 1115 demonstration project, some states extend Medicaid coverage to populations that would otherwise be ineligible for Medicaid. While CMS' intent has been to only count these waiver populations in the Medicaid fraction of the Medicare DSH calculation when inpatient coverage is provided, several courts have found the regulations are more expansive. These courts are requiring CMS to include patient days in the Medicaid fraction when hospitals receive payment from an uncompensated care pool and days of patients who receive premium assistance under section 1115 demonstration programs.

Considering these court decisions, CMS proposed to modify its regulation to ensure that the only section 1115 of the Act waiver days that may be counted in the numerator of the Medicaid fraction are the days of patients for whom the waiver provides inpatient hospital insurance coverage benefits directly to that patient on that day. Due to the number and nature of the comments that CMS received on its proposal, CMS intended to address the public comments in a separate document. However, after further consideration, CMS will not be moving forward with its current proposal. It expects to revisit the issue in future rulemaking.

Payments for Indirect and Direct Graduate Medical Education Costs

Background

Medicare pays hospitals for direct graduate medical education (DGME) and indirect medical education (IME) costs based on the number of FTE residents they train. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare DGME and IME payments the hospital will receive. Since 1997, the law has limited the number of residents a hospital may count for DGME and IME (other than dental and podiatric residents) to the amount they counted in 1996.

The law also provides incentives to reduce the number of residents and disincentives to increase the number of residents by basing DGME and IME payment on a 3-year rolling average count of residents (e.g., the hospital would only gain or lose 1/3 of each FTE resident for each resident added or subtracted from the training program).

One component of the IME payment formula considers the hospital's ratio of residents to beds (known as the IRB). A higher IRB will result in higher IME payments. The law caps a hospital's IRB ratio used for payment at its actual IRB from the prior year. The provision also provides disincentives to increase the number of residents as a hospital will not receive the higher payments from a higher IRB until the following year.

There are rules that allow hospitals that are affiliated to jointly train residents to apply the FTE caps on an aggregate basis. These rules allow flexibility among these hospitals to continue those training relationships and allow increases in resident training above the cap at one hospital to be offset by lower resident training in another hospital. However, there are limitations on new

teaching hospitals that participate in resident training in newly established residency training programs from participating in affiliation agreements for their first five years as a teaching hospital. These rules are designed to prevent arrangements that will circumvent the statutory goal of limiting the number of Medicare subsidized residents nationally to the number counted in 1996.

Provisions of the CAA, 2021

Division CC of the CAA, 2021 contained 3 provisions affecting Medicare DGME 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 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 DGME 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 DGME PRA and DGME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration.

Distribution of Additional Residency Positions

Section 126 of the CAA authorizes the Secretary to distribute 1,000 new FTE slots over 5 years (limited to 200 per year) to applicant hospitals beginning in FY 2023. 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.

In determining the qualifying hospitals for which an increase is provided, the law requires the Secretary to take into account the demonstrated likelihood of the hospital filling the positions made available within the first five training years from the date the increase would be effective. 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:

1) Hospitals located in rural areas or treated as rural for IPPS purposes;
2) Hospitals that are training more residents than their FTE cap;
3) Hospitals in states with new medical schools or additional locations and branches of existing medical schools; and
4) Hospitals that serve patients from areas designated as HPSAs.

Hospitals are limited to receiving no more than 25 additional FTE residency positions and must agree to use all of the slots made available to them.

Application Deadline

CMS proposed that the application deadline will be January 31 of the fiscal year prior to the fiscal year the increase in FTEs becomes effective (e.g., for increases that are effective July 1, 2023, the application deadline would be January 31, 2022). CMS will provide an online application that must include all of the requested information to be considered complete. The application and instructions will be included on the CMS DGME website at: Direct Graduate Medical Education (DGME) | CMS. Section 1886(h)(9)(A)(ii)(II) of the Act requires the Secretary to notify an applicant hospital of the cap increase by January 31 of the fiscal year of the increase (January 31, 2023 for an increase beginning July 1, 2023).

Comments/Responses and Final Decision: Many commenters expressed concern that January 31 is the last day that hospitals can amend their residency quotas for the National Resident Match Program (NRMP). An earlier announcement date of their awards will be needed to accommodate the number of residents that hospitals will request through the NRMP. CMS acknowledged these comments and will consider completing its award announcement earlier if possible.

A commenter recommended postponing the application deadline for the first round to March 31, 2022. In the final rule, CMS changed the application deadline to March 31, 2022 for increases that will be effective July 1, 2023.

HPSA score was one of the items CMS proposed the hospital must furnish with its application for additional residents. CMS has 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 applications for additional residency positions, hospitals should refer to HRSA's Find Shortage Areas by Address (Find Shortage Areas by Address (hrsa.gov)) to obtain the HPSA ID of the HPSA served by the program and include this ID in its application. Each year in November, prior to the beginning of the application period, CMS will request HPSA ID and score information from HRSA so that the most recent HPSA information is available for use in the application for additional residents.

Demonstrated Likelihood

CMS proposed that this criterion will be met by the hospital by demonstrating that it is does not have sufficient room under its existing FTE caps to accommodate a planned new program or expansion of an existing program using Worksheets E, Part A and E-4 from the Medicare cost report CMS-Form-2552-10.

For a new program, the hospital's application must attest to the following:

- The hospital has submitted an application for approval of the new residency program to the Accreditation Council on Graduate Medical Education (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 by the application deadline for that year.
- The hospital has received either:
  - 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 by the application deadline for that year from the accrediting bodies concerning the new program approval process (such as notification of site visit).

For an expansion of an existing program, the hospital's application must attest:

- The hospital has approval by the application deadline from 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.

In the final rule, CMS indicates that "application deadline" means CMS' application deadline for additional resident positions, not the ACGME or ABMS's deadline for applying for a new program or a program expansion.

Comments/Responses: Public comments noted that CMS' proposal requires either expanding an existing program or establishing a new program to meet the "demonstrated likelihood" criterion. They suggested that CMS should allow the additional resident slots to fund existing positions over the current caps (either unfilled or filled) where no request for a program expansion to ACGME or ABMS is required. CMS rejected awarding additional residents for filled positions over the cap arguing that section 1886(h)(9)(C)(ii) of the Act requires the hospital to agree to an increase its total number of FTE residency positions to be awarded additional positions. However, CMS agreed with awarding additional residents to fund unfilled positions above the cap.

Public comments requested that rural hospitals only be awarded cap adjustments under section 126 for expanding existing programs as current regulations already allow them to establish new programs. CMS responded that the law and regulations provide rural hospitals with the opportunity to establish new programs or expand existing ones, and it is not going to establish a limitation on rural hospitals creating new programs under section 126 that are not provided for in the law.

Others commented that rural hospitals will have difficulty meeting the "demonstrated likelihood" criterion given limited teaching capacity and recruiting challenges. While CMS acknowledged challenges rural hospitals faced expanding existing programs, it noted that "demonstrated likelihood" is a statutory criterion. However, in this final rule, CMS is establishing a policy that only 50 percent of the program's training must take place in the HPSA allowing a rural hospital to more easily partner with other participating training sites to meet the "demonstrated likelihood" criterion.

Final Decision: CMS is finalizing its policy as proposed with one modification. For an expansion of an existing program, CMS will allow the hospital to attest that it currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

Four Hospital Categories

Located in a Rural Area or Treated as Rural (Category 1). CMS proposed that a hospital will be considered located in a rural area if it is outside of a MSA or metropolitan division as defined by the Executive Office of Management and Budget. A hospital that is treated as rural is a hospital that is located in an MSA or metropolitan division that has applied for and been granted rural status under section 1886(d)(8)(E) of the Act for purposes of section 1886(d) of the Act (IPPS). To qualify under this criterion, the hospital must be treated as rural by the application deadline for additional resident slots.

Comments/Responses: CMS generally responded to public comments that it is implementing the law as required.

There were public comments that indicated rural-like areas within urban counties (known as rural-urban commuting areas or RUCAs) should be considered rural. CMS noted that one of the criteria that makes an urban hospital eligible to reclassify as rural is being located in a RUCA.

Other commenters indicated that lower priority should be given to urban hospitals that reclassify as rural in the distribution of residents. CMS responded that priority for being awarded additional residents is addressed elsewhere in the final rule although CMS notes that no distinction is made in the law with respect to prioritizing hospitals between those that are geographically rural from those reclassified as rural.

In response to comments, CMS clarifies that RRCs will generally qualify as being rural or treated as rural as these are requirements to be eligible for RRC status. CMS indicates that its policies allow a small number of RRCs to retain RRC status without being rural if the area in which they are located was redesignated from rural to urban. These RRCs will not qualify to be considered rural or treated as rural as they are currently located in an urban area and are not treated as rural for IPPS purposes.

