hfma
healthcare financial management association

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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1752-P
P.O. Box 8013
Baltimore, MD 21244-1850

File Code: CMS-1752-P

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Brooks-LaSure:

Congratulations on your recent confirmation as the Administrator for the Centers for Medicare and Medicaid Services ("CMS"). The Healthcare Financial Management Association (HFMA) would like to thank CMS for the opportunity to comment on *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals* (hereafter referred to as the Proposed Rule) published in the Federal Register on April 27, 2021. HFMA is a professional organization of more than 70,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with numerous rules and regulations that govern the industry.

Introduction
HFMA would like to commend CMS for its thorough analysis and discussion of the many Medicare payment decisions addressed in the 2022 Proposed Rule. Our members would like to comment on the specific proposals related to:

- Repeal of the Market-Based MS-DRG Relative Weight Policy
- Wage Index
- Organ Acquisition Costs and Reimbursement
- Codifying Existing Regulations Related to Organ Acquisition Reimbursement
- Require Donor Community Hospitals to Charge OPOs Reasonable Costs
- Solicitation of Comments Regarding Surgeon Fees for Cadaveric Kidney Donor Excisions
- Close Gaps in Health Equity in Graduate Medical Education (GME)

Repeal of the Market-Based MS-DRG Relative Weight Policy
CMS is proposing to repeal the requirement that hospitals report the median payer-specific negotiated charge, by MS-DRG, that is negotiated with its Medicare Advantage payers for cost reporting periods ending on or after January 1, 2021. CMS estimates this will reduce administrative burden on hospitals by approximately 64,000 hours. CMS is also proposing to repeal the market-based MS-DRG relative weight methodology that was adopted effective for FY 2024 and continue using the cost-based MS-DRG relative weight methodology to set Medicare payment rates for inpatient stays for FY 2024 and subsequent fiscal years.

HFMA members applaud CMS for proposing to repeal the requirement that all hospitals report payer-specific negotiated charges for cost reporting periods ending on or after January 1, 2021. HFMA continues to support price transparency efforts that strengthen consumer friendly disclosure of healthcare prices. We encourage the agency to continue the focus on patient price and not complex negotiated payment rate structures influenced by provider networks and utilization analysis that do not assist consumers in making sound healthcare decisions. HFMA members support CMS efforts to reduce administrative burden and costs for hospitals during the public health emergency and HFMA supports the agency's efforts to focus on expanding access to patient out-of-pocket costs and educational opportunities to assist consumers in becoming more prudent purchasers of health care. **HFMA is cautiously optimistic that the proposed repeal of the requirement to report payer-specific negotiated charges is not a temporary reprieve, and that CMS continues to remain consumer focused when it comes to price transparency initiatives.**

HFMA members commend CMS' repeal of the market-based MS-DRG relative weight methodology that was adopted effective for FY 2024 and support the use of the cost-based MS-DRG relative weight methodology to set Medicare payment rates for inpatient stays for FY 2024 and subsequent fiscal years. As stated in previous comment letters, it is unreasonable to use median payer-specific negotiated charge information by MS-DRG to change relative weights. As set forth in section 1886(d)(4)(A) of the Act, relative weights are intended to reflect "the relative hospital resources used with respect to discharges classified within that group" and not the relative price paid. CMS currently uses "a cost-based methodology to estimate an appropriate weight for each MS–DRG."[1] The previous rationales CMS used for basing MS-DRG relative weights on price had nothing to do with whether median payer-specific negotiated charges were a measure of "hospital resources used" as Medicare statute requires. **HFMA applauds the agency for proposing the repeal of the market-based MS-DRG relative weight methodology.**