Public commenters asked that hospitals in Hawaii, Alaska, Guam, American Samoa, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands be considered rural as these areas face significant health care challenges. CMS rejected this comment and stated the same policy would apply to these states and territories as apply to all other hospitals.

There were public comments suggesting that the majority of residents' training should take place in a rural area to qualify under category 1 to better achieve the goal of training more physicians to remain and serve in communities of need. CMS agrees with that goal but says no such requirement is included in the statute to qualify under category 1 for additional residents.

However, CMS notes that this comment is indirectly addressed through CMS' prioritization policies for awarding additional residents in a different section of the final rule.
Final Decision: CMS is finalizing its policy as proposed. In the final rule, CMS notes that a hospital that is reclassified as rural is only treated as rural for purposes of section 1886(d) of the Act. Such a policy would mean that any increase in the hospital's FTE cap would apply only for purposes of IME and not DGME as IME is governed by section 1886(d) of the Act and DGME is governed by section 1886(h) of the Act. However, CMS indicates that it believes section 126 was intended to apply to both IME and DGME.

Training more Residents than the FTE Cap (Category 2). CMS proposed that this criterion will be met if a hospital's unweighted1 count of residents for a cost reporting period ending on or before the date of enactment of CAA, 2021 (December 27, 2020) is higher than its applicable resident cap as adjusted for participating in affiliated group arrangements, hospital mergers, emergency affiliation arrangements, establishing new medical residency training programs, participating in rural training programs (RTPs) and receiving additional slots under residency redistribution provisions and from closed hospitals.

Comments/Responses and Final Decision: Comments supported CMS' proposal. CMS is finalizing its proposal without modification. CMS clarifies that a hospital will qualify under category 2 if it is over its DGME cap, IME cap or both. However, the hospital must be over its IME cap to qualify for additional IME residents and over its DGME cap to qualify for additional DGME residents. Being above one but not the other cap does not allow the hospital to qualify for additional residents under both the IME and DGME caps.

Hospitals Located in States with New Medical Schools, Additional Locations or Branch Campuses (Category 3). To meet this criterion, the hospital must be in a state where the Liaison Committee on Medical Education or Commission on Osteopathic College Accreditation has accredited a new medical school or an additional location on or after January 1, 2000. The proposed rule listed 35 states and one territory where this criterion is met: 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.

Comments/Responses and Final Decision: Public comments supported CMS' proposal. No public commenters suggested any addition to the list of states and territories. CMS is finalizing its proposal without modification.

Hospitals Serving HPSAs (Category 4). CMS proposed that if a hospital is located in geographic primary care or mental health HPSA, it will meet the criterion of being a hospital "that serve[s]

1 Residents are counted as 1.0 FTE during an "initial residency period" or the period time required to become board certified in the initial specialty that the resident begins training. Beyond this period (generally for subspecialty training), the resident is counted as 0.5 FTE for DGME only.

areas designated as health professional shortage areas." For primary care HPSAs, CMS proposed no limitation on the physician specialty for additional resident slots. For mental health HPSAs, CMS proposed to limit the additional resident slots to psychiatry residents. CMS further proposed that at least 50 percent of the resident's training time over the duration of the program must occur within the HPSA. Hospitals will be able document they meet this criterion under CMS' proposal through an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report.

Comments/Responses: Many public comments indicated that requiring that a hospital or provider-based facility be located in a primary care or mental health only geographic HPSA will result in only a small number of hospitals qualifying for residency positions. CMS responded that it does not believe the goal of category 4 should be to create the most expansive eligibility pool possible.

There were many public comments indicating the statutory requirement is that eligible hospitals serve patients residing in HPSAs, not that the hospitals themselves must be geographically located there. CMS agreed and is modifying the policy to no longer require the hospital to be located in a geographic HPSA. It will only require that at least 50 percent of the training time must be spent at a site physically located in the HPSA and treating the HPSA's population. **CMS further seeks comment on how to develop a measure of how hospitals outside of a HPSA are serving areas designated as HPSAs.**

Some public comments stated the proposal should be modified to include both hospitals located within geographic HPSAs and those within a reasonable distance of one. CMS rejected this alternative stating that the requirement it is adopting in the final rule will most clearly and consistently identify those hospitals that provide services to HPSAs.

There were public comments indicating that population-based HPSAs as well geographic HPSAs should be eligible under category 4. CMS rejected this comment indicating that section 1886(h)(9)(B)(ii)(IV) of the Act references section 332(a)(1)(A) of the Public Health Service Act (PHSA). Subparagraph (A) of section 332(a)(1) of the PHSA describes a geographic HPSA while subparagraph (B) of section 332(a)(1) includes population-based HPSAs.

Many public comments stated that hospitals should be able to count time spent in non-hospital settings (such as critical access hospitals, Federally Qualified Health Centers (FQHCs), and rural health clinics (RHCs) towards the 50 percent requirement. CMS agreed and is allowing training time spent in non-provider sites to count towards the 50 percent requirement (including time spent at Veteran's Affairs hospitals).

A number of public comments indicated that the proposed 50 percent training time requirement is unduly burdensome as it will require tracking individual residents rather than the aggregate number of residents using the Intern and Resident Reporting System (IRIS). CMS responded that hospitals are not expected to establish entirely new training tracks or administrative structures to accommodate FTE slots awarded under section 126 of the CAA. The percentage of training time

that residents in the program spend in the HPSA for purposes of category 4 is required to be substantiated, utilizing existing resident rotation schedules (or similar documentation).

There was one request for 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. CMS replied that the 50 percent requirement applies to the program in its entirety, not to individual residents.

Some public comments indicated that hospitals should not be limited to psychiatry residents in mental health geographic HPSAs as other types of physicians are needed in these areas. CMS responded that there is no evidence of shortages of other physician specialties in mental health HPSAs nor does CMS have a method to uniformly measure a shortage of other, non-psychiatric specialty providers in mental health only geographic HPSAs. In the final rule, CMS will expand eligibility for category 4 to psychiatric subspecialties in mental health HPSAs.

Final Decision: CMS is finalizing its proposal with the modification that the hospital does not need to be physically located in the HPSA to qualify under category 4. An applicant hospital qualifies under category 4 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. As proposed, a category 4 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.

Determination of Qualifying Hospitals

CMS proposed that a qualifying hospital must meet one or more of the four categories previously described. Public commenters suggested allowing many additional hospitals to qualify. CMS responded that the statute limits qualifying hospitals to the four categories described.
e. Limiting and Prioritizing the Number of Residents Available to Each Hospital. CMS is limited by statute to making 200 new residency slots available each year for 5 years. Given this limitation and the number of hospitals that are expected to qualify under each of the four criteria listed above, CMS proposed to limit an award of an additional residency slot to 1.0 per hospital per year.

Comments/Responses: There were comments supporting the limit of 1.0 FTE residents per year and not allowing a hospital to be awarded additional residents in subsequent years if there are other hospitals that applied but were not awarded additional residents in prior rounds. Other comments strenuously objected to the 1.0 FTE limit indicating that if the hospital is awarded only 1.0 FTE resident in the first year, there is no guarantee that the resident position will be subsidized in subsequent years of training.

Among the most common recommendations to address these concerns was linking 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 practice 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). There were several alternative suggestions including that CMS distinguish between establishing new programs and expanding existing ones in the number of additional positions awarded.

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. 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.

Final Decision: CMS is revising its proposal in response to public comments to award a maximum of 1.0 FTE residents per year times the length of the residency program for which the hospital will use the additional residents. For example, if the hospital is awarded 1.0 FTE residents for a family practice program, the total award will be 3.0 FTE residents or the product of 1.0 FTEs and 3 years. The maximum award amount will be 5.0 FTEs or the product of 1.0 FTE residents and a program length of 5 years.

Given the limited number of residency positions available and the number of hospitals expected to apply, CMS will continue to limit hospitals to one application in any fiscal year.2 CMS expects 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.

CMS proposed to further prioritize among hospitals receiving residents based on the following criteria:

- Residency Programs that Treat Underserved Populations. CMS proposed to give priority to hospitals with residency programs that provide services to medically underserved populations in a population-based HPSA3 with the same requirements that apply to geographic HPSAs, (i.e., that 50 percent of the training time occur in the HPSA in order use HPSA scores to further prioritize among competing hospitals for a limited number of resident slots).

2 It is not entirely clear whether this application is limited to a single specialty but that is implied by CMS' statement that "our focus under this modification continues to be on hospitals that are applying to establish or expand a single residency program."

3 In a geographic HPSA, the entire population of that HPSA is designated as underserved for a particular type of service. In a population-based HPSA, a particular population (low-income populations, Medicaid-eligible, Native American, homeless, migrant farmworker, etc.) are designated as medically underserved.

- Use of HPSA Scores. The Health Resources and Services Administration 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. CMS proposed to prioritize awarding of resident slots based on HPSA score.