Wage Index
Low Wage Areas: The area wage index (AWI) is used to adjust Medicare operating and capital payments for geographic variations in labor costs. For FY 2020 and at least three additional years, FY 2021-2023, CMS has proposed to reduce disparities in the Medicare AWI among hospitals that have a low AWI value by increasing the AWI for hospitals in the bottom quartile funded by a decrease in the national standardized operating rate for all hospitals. HFMA appreciates CMS' recognition of hospitals with low wage rates but recommends an approach CMS supported in the past when buoying frontier states to an AWI of 1.0 through new funds. HFMA and other healthcare industry leaders have repeatedly expressed concern that Medicare's wage index is flawed in many respects, including its accuracy, volatility and substantial reclassifications and exceptions. Members of Congress and Medicare officials also have voiced concerns with the present system. To date, a consensus solution to the wage index's numerous shortcomings has yet to be proposed. While the HFMA strongly supports improving the wage index for

[1] Id. at 32,791.

hospitals with low wage rates, especially in rural areas of the country, **HFMA opposes CMS' proposal to buoy AWI values for some hospitals only to be funded by a reduction to the standardized operating rate for other hospitals, especially when Medicare pays less than the cost of providing care in many cases.**

Stop Loss Transition Policy: In the FY 2021 IPPS final rule, CMS seeks comment on continuing the policy to cap at 5% any decrease in a hospital's final FY 2021 wage index compared to its FY 2020 wage index. This policy is currently set to expire Sept. 30, 2021 but considering the strong impacts of the public health emergency, the agency is contemplating continuing the transition policy. **HFMA urges CMS to locate additional monies to extend the stop loss transition policy in FY 2022 to protect all hospitals with a wage index decline that exceeds 5%, regardless of circumstance. We also request that CMS implement the policy in a non-budget-neutral manner, given the extreme impacts the COVID-19 pandemic has had on all hospitals.**

Hospital Market-Basket Rebase: CMS is proposing to update and rebase the hospital market-basket from 2014 to 2018, proposing to use a revised national labor-related share of 67.6 percent to adjust payments in FY 2022 for hospitals with a wage index of 1 or greater. The agency currently uses a national labor-related share of 68.3 percent to adjust payments to hospitals with an area wage index greater than 1. The difference of .7 percentage points is estimated to drastically reduce operating payments for many of HFMA's member hospitals.

The above reduction of .7 percentage points in labor related share is a result of weighting shifting from the Wages and Salaries and Benefits categories to the Professional Fees: Labor Related categories. The Professional Fees category includes both Home Office/Related Organization salary, wage, and benefit costs and Non-Medical Professional Fees (e.g., accounting & auditing, legal, engineering, and management consulting services) cost categories.

CMS proposes to separate costs associated with professional fees for the proposed 2018-based IPPS market basket into "Professional Fees: Labor-Related" and "Professional Fees: Nonlabor-Related" cost categories. CMS explains this mapping by stating it "includes a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market."

Of the 6.4 percentage points CMS assigns to the Non-Medical Professional Fees cost category, the agency proposes to assign 4.1 percentage points to the Labor-Related Cost category using the results of a 2008 survey of 108 hospitals. The remaining 2.3 percentage points are to be assigned to the Nonlabor-Related Cost category.

In redefining the portion of home office costs that CMS states, "vary with the local labor market," CMS compared the location of the hospital to the location of the hospital's home office and calculated the percentage of home office labor costs that were located in the same MSA as the hospital. Based on this methodology, CMS determined that 60 percent of hospitals' home office compensation costs were for home offices located in their respective MSA and therefore is proposing to allocate 60 percent of Home Office/Related Organization cost weight to the Labor-Related Cost category.

As a result, of the 5.9 percentage points related to the home office costs, CMS is assigning 3.5 percentage points to the Professional Fees: Labor-Related cost category and designating the remaining 2.4 percentage points into the Professional Fees: Nonlabor-Related cost category. Based on this movement, it would appear CMS assumes that Home Office/Related Organization wage related costs

and the reduction to the Professional Fees: Labor-Related category is a non-trivial portion of Home Office/Related Organization wage related costs and Non-Medical Professional Services Fees and they do not vary based on geography.