Hospitals can find information about the HPSA or HPSAs associated with their training program locations using the HRSA search tool at: Find Shortage Areas by Address (hrsa.gov). Under the proposal, 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. 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.

CMS would prorate residents in the above prioritization categories only in the event that the number of qualifying hospitals under the first category or the highest HPSA score under the second category exceed the number of residency positions available. Hospitals applying for residency positions for programs that do not serve HPSAs are not categorically excluded, but those applications would have the lowest priority.

Comments/Responses: There were public comments indicating that CMS prioritization policy will not result in the minimum 10 percent of awarded residents in each of the eligible four categories specified by statute. While CMS disagrees, it is also collecting of information on qualification for all four categories to track progress in meeting all statutory requirements. CMS will evaluate the need to modify the distribution methodology in future rulemaking if the 10 percent requirement in each of the four categories is not met.

There were objections to requiring that at least 50 percent of a program's training time occur at applicant hospital locations inside a HPSA. Again, commenters indicated that hospitals located outside of HPSAs provide services to patients that reside in HPSAs. CMS responded that it will not limit training to hospital settings physically located in the HPSA and will expand the 50 percent requirement to incorporate training in non-provider settings and Veterans Affairs facilities (as it did with category 4 qualification).

One commenter requested that all Indian and Tribal facilities be considered for prioritization regardless of where they are located. CMS agreed and will prioritize applications from programs where the residents rotate into Indian and Tribal facilities regardless of where they are located. For purposes of this prioritization, CMS 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.

Some public commenters questioned the accuracy of HPSA scores, and, therefore, their propriety for this purpose. While CMS acknowledges the limitations of HPSA scores, it continues to believe

that HPSA scores are best source available for prioritization. **CMS seeks comment on feasible alternatives to HPSA scores as a proxy for health disparities to inform potential future rulemaking.**

There were comments indicating that population-based HPSAs are so numerous that their use will undermine legislative intent to target the distribution of residency positions to areas with the greatest need. CMS disagrees indicating that both geographic and population-based HPSAs reflect severity of need for physicians. 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.

There were a variety of other methodologies suggested for prioritizing among applications. CMS acknowledged these comments but continues to believe that HPSA scores provide the best prioritization approach available at this time. CMS is adopting one of these suggestions—use of hospital bed counts as a tiebreaker—when prioritizing applications with equal HPSA scores.

Final Decision: CMS is finalizing the policy as proposed with the modification that number of beds will be used as a tiebreaker for applicants with the same HPSA score. Applications will be prioritized by descending HPSA score. Priority will be given to hospitals with fewer than 250 beds when HPSA score is tied. If there are insufficient slots available to be distributed to all applications with both the same HPSA score and number of beds, the remaining available slots are prorated among those applications.

Alternative to using HPSA scores, CMS considered prioritizing hospitals that qualify in more than one of the four statutory eligibility categories. 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. Again, CMS would only prorate if the number of qualifying hospitals exceeds the number of available residents. Public comments both supported and opposed this alternative prioritization method. CMS is not adopting the alternative prioritization method it considered.

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

The statute requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions within each of the qualifying four categories. CMS believes this will occur through prioritizing applications by HPSA score as hospitals may qualify for additional residents through more than a single category. CMS proposed to collect information regarding qualification categories to track progress in meeting the statutory requirement that at least 10 percent of residents be allocated to each of the qualifying categories. CMS did not receive any comments on this proposal that it is finalizing without change.

Hospital Attestation to National CLAS Standards

CMS 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). Several comments supported the proposal. Others noted that this requirement overlaps with Internal Revenue Service requirements for non-profits, Joint Commission Standards and ACGME core competency requirements and if these requirements are met, CLAS standards should not have to be additionally met. CMS acknowledged these overlaps but believes that the National CLAS standards are more aligned with the Administration's commitment to ensuring that residents are educated and trained in culturally and linguistically appropriate policies and practices. CMS is finalizing the policy as proposed.

Payment for Additional FTE Residency Positions

There are different DGME PRAs for primary care residents and residents that train in obstetrics and gynecology than for residents training in all other specialties. CMS proposed to pay for the additional residents using the PRA that correlates to the specialty the resident is training in. There were no public comments on this proposal that CMS is finalizing without change.

Conforming DGME and IME Regulations

CMS proposed to make the same changes to the DGME and IME regulations with respect to application of the DGME and IME resident caps. There were no comments on this proposal that CMS is finalizing without change.

Use of Residents in DGME and IME Affiliation Agreements

Medicare statute and regulations allow hospitals that jointly train residents to affiliate and apply their FTE caps on an aggregate basis. CMS proposed that additional resident slots awarded under this program may be used in affiliation agreements beginning in the 5th year after the effective date of those FTE resident cap positions.

Public comments either expressed concern that the residency positions remain consistent with CMS' program goals of supporting training in medical underserved areas after five years or asked clarifying questions about whether program goals for the first five years will be an ongoing requirement. CMS replied that the residency positions awarded should be used for training residents in the program associated with the hospital's section 126 of the CAA application. It noted that the Comptroller General of the U.S. (GAO) is required to study this provision and report to Congress by September 30, 2025, and again by September 30, 2027. CMS will consider the GAO study and additional guardrails for future rulemaking if residency positions awarded under section 126 are not being used for their intended purposes.

Prohibition on Administrative and Judicial Review

Consistent with statute, CMS proposed to prohibit administrative or judicial review of the determinations and distribution of additional residency positions. There were no comments on this proposal that CMS is finalizing without change.

Rural Training Programs (RTP) (previously known as Rural Training Tracks (RTTs))

RTPs are graduate medical education programs that are specifically designed to train residents to practice in rural areas. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 allowed urban hospitals to count residents training in RTPs above their caps

effective in 2000. CMS regulations allowed payment for FTE residents in these programs above the hospital caps for 5 years. In the sixth year, additional residents in these programs were incorporated into hospital FTE DGME and IME caps.

While the BBRA exempted the additional RTP residents from an urban hospital's FTE cap for 5 years, it did not exempt those additional residents from the 3-year rolling average count of residents to determine DGME and IME payment in existing teaching hospitals that already had established DGME and IME caps. For newly established teaching hospitals, the 3-year rolling average would apply to the RTP residents after 5 years.

Similarly, the BBRA provisions did not exempt the additional RTP residents from the annual cap on the IRB ratio in existing teaching hospitals that already had established DGME and IME caps. For newly established teaching hospitals, the IRB cap applies to RTP residents after 5 years. Finally, while the BBRA provisions exempted the urban teaching hospital participating in the RTPs from the FTE caps, the law did not provide an analogous adjustment for a rural hospital for training a resident in an RTP.

Section 127 of the CAA addresses these and other concerns that stakeholders have raised about RTT provisions of the law.

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

Section 1886(h)(4)(H)(iv) of the Act (as modified by section 127 of the CAA) provides for adjustments to FTE caps for both a rural and an urban hospital that "established or establishes" an RTP effective for cost reporting periods beginning on or after October 1, 2022.
CMS described RTPs as "hub and spoke" programs in the proposed rule. However, in response to public comments on terminology and consistent with ACGME guidance published in May of 2021 (Medically Underserved Areas and Populations (acgme.org)) CMS will refer to RTTs as RTPs and will no longer use the terms "hub" and "spoke". Instead, CMS will use "primary clinical site" for the urban hospital training site, and "rural hospital participating site" if the site is a rural hospital, or "rural non-provider participating site" if the site is an ambulatory clinic or some other non-hospital site.

The urban hospital is the primary clinical site and each rural hospital is the rural participating site. Under current policy, an urban primary clinical site may be an existing medical residency training program and neither the urban nor rural hospital would qualify for a cap adjustment when a new rural participating site is added. CMS proposed that each time an urban hospital adds a new rural participating site, the urban and rural hospital would qualify for a cap adjustment.

While CMS proposed allowing cap adjustments when new rural participating sites are added to an existing RTP, CMS did not propose to allow expansion of existing RTP programs when a new rural participating site is not added. CMS justifies this limitation as being consistent with the statute's direction that allows CMS to prescribe rules for adjustments to FTE caps while considering that Congress established caps to limit the number of residents subsidized by

Medicare in the aggregate nationally. Further, CMS notes that the statute authorizes the Secretary to "adjust in an appropriate manner" the FTE cap for hospitals participating in RTPs.

CMS notes that the slots associated with the RTP FTE limitation are fungible. Urban and rural hospitals with multiple RTP rural participating sites may reduce the number of FTE residents training between the primary urban hospital and rural participating site in order to accommodate an increase in training at the urban hospital participating site or each rural participating site subject to the proviso that 50 percent of the training must continue to occur in rural areas. Further, urban and rural hospitals can receive cap adjustments for new RTP programs in different specialties.

Removal of Requirement that Rural Track Must Be "Separately Accredited"

Section 127 of the CAA removes the requirement that the rural track be "separately accredited." Specifically, section 1886(h)(4)(H)(iv)(II) of the Act 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 FTE caps. CMS 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 a RTP and urban and/or rural hospitals receive rural track FTE cap adjustments assuming all other requirements are met.

CMS further notes that the statute adopts a requirement that was previously only in regulations that at least 50 percent of the training occur in a rural area for a residency program to qualify as an RTP. Consistent with this requirement, CMS proposed to allow any specialty program where more than 50 percent of the training occurs in a rural area to qualify as an RTP.

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

As noted above, the law bases IME and DGME payment based on a 3-year rolling average count of residents. 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 and rural hospital during the 5-year growth window for FTE residents participating in RTPs. CMS proposed that during the 5-year cap growth window for RTPs, the FTE residents participating in the RTP either at the urban hospital or a rural hospital would not be included in a hospital's 3-year rolling average calculation effective for RTPs started in cost reporting periods beginning on or after October 1, 2022.

Documentation Required for Medicare Administrative Contractor (MAC)

In order to facilitate the implementation of increases to RTP FTE limitations, either via interim payments or cost report adjustments, an urban hospital primary care site that adds one or more rural training sites in one or more specialties, CMS proposed documentation that urban and rural hospitals must show their MACs. In response to public comments, the below shows the final rule documentation that will be required which is modified slightly from the proposed rule based on public comments:

- 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 a 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. In the instance where only a subset of the residents in the particular program are participating in the RTP, the hospital must specifically highlight the names of the residents on the main rotation schedule, and highlight their urban and rural training locations.
- 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 the RTP.

Comments/Responses: Public comments said CMS should allow expansion of existing RTT programs as well as allow for creation of new rural clinical training sites in existing programs as the law uses "established or establishes"' (both past tense and future tense) to grant the Secretary unique authority to prospectively allow (under certain circumstances) cap adjustments to existing RTTs. Using this authority, CMS could make a one-time exception and limit the total number of residents allowed to 3.0 FTEs per program. CMS disagrees with this statutory interpretation and argues that use of the past tense allows an existing urban RTP to create new rural clinical sites but not expand existing programs.

In the absence of distinct ACGME criteria identifying programs where greater than 50 percent of the training occurs in a rural area, a commenter provided specific criteria CMS should establish to identify programs eligible for FTE cap adjustments. CMS rejected this comment arguing that its rules will provide maximum flexibility to stakeholders by adhering to the criteria specified in section 127 of the CAA. CMS expects ACGME to develop additional criteria as both the industry and the ACGME gain more experience with operating RTPs in a variety of specialties.

In response to a comment, CMS clarifies that a geographically urban hospital that reclassifies as rural under section 1886(d)(8)(E) of the Act may only be considered rural for IME and not DGME as section 1886(d)(8)(E) of the Act only applies to section 1886(d) of the Act. IME is included in section 1886(d) of the Act while DGME is included in section 1886(h) of the Act. This means that any training in an urban hospital reclassified as rural will count as rural for IME and urban for DGME. CMS advises hospitals reclassified as rural to synchronize training at geographically rural hospitals to meet the requirement that 50 percent of training occur in a rural area to avoid the potential for the hospital to meet the criteria for a RTP cap adjustment for IME and not DGME.

In the proposed rule, CMS provided detailed examples for how resident caps, including those involving RTPs, are fungible. In response to a comment, CMS clarifies that each hospital has its own cap and may reduce or increase RTP training in a specialty. However, the caps do not apply across multiple hospitals and cannot be aggregated.

Some public comments said the exemption from the 3-year rolling average should begin based on an academic year (July 1) and special consideration should be provided for 7 programs expected to begin July 1, 2022. CMS responded that the statutory provision exempting new RTPs from the 3-year rolling average is effective for "cost reporting periods beginning on or after October 1, 2022." As such, CMS does not have the authority to begin the exemption from the cap for any portion of a cost reporting period that begins prior to October 1, 2022.
Final Decision: CMS is finalizing all of its policies as proposed with minor modifications as noted above in response to comments.

Hospitals that Hosted a Small Number of Residents for a Short Duration

Section 131 of the CAA provides CMS with the opportunity to reset low or zero IME and DGME FTE caps and DGME PRAs of hospitals that hosted a small number of residents for a short duration. Hospitals with a low PRA may have first served as a training site for a small number of residents on rotation from an existing training program at some point in the past. In this circumstance, the resident salaries and other costs may have been predominantly incurred at the other hospitals where the resident was training. As a result, the hospital that served as a training site may have had no or very low per resident costs to set the PRA in the first year of training residents.

Hospitals with a very low DGME and IME FTE cap may have served as a training site for a small number of residents in a new medical residency training program on rotation from another hospital. As a result, the cap was established at the hospital based only on residents that rotated in for a short duration of time. These hospitals may have later decided to engage in establishing their own new medical residency training programs and found they already had DGME and IME FTE caps that would not have accommodated the number of residents in a new program.
Sections 131(a) and (b) of the CAA address concerns of these hospitals by allowing the Secretary to recalculate the PRA and redetermine the FTE caps if the hospital trains resident(s) in a cost reporting period beginning on or after December 27, 2020 and before December 26, 2025. The statute classifies two categories of hospitals that CMS refers to as "category A" and "category B":

- Category A.A hospital that, as of 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.
- Category B. A hospital that, as of 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 December 27, 2020.

Hospitals Qualifying to Reset their PRAs

The law allows the PRA to be reset 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). CMS will not round up to determine whether a hospital qualifies for a recalculated PRA. The recalculation period begins on December 27, 2020 and ends 5 years later.
Training occurring at a category A hospital or a category B hospital need not necessarily be in a new program; the residents may be in either an approved program that is "new" for Medicare DGME and IME purposes, or may be in an existing approved program.

Further, CMS indicates that it is not relevant whether these hospitals 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. The relevant factor in determining when to reset PRAs is 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 before December 26, 2025 (5 years from enactment). 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.

Calculating the Revised PRA and Cost Reporting Requirements

CMS will calculate the revised PRA under the normal existing rules as the lower of:

- The hospital's actual cost per resident incurred in connection with the GME program(s) in the first cost reporting period beginning on or after December 27, 2020 and before December 27, 2025 in which the hospital trained more than 1.0 or 3.0 FTE residents depending on whether the hospital qualifies under category A or category B; or
- The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area (or, if there are fewer than three PRAs for this calculation with base periods beginning on or after October 1, 1997, the updated weighted mean value of per resident amounts of all hospitals located in the same census region).

For hospitals that do not have PRAs as of the December 27, 2020, CMS notes that the law specifies that the Secretary shall not establish a PRA until such time as a hospital that is not in an affiliation agreement with another hospital for training residents has trained as least 1.0 FTE resident in a cost reporting period. The law is silent on hospitals that are in affiliation agreements. Thus, effective for a cost reporting period beginning on or after enactment (December 27, 2020), CMS proposed:

- A hospital that is not in an affiliation agreement must have at least 1.0 FTE residents to have a PRA calculated.
- A hospital that is in an affiliation agreement may have a PRA calculated if it has fewer than 1.0 residents.

The statute requires a hospital that trains at least 1.0 FTE in an approved program on or after December 27, 2020 to report the number of FTEs it trains on its cost report. Effective for a cost reporting period beginning on or after December 27, 2020, CMS proposed that a hospital must report FTE residents on its Medicare cost report for a cost reporting period if:

- In the absence of a Medicare GME affiliation agreement, a hospital trains at least 1.0 FTE in an approved program or programs; or
- If there is a Medicare GME affiliation agreement, a hospital trains less than 1.0 FTE in an approved program or programs.

The proposed policy is intended to put hospitals on notice that CMS will establish a PRA when FTE residents are reported on a Medicare cost report beginning on or after December 27, 2020.

CMS notes that newly added clause 1886(h)(2)(F)(v) of the Act states that "as appropriate, the Secretary may consider information from any cost reporting period necessary to establish a [new PRA]." CMS then discusses its "predicate facts" rule. The predicate facts rule allows CMS to use information from a prior cost reporting period—even if that cost reporting period has been settled for more than 3 years and is not subject to reopening—to determine payments in a subsequent cost reporting period (provided that cost reporting period remains subject to reopening) or future cost reporting period. The predicate facts rule does not substantively change any of CMS' proposals regarding calculating a revised PRA if a hospital qualifies as result of having a PRA based on less than 1.0 FTE (category A hospital) or less than 3.0 FTE (category B hospital).

Hospitals Qualifying to Reset their FTE Resident Caps

CMS explains that to qualify for resetting the FTE cap, the statute states the Secretary shall adjust the FTE resident caps in the manner applicable to a new program if the hospital "begins training" the requisite number of FTE residents (1.0 or 3.0 depending on whether the hospital is category A or B). To reset a PRA, a training program does not necessarily need to be new. However, the statute requires a training program to be new for the hospital to qualify to have its FTE cap reset.