HFMA questions CMS' assumption that a portion of home office labor costs and professional services fees do not vary based on geography and labor market. We also question the methodology that CMS uses to determine the non-labor portion for home office salary and wages and benefits.

> *Professional Services Fee Cost Weight*: First, HFMA questions the validity of CMS' assumption that fees for services provided by firms outside of a hospital's CBSA do not vary based on geography. The assumption is that national and regional professional services firms do not compete with local professional services firms based in a hospital's CBSA. However, this is not true. When hospitals seek professional services, the services they are seeking are not area regionally (e.g., accounting, engineering, management consulting) and they can be provided by regional or national firms. **HFMA respectfully requests CMS to provide evidence that market-based pricing for professional services provided by regional and national firms to hospitals does not exist. Unless the agency can produce strong evidence that prices for professional services provided by firms outside of a hospital's local labor market are homogenous, HFMA requests CMS to restore the 2.3 percentage points it proposes to reclassify to professional services: non-labor related to the professional services: labor related category.**
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> *Home Office/Related Organization Cost Weight*: CMS assumes, without providing additional data to support the assumption, that because 40% of hospitals' home office compensation costs were for home offices located outside of their respective local labor markets that those costs are not subject to geographic variation. Based on this limited analysis, CMS proposes to assign 3.5 percentage points of the 5.9 percentage points to the Professional Fees: Labor-Related cost category and designate the remaining 2.4 percentage points into the Professional Fees: Nonlabor-Related cost category. **HFMA strongly disagrees with the assumption that home office compensation costs that occur outside of a hospital's labor market are not subject to geographic wage variation and do not believe the proposed reclassification to the Professional Fees: Non-Labor Related cost category is justified based on the lack of data provided by CMS.**

Finally, if the agency determines that a reduction in the labor-related share is supported by data and appropriate for either Professional Services Fees or Home Office/Related Organization cost weight categories, HFMA asks that CMS phase in a reduction of the labor-related share. We ask that any phase-in be over a period of three years and implemented in a non-budget neutral manner in recognition of the precarious nature of hospital finances in the wake of the COVID-19 PHE.

Proposed Changes to "Medicare Organ" Acquisition Costs

The proposed rule states that Medicare organ acquisition payment policy includes the presumption that some organs are not transplanted into Medicare beneficiaries, despite the category name "Medicare usable organs" or "Medicare kidneys." As a result (and contrary to Medicare's general policy prohibiting cross-subsidization) Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries.

The rule also explains that Medicare's decades-old presumption that most kidney transplant recipients are Medicare beneficiaries included non-renal organs because of the lack of organ tracking capabilities. This presumption led Medicare to reimburse transplant hospitals and organ procurement organizations

(OPOs) for organ acquisition costs for organs that were not actually transplanted into Medicare beneficiaries. CMS now believes that organ tracking capabilities allow transplant hospitals and OPOs to discern organ recipients' health insurance payer information so that organ acquisition costs can be more appropriately assigned to the Medicare program for organs transplanted into Medicare beneficiaries.

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 Transplant Hospitals also optionally use organ tracking capability.

Based on these assumed tracking capabilities, CMS proposes that transplant hospitals must accurately track, 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, CMS is proposing at (§413.408b) to narrow the definition of Medicare usable organs include:

1) Only organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage beneficiaries with dates of service after January 1, 2021)
2) Organs for which Medicare has a secondary payer liability for the organ transplant
3) 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.

HFMA strongly opposes CMS' proposal to remove excised organs from the excising transplant hospital's count of Medicare organs unless the excising transplant hospital can provide auditable documentation that the organ in question was transplanted into a Medicare beneficiary. Facts gathered from conversations with HFMA hospital transplant program staff conflict with key assumptions that CMS makes about transplant hospitals' ability to obtain an organ recipient's insurance information. The access to organ recipient's current insurance information that CMS describes in their proposal does not exist. It is also highly unlikely that an OPO or Transplant Hospital would share their transplant recipient's demographic information with a community donor hospital or transplant hospital that excised the organ due to patient privacy and HIPAA laws. Further, the proposed rule fails to outline the quality, amount and type of documentation that an excising transplant hospital would need to obtain and maintain to meet the agency's (and a MAC auditor's) burden of proof that an excised organ was, in fact, transplanted into a Medicare beneficiary.

Given the considerable issues with the proposed change, as discussed below in detail, HFMA respectfully asks CMS to ensure that Medicare beneficiaries and other individuals who require organ transplantation have access to these services by withdrawing the agency's proposed change to the definition of Medicare organs. If CMS wishes to continue pursuing this policy HFMA asks the agency to allow sufficient time for the capabilities that CMS presumes to exist to be developed and any actual or perceived legal barriers be addressed.

According to a report published by Fior Markets in May of 2021, the global organ care products market is expected to grow from $95M in 2020 to $271M by 2028, at a compounded annual growth rate (CAGR) of 14% for the forecast period. The factors driving the demand for organ transplantation in the market include increasing organ failure in the elderly population, growth of chronic cardiovascular diseases, rising prevalence of kidney failure, emerging occurrence of obesity and adoption of smoking.

Factors inhibiting market growth for organ transplants include lack of human donors, lack of awareness about organ donation and high cost of organ transplantation.

Medicare fee-for-service spends $144 billion a year, or about 20% of its budget, on beneficiaries with kidney disease. Of that $114 billion, Medicare expects to pay $10.3 billion to approximately 7,400 ESRD facilities for renal dialysis services. More than 100,000 Americans begin dialysis to treat ESRD annually, while one in five dies within a year.

During a time when health equity, quality outcomes, healthcare spending and patient centered care are all key focus areas of healthcare, CMS' proposal to redefine what a Medicare Organ is seems to undermine the future solvency of life saving care provided by transplant programs.

CMS' proposal is built on three key assumptions related to the ability of an excising transplant hospital to access information about the recipient of an organ sent to an OPO or transplant hospital. The following are detailed concerns about the validity of each of these assumptions based on conversations HFMA has had with healthcare professional working in hospital transplant programs.

1) *Insurance Information Is Available in Unet*: CMS states that all transplant hospitals are required to input information, including insurance information, into Unet when an individual is registered for a transplant waitlist. Based on this, CMS assumes that information about an organ recipient's insurance coverage is readily available to either the excising transplant hospital or the OPO. Based on conversations with HFMA's members, excising transplant hospitals can only access information in Unet about individuals that it has placed on a transplant waitlist. An excising transplant hospital cannot access information about individuals placed on a transplant waitlist by other transplant hospitals. **Therefore, an excising transplant hospital (hospital A) cannot obtain insurance information from Unet related to an individual who receives the organ at another transplant hospital (hospital B) – even if that organ was excised at hospital A and provided to hospital B via an OPO.**

   OPO staff confirm that the information they can access in Unet is limited to what is clinically necessary to successfully match an individual on a waitlist to a donated organ. Given that an OPO is paid for its services by the transplanting hospital it provides an organ to, OPO staff stated that they have no need to (or right to) know the organ recipient's insurance information. Further, concern was expressed by OPO staff that if the OPO had access to detailed demographic information, like source of insurance coverage, it could create the mistaken impression that socio-economic factors were inappropriately influencing decisions about who ultimately receives an organ, specifically in inner-city transplant programs where Medicaid recipients make up much higher percentages of the recipient population. **The OPO does not have access to an organ recipient's insurance information; therefore, an excising hospital cannot obtain an organ recipient's insurance information from the OPO it sent the organ to.**

2) *Determining Recipient of an Excised Organ Electronically*: CMS asserts that an excising transplant hospital can electronically track the recipient of an organ provided to an OPO. HFMA's members with transplant programs state that they do not have this capability. **Given that transplant hospitals' access to information on Unet is limited to individuals the transplant hospital has placed on a waitlist; there is currently no way for an excising transplant hospital to know who the recipient of an organ donated to an OPO is, much less their insurance coverages.**