CMS proposed that "begins training" means future training in a new program for the first time on or after December 27, 2020. For both category A and B hospitals, CMS says that the relevant factor in determining the timing of resetting their FTE resident caps is 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 before December 26, 2025 (5 years from enactment).

Based on the examples that CMS provides, the relevant considerations to make a determination if a hospital with an FTE cap qualifies to have its cap reset are:

- Did the hospital FIRST begin training residents before 12/27/2020 in a new program? If yes
- Did the hospital train less than the requisite number of residents (e.g., less than 1.0 FTE (category A) or less than 3.0 FTE (category B))?

If the answer to the first and second question is "YES", the hospital qualifies to have its cap reset. If the answer to the first question is "YES" and to the second question is "NO", then the hospital does not qualify to have its cap reset. If the answer to the first question is "NO", the 2nd question is moot. Either the hospital has not participated in GME training before and would qualify under the normal rules to have its cap set in the 6th year after beginning to train residents in new programs or the hospital has an established cap based on training residents in established programs but does not qualify to have its cap reset.

Calculating Replacement FTE Resident Caps

CMS proposed to use its existing regulations to calculate each qualifying hospital's FTE cap (e.g., the cap would be determined in the 5th year of the new program based on the number of residents in training at that time).

CMS further proposed not to set an FTE cap for any hospital that has trained fewer than 1.0 FTE residents in a cost reporting period beginning on or after December 27, 2020. For all hospitals that do not yet have caps triggered, CMS proposed that a cap will only be triggered in a hospital that did previously train residents as of December 27, 2020 when the hospital trains at least 1.0 FTE in a new medical residency training program.

CMS further reiterates its "predicate facts" rule applies to FTE caps as it does to the determination of the PRA. That is, CMS proposed to not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation it would need to establish the FTE resident caps from that period to determine future payments.

Comments/Responses: There were many detailed comments in the following issue areas:

Predicate Facts. Public comments were concerned and confused by CMS' reference to its predicate facts rule. Commenters are concerned that MACs may find records of past training that will leave them with an extremely low PRA or FTE cap. They requested assurances that MACs will not be encouraged to search for predicate facts that may suppress hospitals' GME support from Medicare.

CMS responds that it proposed no changes to its predicate facts rules that permit a MAC to determine a PRA from a prior cost reporting even if that cost report is not reopenable. That PRA would only be used to determine future year payments, not revise payments from the year that is not reopenable. CMS says:

> [H]ospitals 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".

Process Issues. Many commenters provided feedback regarding the review process CMS and the MACs would use to determine eligibility for PRA or FTE cap resets. Commenters raised a variety of questions for CMS to consider in implementing section 131.

CMS acknowledged the complexities raised by the commenters and believes that there are many hospitals potentially eligible for PRA or FTE cap resets. To manage workload, CMS is instructing 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. CMS is 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). Below are the steps that CMS will use to undertake implementation of PRA and FTE cap reset reviews:

(1) Use of HCRIS to Assist in Determining Reset Status. CMS will post a file 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 at: Acute Inpatient - Files for Download | CMS or Direct Graduate Medical Education (DGME) | CMS

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 may get a reset without further review by the MAC. CMS provided several examples where hospitals would qualify for a reset based on the HCRIS extract without need for further MAC review.

(2) One-Time Deadline to Request Reconsideration and Review (Category B Only). For an open or reopenable cost report, if CMS' HCRIS posting shows a potential category B hospital is ineligible for a PRA or FTE cap reset, the hospital will have 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. "Complete and unambiguous" documentation must support the request. 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. The decision issued by the MAC to the hospital would be final but appealable to the Provider Reimbursement Review Board (PRRB) for review, assuming that all conditions for appeal are met.

(3) Cost Reports Not in HCRIS or Not Yet Settled. For cost reports that are not present or are not settled or the PRA or FTE caps are missing, the 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. "Complete and unambiguous" documentation must support FTE counts and FTE cost and payment information. MACs will reject incomplete or untimely submissions, with no opportunity for a later or second MAC review. The decision issued by the MAC to the hospital would be final but appealable to the PRRB for review, assuming that all conditions for appeal are met.

(4) PRA Base Periods Initiated Prior to Enactment, with Cap-Building Period Ending After Enactment. CMS indicates that a hospital has a PRA or an FTE cap potentially eligible for a reset if its cost reporting period that determines the PRA or FTE cap (after the 3- or 5-year cap building period) begins before the December 27, 2020 enactment date but ends after that date. This policy could result in a hospital qualifying for a PRA reset but not an FTE cap reset because the base year for determining the PRA could be from a cost reporting period that begins prior to December 27, 2020 while the FTE cap building period ends in a cost reporting period that begins after December 27, 2020. Hospitals submitting documentation to their MACs by July 1, 2022 for a determination regarding a 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.

Documentation. CMS is not changing documentation requirements for the purpose of section 131 of the CAA and refers commenters to the August 29, 1989 final rule (54 FR 40286, 40291 and 40304), the August 18, 2006 IPPS final rule (71 FR 47869, 48077) implemented at 42 CFR 413.75(d). This final rule also lists examples of documentation that would be acceptable to support DGME and IME FTE counts and per resident costs.

While CMS understands 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, 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 directors to obtain definitive FTE information. All documentation must be furnished to the MACs for reset by the July 1, 2022 deadline.

Base Year Cost Report for Reset PRA or FTE Cap. A commenter requested that CMS provide hospitals with the flexibility to choose the base year cost reporting period for a PRA reset that begins at the earliest after enactment of the CAA, 2021 or at the latest after CMS issues instructions to the MACs implementing this provision. CMS is 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 first cost reporting period beginning after issuance of the final rule. If a hospital begins training at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period beginning after the final rule (but still within 5 years after enactment), then the hospital must use that cost reporting period as its new PRA base period.

Clarifying Eligibility for an FTE Cap Reset. Commenters were concerned that CMS' proposal to limit eligibility for a cap reset to hospitals that "first" begin training residents in a new program on or after the date of enactment restricts the applicability of section 131 of the CAA to a much smaller set of hospitals than they believe was intended. 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. CMS agreed with these commenters that a hospital could have a cap established at less than 3.0 FTEs and then have started a new program before enactment of the CAA, 2021 but still be eligible for a cap reset based on new programs established after December 27, 2021. The cap would be set only based on residents training in the program started after December 27, 2021 and before December 27, 2026.

Other Issues. In response to public comments, CMS makes the following points:

- Inclusion in the statute of the phrase "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" was intended to put hospitals on notice that they are obligated to report their residents on the cost report for training as few as 1.0 FTE.4
- Section 131 states that a qualifying hospital's cap or PRA must be in effect "as of enactment," in order to be reset. Hospitals with a low FTE cap or PRA that results from a training program that begins after December 27, 2020 are ineligible for a reset.
- Commenters expressed concern that any audits of PRA or FTE caps not be revisited once completed (except in cases of fraud). CMS' final rule policy of requiring all requests for a reset to be provided to the MAC by July 1, 2022 is consistent with the commenters' requests that the MACs' determinations should not be revisited, and they should be binding, unless fraud is suspected.

Final Decision: CMS is finalizing the following policies for resetting the PRA or FTE cap for qualifying hospitals:

- Resets will be completed using cost reports that are open, reopenable, or not yet settled.
- CMS 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.
- **CMS is 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 will be eligible for 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 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.

4 "For purposes of carrying out this subparagraph" precedes the language CMS quotes. "This subparagraph" is the requirement to establish a PRA for a hospital that did not participate in GME training in 1984.

- 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 the hospital trains at least 1.0 FTE.
- 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.

Organ Acquisition Payment Policies

Background

History of Medicare Organ Acquisition Policies

Medicare supports organ transplantation by providing a payment for the variety of organ acquisition services. Organ acquisition costs are excluded from the IPPS and paid separately on the basis of reasonable costs. 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 who required dialysis or transplantation.

In 1978, Congress added section 1881 to the Act that set forth Medicare payment for kidney transplantation and the coverage of organ procurement costs and living donor expenses, including Part A and Part B benefits for the living donor. The final rule recounts the history of Medicare payment for organ acquisition costs including that much development of policy was done through sub-regulatory guidance.

In the final rule, CMS codifies some longstanding Medicare organ acquisition payment policies in its regulations, with clarifications where necessary, and codifies some new organ acquisition payment policies with modifications in response to public comments. It finalizes proposals to move existing organ acquisition payment regulations, or portions of existing kidney acquisition

regulations, to a new part 413, subpart L and makes conforming changes and technical corrections to the regulations.

Overview of Medicare Payment for Organ Transplantation

CMS provides the following definitions to improve clarity regarding how to refer to entities that are involved in acquiring and transplanting organs and how those organizations are paid.