3) *OPOs Will Provide Recipient Information to Excising Hospitals Allowing for Manual Tracking*: CMS asserts excising transplant hospitals that lack automated organ tracking capabilities can obtain information about an organ recipient from the OPO "manually." As discussed above in item 1, the OPO also does not have access to the recipient's insurance information. But even if it did, OPO staff have stated they would not provide the insurance information, name of the recipient, or the transplanting hospital. OPO staff believe that sharing any information about the organ recipient with the excising hospital would "violate general privacy laws." Further, staff stated that there is no legal requirement for an OPO to share any information about the ultimate recipient of an organ provided by an excising transplant hospital to an OPO.
If OPOs refuse to provide the necessary information about the recipient of an excised organ, an excising transplant hospital cannot "manually" track an organ to determine the recipient's insurance information.

   HFMA believes it is possible that state medical privacy and security laws apply to OPOs and do not permit disclosures of patient information to a hospital that is not treating the patient (recipient of the organ). It is unclear whether OPTN or OPOs are "health information networks" subject to the information blocking rules; even if they are, this would not be helpful to the extent that state medical privacy laws prohibit disclosure of information about a patient to a hospital that is not caring for that patient. Further, OPOs are also subject to Medicare Requirements for Certification and Designation and Conditions for Coverage (CfCs), which require OPOs to develop and implement policies and procedures to ensure the confidentiality and security of patient information. If CMS elects to pursue this policy, we ask the agency to revise the OPO CfCs to provide a mechanism that, in absence of state a privacy law prohibiting disclosure, compels an OPO to provide an excising transplant hospital with insurance and other necessary demographic information about the recipient to determine if an organ provided to an may be included in the count "of Medicare organs."

Beyond the insurmountable operational issues discussed above, HFMA has concerns about the accuracy of insurance data collected and maintained in the Unet system. These concerns include the frequency with which a potential organ recipient's insurance information is updated in Unet, the availability of secondary payer information and the documentation required to substantiate an organ recipient's insurance status.

Frequency of Insurance Information Update: Based on conversations with HFMA members, insurance information is collected by the transplant hospital when that individual is registered for the transplant waitlist. However, this information is not used by the transplanting hospital to bill the organ recipient's health plan when transplantation occurs. The billing information is maintained in the hospital's patient accounting system. As CMS staff are aware insurance status, particularly for individuals with a servere chronic illness that requires an organ transplant, is not static. It is not uncommon for recipients to wait three or more years for an organ to become available for transplant during which time the individual may have aged into Medicare eligibility or become eligible due to ESRD rules or disability. However, there is no requirement to update the recipient's information in Unet after the candidate is initially placed on a transplant waitlist.

Given Unet insurance data is typically not updated once an individual is placed on an organ transplant waiting list, quickly becoming stale information, HFMA does not believe it is sufficiently accurate for use in determining which organs that are excised and sent to an OPO

are ultimately transplanted into a Medicare beneficiary. Therefore, Unet insurance data should not be used for this purpose or for the purpose of calculating Medicare organ share based on the Scientific Registry of Transplant Recipient data CMS provides at 86 FR 25666 to allege that Medicare is inappropriately cross-subsidizing organ acquisition costs that should be borne by other payers.

Secondary Payer Information: As CMS discusses and proposes to codify on 86 FR 25668 and 86 FR 25669, organs where Medicare is the secondary payer in qualifying situations are included in both the allowable cost and count of acquired organs for a transplant hospital. **HFMA strongly supports this continuation and codification of existing policy.** However, secondary insurance information is not captured when an individual is placed on a transplant waitlist. HFMA points out that the form CMS references (O.M.B. NO. 0915-0157) only has space for a single HIC number and conversations with members confirm that only primary payer information is collected when an individual is registered for an organ transplant waitlist. An example of the form is available here: https://unos.org/wp-content/uploads/unos/Adult-TRR-Kidney.pdf.