- Transplant Hospitals (TH). Paid for the costs of the transplant surgery and follow-up care through the IPPS. Organ acquisition costs are paid for on a reasonable cost basis. Hospitals must meet specific conditions of participation to be considered a TH.
- Organ Procurement Organizations (OPO). Coordinate the procurement, preservation and transportation of organs from deceased donors, and maintain a system for locating prospective recipients for organ transplantation. OPOs must meet specific requirements of statute (the Act and the Public Health Service Act) and Conditions for Coverage (CfCs) in order to receive payment under Medicare or Medicaid for organ procurement costs. Payments are made on a reasonable cost basis.
- Hospital-based organ procurement organization (HOPO). 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. Payments are made on a reasonable cost basis.
- Histocompatibility Laboratories. Provide laboratory services to ensure compatibility between donor organs and potential recipients in preparation for transplants. May be independent or hospital-based. Paid on a reasonable cost basis unless payment under the IPPS is applicable.

Organ Acquisition Payment Policy Proposals

The below describes clarifications or changes CMS is finalizing as part of adopting sub-regulatory guidance in regulations or moving existing provisions of regulations to new subpart L.

Definitions

The preamble clarifies the distinction between a TH and a transplant program and the meaning of "freestanding":

- 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.
- Freestanding. Means independent OPO (IOPO). For an OPO to be an IOPO, it must file a Medicare cost report separate from the hospital. Additionally, (i) it may not be subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees; (ii) it may not be considered as a department of a hospital for insurance purposes; and (iii) it must report the organ acquisition costs it incurs on the IOPO Medicare cost report.

This terminology is intended to establish consistent use of the above terms in place of "transplantation center" which meant a "transplant program" and "certified transplant center" that meant a TH.

Some commenters asked CMS to expand the definition of organ to include vascular composite allografts (VCAs) and include them in organ counts for OPOs and THs in order to calculate a share of acquisition costs for VCAs. CMS declines to do so in part because it may lead to changes that would be outside the scope of the proposed rule; however, it may do so in the future. Other commenters suggested expanding organ reimbursement to include other clinical trials and disease states. CMS notes that its policies for payment 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 is specifically required under statute5; it believes expanding that policy to include other clinical trials and disease states is inappropriate.

With respect to IOPOs, CMS clarifies that an IOPO that seeks to have the cost of pre-transplant services reimbursed under Medicare must agree to certain requirements specified in 42 CFR 413.200(c) (relating to CMS agreements with IOPOs and laboratories). If an IOPO operates a histocompatibility laboratory, the costs of the histocompatibility laboratory are included on the IOPO's cost report.

Organ Acquisition Costs (§413.402)

CMS finalizes its proposals with respect to organ acquisition costs with clarifications. It codifies its existing policies (with clarifications) in §413.402 and specifies that costs incurred in the acquisition of organs from a living donor or a cadaveric donor by the hospital or by an OPO are organ acquisition costs.

Registry Fees. CMS received a number of comments in response to its proposal to limit registry fees to the OPTN fee. CMS clarifies that it will cover only the reasonable fees for actually registering a potential recipient for an organ transplant as a registry fee; it also finalizes a modification to its proposal (at §413.402(b)(6)) to cover as organ acquisition costs 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.

Transportation. Many commenters disagreed with the policy that organ acquisition costs include costs to transport the excised organ to the transplant hospital but excludes costs for transporting the cadaveric donor. CMS agrees with commenters, and finalizes a policy under which it will cover as an organ acquisition cost transportation of the excised organ to the transplant hospital and of

5 See section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003

(Pub. L. 108-173).

the cadaveric donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organ.

Travel. CMS differentiates transportation (which refers to the organ or the cadaveric donor) from travel. Travel 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 to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation. If multiple organs are procured, travel costs for the procurement team should be apportioned equitably to all organs.

Application to Living and Cadaveric Donors. With respect to other costs associated with excising organs, CMS agrees with commenters that general routine services and special care services provided to the donor, and operating room and other inpatient ancillary services applicable to the donor, should apply to both living and cadaveric donors; its final regulations specifically reflect this policy.

Excluded Costs. The final rule codifies a non-exhaustive list of examples of costs that are not related to organ acquisition at §413.402(d). Generally, costs not related to organ acquisition are (i) items or services that are not related to acquiring an organ for transplantation, (ii) costs that are not reasonable under section 1861(v)(1)(A) of the Act, (iii) costs that are non-allowable administrative and general costs, or (iv) costs that are not related to patient care. These include donor burial and funeral expenses, transportation of a 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, and unreasonable costs incurred for administrator's duties associated with professional organizations.

Standard Acquisition Charges (SAC) (§413.404)

CMS notes that an SAC for an organ is an amount that represents the estimated costs a TH or an OPO expects to incur to acquire an organ; it does not represent the actual acquisition cost for an individual organ. Rather, 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. Reasonable costs of procuring an organ are reimbursable when billed in connection with a Medicare covered transplant. CMS finalizes the following policies with only minor technical modifications or clarifications.

THs and HOPOs.
i. Living Donors. THs must develop an SAC for living donor organs, by organ type, and THs/HOPOs must develop an 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, and it must be established before the TH bills its first living donor transplant to Medicare. Costs may include tissue typing services, physician pre-admission transplant evaluation services,

OPTN registration fees, donor and recipient evaluation and workup furnished before admission for transplantation, other procurement costs (e.g., general routine and special care services related to the donor), operating room and other inpatient ancillary services related to the donor, preservation and perfusion costs, and transportation costs of the excised organ.

ii. Cadaveric Donors. THs/HOPOs calculate their initial cadaveric donor SAC for each cadaveric organ type, by estimating the reasonable and necessary costs they expect to incur in procuring cadaveric organs, combined with the expected costs of acquiring cadaveric organs from OPOs or other THs. The estimated amount is divided by the projected number of usable cadaveric organs to be procured by the TH/HOPO within the TH's cost reporting period. Subsequent years' SACs for each cadaveric organ type are calculated 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 estimated amount is divided by the actual number of usable cadaveric donor organs procured by the TH/HOPO during that prior cost reporting period. Usable organs are discussed below.

Costs may include costs of organs acquired from other THs or OPOs, transportation of the excised organs, surgeons' fees for excising cadaveric organs, tissue typing services, preservation and perfusion costs, general routine and special care service costs, and operating room or other inpatient ancillary service costs.

Independent OPO Standard Acquisition Charge. Medicare contractors establish the kidney SAC for IOPOs which is an estimate of the reasonable and necessary costs an 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 cadaveric kidneys procured. The initial kidney SAC is based on the IOPOs budget information and the subsequent years' SACs are based on the IOPOs cost report.

An IOPO establishes non-renal SACs based on its costs of procuring organs, similar to procedures followed by THs. It estimates the reasonable and necessary costs for services furnished to procure cadaveric donor non-renal organs during the IOPO's cost reporting period. The estimated amount is divided by the projected number of cadaveric donor non-renal organs the IOPO expects to procure within its cost reporting period.

An IOPO that receives an organ from another IOPO must pay the procuring IOPO's SAC, but it uses its own SAC when billing a TH that receives the organ.

In response to comments, CMS clarifies that the costs of "imported" organs (i.e., organs one OPO receives from another OPO or from a transplant hospital) are recorded as organ acquisition costs. Thus, an IOPO may include the estimated costs of organs received from another OPO or TH in its expected acquisition costs (whether for a kidney or for another organ). CMS modifies its regulation to state that an IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

One commenter noted that there is no comparable reconciliation for non-renal organs procured by OPOs as there is for kidneys. CMS agrees and notes that it did not propose to reconcile non-renal organs procured by OPO but may do so in future rulemaking. In response to another comment, CMS notes that the SAC incorporates all allowable costs of procuring an organ; therefore, there should be no additional amounts billed such as additional surgeon fees or other extra costs. MACs may adjust kidney SACs due to cost changes, and IOPOs may adjust non-renal SAC amounts due to cost changes.

Accounting for Outpatient Costs and Laboratory Services

CMS finalizes its proposals (without modification) to codify its policies with respect to inclusion of outpatient costs, including pre-transplant evaluation service costs, and laboratory services. These include hospital costs normally classified as outpatient costs that apply to organ excisions, including donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission and the costs of services rendered by interns and residents not in an approved teaching program.

Pre-transplant evaluation services for both recipients and donors that are provided by the TH, including laboratory services, are paid through the organ acquisition costs of the TH.

Section 1881(b)(2)(A) of the Act requires histocompatibility laboratories to be paid on a reasonable cost basis. MACs establish interim rates that histocompatibility laboratories may bill a TH or an OPO. Final payment for kidney-related transplant tests furnished by these laboratories is determined by reconciling interim payments and reasonable costs during final settlement of the cost report.

Accounting for the Cost of Services Provided to Living Kidney Donors

Any individual who donates a kidney for transplant surgery is entitled to benefits under Medicare parts A and B with respect to such donation without any premiums or other cost-sharing.6 Coverage is limited to donor expenses that are incurred directly in connection with the kidney donation.

Hospital Services. Kidney acquisition costs with respect to a living donor include hospital outpatient costs for medical evaluation in anticipation of donation, hospital costs incurred for the actual acquisition of the kidney, and inpatient care for the organ removal (for an unlimited number of days).

Physician Services. When a living kidney donor receives hospital outpatient services for medical evaluation in anticipation of donation, kidney acquisition costs include physicians' services applicable to the medical evaluation. Upon admission of the donor to a hospital for kidney excision, physicians' services are no longer considered kidney acquisition costs and thus are not reimbursable under Part A. The surgical excision of the kidney from a living donor is included in the global surgery policy, with a reasonable post-surgical follow-up period defined as 90 days,

6 See section 1881(d) of the Act.

which includes all services by the primary surgeon during the 90-day 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.

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. The period of postoperative recovery for routine follow-up care ends when the donor no longer exhibits symptoms related to the kidney donation. Routine follow-up services from physicians other than the operating physician are available for up to 6 months; MACs will review claims for such services furnished more than 3 months after the donation surgery.

OPTNs collect follow-up data at 6, 12, and 24 months after the donation. Routine clinical visits to comply with the OPTN follow-up data collection are not allowable or reportable as organ acquisition costs on the cost report and may not be billed to Medicare. Medical services for a living kidney donor who experiences a complication directly related to the kidney donation procedure are covered and billable to the program. CMS clarifies that payments for services furnished for living donor follow-up are not being eliminated and that it did not propose any changes to existing policies related to living donor follow-up visits.

Medical Complications. In the proposed rule, CMS noted receiving questions as to whether medical complications of a living organ donor are considered organ acquisition costs. It 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. One commenter worried that the proposed language requiring that complications be directly attributable to a kidney donation would narrow the scope of complications for which coverage was available and would have a chilling effect on donation. CMS declines to change its policy though it does modify the language in the regulation text in the final rule with respect to the scope of complications to refer to "directly related" to the surgery to remove the kidney as opposed to "directly attributable".

CMS further clarifies that while living kidney donor complications are organ acquisition costs, they are not reported on the cost report nor paid through the cost report as organ acquisition costs. Rather, the costs of living kidney donor complications are billable under Parts A and B using the Medicare kidney transplant recipient's beneficiary identifier. The costs and charges for living kidney donor complications are reported on the cost report as normal patient care expenses and not organ acquisition costs or charges.

CMS notes that it does not have similar statutory authority to pay for living non-renal donation complications in the same manner as living kidney donor complications, but it does consider the hospital costs related to living non-renal donor complications to be organ acquisition costs when they are directly related to the donation. It states that hospital costs for living non-renal donor complications are not separately billable to Medicare using the recipient's beneficiary identifier, and, unlike the costs of complications for living kidney donors, they must be reported and paid through the hospital's cost report as organ acquisition costs.

Accounting for the Cost of Services Provided to Transplant Recipients

CMS notes that certain costs related to a recipient of an organ transplant are not organ acquisition costs; rather, these are Part B services billed to the recipient. These costs include standard backbench preparation services; physician services for the surgeon who performs the transplant and provides days of post-operative surgical care; immunosuppressant therapy management; and recipient laboratory services occurring after discharge from the hospital.

Codification of Statutory Provisions Related to Pancreata Used for Pancreatic Islet Cell Transplants (§413.406)

CMS finalizes its proposals (without modification) to codify its policy to define pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation for Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial as an organ for purposes of organ acquisition payment. This applies to pancreata procured on or after October 1, 2004; the effective date is statutory.

Calculation of Medicare's Share of Organ Acquisition Costs, Counting of Organs

Background

Medicare organ acquisition payment policy includes the presumption that some organs are transplanted into Medicare beneficiaries, despite the category name “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.

In a 1978 final rule (43 FR 58370), Medicare established its intention to pay for kidney acquisition costs incurred for kidneys transplanted into Medicare beneficiaries only. In a 1988 proposed rule, CMS expressed its 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).

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. CMS believes 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.

CMS presents data from the Scientific Registry of Transplant Recipients (SRTR) and how it compares to the shares reported on Medicare cost reports regarding the percentage of organs transplanted into Medicare patients. The below table indicates that Medicare has been paying a higher share of organ acquisition costs than demonstrated by the SRTR data.

Organ	2017 Medicare Share	2017 SRTR Medicare Share	2018 Medicare Share	2018 SRTR Share
Kidney	68.2%	58.9%	67.8%	58.6%
Heart	42.0%	31.6%	42.8%	33.0%
Liver	39.1%	28.4%	38.6%	29.2%
Lung	44.2%	43.9%	46.6%	45.7%
Pancreas	61.6%	49.1%	58.0%	45.8%
Intestine	18.1%	14.7%	14.9%	15.4%

CMS notes that each OPO must be a member of, participate in, and abide by the rules and requirements of the Organ Procurement Transplantation Network (OPTN). OPTN policy provides that OPOs use organ tracking capability, and some THs also optionally use organ tracking capability. Per OPTN policies, THs, histocompatibility laboratories, and organ procurement organizations enter data into the OPTN database that links all 57 OPOs, 254 THs and 150 histocompatibility labs to list patients for transplant, match patients with available donor organs and submit required OPTN data.

Proposed Rule Policies
For the reasons noted above, CMS proposed 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 cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, it proposed that Medicare usable organs include only organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage beneficiaries with dates of service after January 1, 2021), organs for which Medicare has a secondary payer liability for the organ transplant, and pancreata used for pancreatic islet cell transplants. Other provisions of the regulations for determining Medicare's share would be unchanged.

Comments/Responses
Commenters did not support 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. They cited, among other concerns, loss of revenue, increasing procurement costs, and shifting costs to other parties involved with organ acquisition and transplantation. CMS believes these concerns warrant further consideration and does not finalize its proposed policies for counting organs for determination of Medicare's share of organ acquisition costs as it had proposed at §§413.408 and 413.410 at this time. However, the agency notes it may consider these policies in future rulemaking.

CMS does not believe its 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. However, it acknowledges that children's hospitals would have experienced significant revenue losses if they were required to only count organs transplanted into Medicare beneficiaries. CMS also wants to further investigate claims that reporting only organs transplanted into Medicare beneficiaries on the Medicare cost report would

be burdensome. With respect to the impact analysis included in the proposed rule, CMS notes its estimate 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; it believes that this is the best available data and that it serves as a reasonable proxy for the Program's share of organ acquisitions costs.

Some comments pointed to a 1995 CMS letter 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. (The letter also stated 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.) In this final rule, CMS states that the methodology in the 1995 letter no longer aligns with its anti-cross subsidization principles or with reasonable cost principles upon which the Program's organ acquisition cost reimbursement policies are based. However, as noted above, it does not finalize its organ counting proposal.

CMS disagrees with those commenters who asserted the counting proposals raised privacy or HIPAA concerns with respect to THs or OPOs disclosing or receiving payor status of an organ recipient.

Final Decision
With the exception of counting pancreata used for pancreatic islet cell transplants as an organ for purposes of organ acquisition payment (described in paragraph (g) above), CMS does not finalize its proposals for counting organs. However, CMS believes that OPOs could reasonably determine whether an organ recipient is a Medicare beneficiary; this is because OPOs have access to the OPTN database and to the identity of recipients of each organ procured by the OPO. Further, 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, and 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. However, the agency acknowledges that there are still information gaps that should be examined; for example, when an OPO or TH excises and furnish organs to a recipient TH or OPO, it may not have access to the OPTN data for the organ recipient in order to determine the primary payor. CMS may pursue these policies in future rulemaking.

Provisions Related to Intent to Transplant, and Counting En Bloc, Research, and Discarded Organs (§413.412)

CMS explains that organ acquisition costs include costs incurred in obtaining an organ intended to be transplanted even though the organ may ultimately be unusable. Costs for organs acquired for research purposes are not included in organ acquisition costs except for those organs intended to be transplanted that were unusable and donated for use in research.

Intent to Transplant

The agency presumes that THs and OPOs intend to procure all donor organs that are medically suitable for transplant. CMS finalizes its proposal (without modification) to specify that, for the purpose of organ acquisition payment, an organ is intended for transplant when the OPO or TH designates it for transplant before the time the donor enters the hospital's operating room for surgical excision/recovery of the organ. This is because regardless of whether the OPO or TH procures the organ for transplant, it incurred costs in trying to procure it. The OPO and TH must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type.

CMS also clarifies that an OPO or TH may demonstrate that it did not intend to procure a particular organ if (i) the donor does not meet the criteria for eligible death as specified by the OPTN; (ii) the organ has been eliminated for eligibility because of donor information; (iii) the organ has been ruled out by laboratory data prior to the donor entering the operating room for excision of organs; (iv) the family does not provide consent to donate the organ or the donor is not a registered organ donor; or (v) the search for a recipient for that particular organ has ended unsuccessfully prior to the donor's entrance into the operating room.