Even if secondary payer information is eventually captured, it will not be sufficient by itself, based on Medicare regulations, to conclude that an excised organ sent to an OPO and transplanted by another transplant hospital into an individual who has Medicare as a secondary payer may be counted as a Medicare organ. CMS proposes to codify that when Medicare is the secondary payer the program will only cover the organ acquisition costs if 1) the transplanting hospital's contract with the recipient's primary insurance does not require acceptance of the primary payment as payment in full and 2) the payment from the primary payer, after being prorated and allocated based on the costs of the transplant procedure and the organ acquisition costs is insufficient to cover the costs of acquiring the organ. In cases where Medicare is the secondary payer for the recipient of an excised organ, the excising transplant hospital will need documentation from the transplanting hospital to support that the organ meets both criteria. This will require the transplanting hospital to share contracting, payment and cost structure details with the excising hospital.

HFMA is concerned that even if the operational issues discussed above are eventually resolved obtaining information to prove that an excised organ may be counted where Medicare is the secondary payer will create a significant, unnecessary administrative burden for excising transplant hospitals. Furthermore, many health plans as part of their standard contracting practices, prohibit hospitals from publicly disclosing the terms of their contracts. Therefore, an excising transplant hospital may not be able to obtain the required information from the transplanting hospital to determine if an excised organ transplanted into a recipient with Medicare as a secondary payer can be counted as a Medicare organ.

Auditable Documentation of an Organ Recipient's Health Insurance Coverage: The proposed rule does not discuss what specifically an excising transplant hospital will need to produce when a Medicare cost report is audited to support a transplant hospital's count of excised organs that were sent to an OPO and subsequently transplanted into a Medicare beneficiary at another transplant hospital. **In addition to resolving the operational issues discussed above CMS must clearly articulate for both their MACs and transplant hospitals what documentation is required to support an excising transplant hospital's assertion that a given organ that was excised and sent to an OPO was in-fact transplanted into a Medicare beneficiary.**

HFMA is concerned that if this policy is finalized, excised organs that are sent to an OPO will no longer be allowed in the Medicare organ count, regardless of whether they were ultimately transplanted into a Medicare beneficiary. As discussed above, the operational capabilities do not exist for an excising transplant hospital to obtain an organ recipient's insurance information or track an organ sent to an OPO to the final recipient. And OPOs neither believe they can share organ recipient information with the excising hospital, nor believe they should do so.

Instead of ensuring that Medicare only pays for the costs associated with transplanting organs into Medicare beneficiaries, if finalized, the agency's proposal will no longer reimburse the excising transplant hospital for their allowable organ acquisition costs when an organ is sent to an OPO and subsequently transplanted into a Medicare beneficiary. This policy change is contrary to 42 CFR 412.113(d) which states "payment for organ acquisition costs incurred by hospitals with approved transplantation centers is made on a reasonable cost basis" and will inappropriately transfer the costs of organ acquisition for some Medicare beneficiaries from the program to the transplant hospitals that excise these organs. This additional unreimbursed cost is not sustainable for transplant hospitals will ultimately reduce access to organ transplantation for both Medicare and non-Medicare individuals who require this life and cost saving procedure.

HFMA respectfully asks that CMS withdraw this proposal as it is unworkable given the inability of excising transplant hospitals to obtain recipient payer information when an organ is donated via an OPO to a separate transplant hospital. If CMS does not withdraw this proposal, we ask the agency to delay implementation for at least five years. This will give transplant hospitals, the OPTN and the OPOs sufficient time to develop and implement the processes and safeguards necessary to track organs from the excising hospital to the transplant recipient and report the recipient's insurance information. It will also give CMS and its MACs time to define the necessary supporting documentation excising transplant hospitals will be required to obtain and maintain. Additionally, HFMA strongly recommends that if CMS intends to implement this policy the agency must first clarify how federal data privacy and security laws, including HIPAA and Information Blocking, apply to OPOs in this situation. Further, the agency must understand how individual state privacy laws may prohibit an OPO from providing this information to excising transplant hospitals before implementing this policy. Finally, CMS must modify the OPO CfCs to provide a mechanism to compel OPOs to provide the necessary organ recipient and demographic information to the excising transplant hospital, assuming this is not prohibited by state law.