Counting and Cost Allocation of En Bloc Organs

CMS finalizes its proposal (without modification) to codify its longstanding policy for counting en bloc organs (two organs transplanted as one unit) procured for transplant. Thus, OPOs and THs count en bloc lungs or en bloc kidneys procured and transplanted en bloc as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney. However, en bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients are counted as two total usable organs. For each organ transplanted into a Medicare beneficiary, OPOs and THs count each as one Medicare usable organ or one Medicare usable kidney. CMS notes in response to comment that it did not propose changes to the calculation of the Program's share of the costs to acquire en bloc organs.

Research Organs

CMS had 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). It proposed to specify requirements for 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.

Commenters objected to the proposals arguing that they represented a change in policy and they would negatively impact the availability and affordability of research organs. CMS does not finalize the following proposals included in the proposed rule:

- Specifying that OPOs and THs do not count organs designated for research activities before the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organ.

- Specifying that OPOs and THs do not count organs designated for transplant before 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.

It had intended to clarify its 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. CMS notes that under 42 CFR 413.90(a), costs incurred for research purposes, over and above usual patient care, are not includable as Medicare allowable costs.

CMS does finalize its proposals to state that organs used for research (other than pancreata) are not counted as Medicare usable organs in Medicare's share of organ acquisition costs and kidneys used for research are not counted as Medicare usable kidneys in Medicare's share of kidney acquisition costs.

Counting and Cost Allocation of Discarded/Unusable Organs

CMS had proposed to specify that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded. This would have included organs that are determined to be unusable and subsequently donated to research.

The agency finalizes the proposal with a modification to remove the language related to organs determined to be unusable and subsequently donated to research. It may consider the issue of unusable organs donated to research in subsequent rulemaking. CMS notes that 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.

In response to a comment, CMS notes its longstanding policy is to exclude unusable organs or organs procured and subsequently determined unusable from the numerator and the denominator of the Medicare share calculation. This policy allows the costs to be included and spread out amongst all the remaining transplantable organs and shared by all payors.

Provisions Related to Medicare as Secondary Payer—Organ Acquisition Costs and Medicare Organ Count (§413.414)

CMS finalizes its proposals to codify the Medicare as secondary payor provisions for organ acquisition costs and counting Medicare usable organs with one modification described below.

General Principle

Where the Medicare program is not a beneficiary's primary health insurer and where the primary health insurer has primary liability for transplant and organ acquisition costs, Medicare may share liability to the TH for the organ acquisition costs as a secondary payer. The TH must review its agreement with the primary insurer.

No Secondary Payer Liability

Where the primary health insurer's agreement requires the TH to accept its payment as payment in full for the transplant and organ acquisition costs, Medicare has zero liability as a secondary payer for either the transplantation costs or the organ acquisition costs. Additionally, the organ is not counted as a Medicare usable organ.

Potential Secondary Payer Liability

Where the primary health insurer's agreement does not require the TH to accept its payment as payment in full for the transplant and organ acquisition costs, Medicare may have liability as a secondary payer.

- The TH must submit a bill to its MAC and must compare the total cost of the transplant (e.g., the transplant DRG amount and the organ acquisition costs) to the payment received from the primary health insurer.
- If the primary insurer's payment is greater than the transplant DRG amount and the organ acquisition costs, there is zero Medicare liability. Additionally, the TH may not count the organ as a Medicare usable organ.
- If the primary insurer's payment is less than the transplant DRG amount and the organ acquisition costs, then:
    1) The TH must prorate the payment from the primary payer between the transplant DRG amount and the organ acquisition costs;
    2) Only the TH that performed the transplant may count the organ as a Medicare usable organ; and
    3) The portion of payment applicable to organ acquisition is used on the cost report (to reduce Medicare organ acquisition costs).

CMS modifies its proposal to clarify that only the TH that performs the transplant may count the organ as a Medicare usable organ when there is a Medicare secondary payer liability.

Organ Acquisition Charges for Kidney Paired Exchanges (§413.416)

In a directed living kidney donation, the donor names a specific recipient who will receive the donor's kidney. A kidney paired exchange is similar to a directed living donation, but when the living donor and recipient do not match, they may 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.

CMS proposed to codify its policies for kidney paired exchanges. CMS received no comments on its proposal and finalizes it without modification. A brief description of the policies follows.

Where different THs may be involved 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 costs of all hospital and physician services for pre-transplant living donor and recipient evaluations become acquisition costs and are included in the cost report of the recipient's TH, regardless of whether the recipient is a Medicare beneficiary.

Further, 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 cost report.

Where a donor's TH procures and furnishes a kidney to a recipient's TH, all costs must be reasonable and necessary and the following requirements must be met:

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 the costs associated with procuring, packaging and transporting the kidney on its cost report as kidney acquisition costs and offsets any payments received from the recipient's TH against these costs.
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.

Additionally, where 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 cost report of the recipient's TH, and the travel expenses of the living donor are not allowable Medicare costs.

Donor Community Hospitals (§413.418)

Background

Medicare-certified hospitals that are not THs but collaborate with OPOs to procure organs from cadaveric donors for transplantation are referred to as "donor community hospitals." 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.

Stakeholders have made CMS aware that some donor community hospitals are charging OPOs amounts that are in excess of reasonable costs for harvesting organs from cadavers, resulting in Medicare paying more than reasonable costs for the acquisition of cadaveric donor organs for transplant. 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. CMS indicates that not reducing the charges to costs is inconsistent with reasonable cost payment principles under section 1861(v) of the Act.

Stakeholders have also made CMS aware 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 the 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.

Proposed Rule Policies
CMS proposed 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.

CMS also proposed 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.

Comments/Responses
Some commenters said if Medicare does not cover expenses before the donor's death, there would be uncompensated donor testing which may become the responsibility of the donor's family or other third-party payers. CMS notes that the program 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 provided. Thus, costs for services incurred for potential organ donation before the declaration of death may not be included in the cost report.

Other commenters claimed that the proposal to limit amounts paid to donor community hospitals would limit the number of organs for transplant and that donor community hospitals may not work cooperatively with OPOs. While CMS acknowledges that donor community hospitals may receive less compensation, it reiterates that the hospitals will still be paid under the reasonable cost methodology. Additionally, the regulations currently require donor community hospitals to work with OPOs per the CoPs.

CMS believes OPOs and donor community hospitals and THs should have some flexibility 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. It also agrees with comments indicating that THs are in a similar situation to donor community hospitals when they provide services with respect to cadaveric donors; CMS clarifies that in these circumstances, THs must bill the OPO the lesser of 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. The hospital-specific CCR for a donor community hospital is the same CCR that is used in the IPPS outlier calculation. CMS also notes that 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.

Final Decision
CMS finalizes its proposals with modifications that a donor community hospital (a Medicare-certified non-transplant hospital) and a TH incur organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate. Additionally, for cost reporting periods beginning on or after the effective date of the final rule, when a donor community hospital or a TH incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of (i) its customary charges 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 (ii) a negotiated rate.

Technical Corrections and Conforming Changes

The preamble to the final rule describes numerous revisions, technical corrections and conforming changes to relevant regulations in parts 412 and 413 with respect to which no comments were submitted. They are finalized as proposed.

Comment Solicitation Regarding Surgeon Fees for Cadaveric Donor Kidney Excisions

CMS indicates that cost report data from 48 OPOs showed average surgeon fee costs per local kidney of $745. Medicare's payment is limited to $1,250 for excising a cadaveric donor kidney. While this limit is above the costs that OPOs are incurring, CMS has received comments suggesting the $1,250 limit needs to be raised. CMS did not make a proposal on this issue, but it requested comment.

Some commenters supported increasing the limit; they believe $1,250 is insufficient to cover surgical costs, travel costs, and costs related to dry runs and wait times. Others cited increased costs due to medical and technological advancements. A commenter noted that OPOs sometime pay more than $1,250 to ensure availability of surgeons to excise kidneys. Another commenter believed the use of 2017 cost report data is flawed because the cost report would only show the limit rather than the actual amount paid in the case of payments in excess of the $1,250 limit. One commenter queried whether the cadaveric kidney retrieval cap applies to THs, and if so, how the cap applies when multiple organs are excised. The commenter also questioned whether CMS imposed the same retrieval cap for excision of other organs.

A few commenters suggested that CMS survey transplant programs to collect the requisite data to rebase payments for this service. It was also suggested that the agency establish an annual process to provide input to update pricing. Another commenter suggested an inflationary increase to the limit while collecting data to update the fee.

CMS indicates it may take this input into account if it engages in future rulemaking for surgeons' fees for recovering cadaveric kidneys.