Codifying Existing Regulations Related to Organ Acquisition Reimbursement

CMS proposes to codify a number of payment policies related to organ acquisition cost reimbursement that currently exist in sub-regulatory guidance. HFMA is concerned that the specific language the agency proposes to codify related to allowable organ acquisition cost and living donor complications does not match the language that currently exists in the relevant sections of Chapter 31 of the Provider Reimbursement Manual (PRM) or may be subject to misinterpretation by a MAC auditor. We do not believe it is CMS' intent to engage in retroactive rule making; therefore, we ask that the agency address the issues discussed below.

Proposed Items and Services Considered Organ Acquisition Costs: CMS at 86 FR 25659 proposes to codify the items and services it considers Medicare Part A covered organ acquisition costs at § 413.402(a) for both renal and non-renal organs. The specific items and services the rule proposes to codify include:

1) Tissue typing, including tissue typing furnished by independent laboratories
2) Donor and beneficiary evaluation

3) Other costs associated with excising organs, such as general routine and special care services provided to the donor
4) Operating room and other inpatient ancillary services applicable to the donor
5) Preservation and perfusion costs
6) OPTN registration fees
7) Surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys)
8) Transportation of the excised organ to the transplant hospital
9) Costs of organs acquired from other hospitals or organ procurement organizations
10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up and related services furnished prior to admission)
11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs
12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and surgeons' fees for cadaveric excisions, applicable to organ excisions including the costs of physicians' services.

PRM 3101A and PRM 3101B currently define the allowable Medicare Part A standard organ acquisition cost for living and cadaveric donors respectively. Specific to item three above (general routine and special care services) HFMA notes that the emphasized language related to the "donor" is not currently included in either PRM 3101A or PRM 3101B. We also note that in item four above (operating room and other inpatient ancillary services) PRM 3101B does not include the emphasized language related to donor.

HFMA is concerned that the change in language may be inappropriately interpreted by some to imply that the costs associated with the services described by items three and four are only allowable when provided to a living donor. Therefore, we respectfully ask that in the final rule, CMS clarify that these costs will be covered for living and cadaveric donors. This can be achieved amending the proposed language for items three and four above to read at § 413.402(a) as follows:

3) Other costs associated with excising organs, such as general routine and special care services *provided to the living or cadaveric donor*
4) Operating room and other inpatient ancillary services *applicable to the living or cadaveric donor*

We believe these additions will clarify CMS' intent and eliminate the possibility of confusion as to whether costs associated with general routine, special care services, operating room and other inpatient ancillary services are covered for cadaveric donors.

Medical Complications Related to Living Kidney Donors: The proposed rule at 86 FR 25663 notes that CMS has received questions as to whether medical complications of a living organ donor are considered "organ acquisition costs." In response to this, CMS proposes to codify the language below at 42 CFR 413.402(c) to new subpart L:

> *Medicare covers costs incurred for living kidney donor complications only if they are directly* ***attributable to the kidney donation.*** *Costs incurred for complications arising after the kidney donor's discharge date are billed under the Medicare transplant recipient's MBI, including facility costs and physician services. The contractor reviews costs for kidney donor complications billed under the transplant recipient's MBI.*

HFMA notes that the current language at PRM 3105B related to living donors reads as follows:

> *Expenses incurred for complications that arise with respect to the donor are covered only if they are directly **attributable to the organ donation**. Complications that arise after the date of the donor's discharge are billed under the recipient's health insurance claim number. This is true of both facility costs and physician services.*

Living donations are possible for organs other than kidneys (e.g., living donation of partial livers). In limited instances, like living kidney donations, these donors may experience post-discharge complications. We note, as emphasized above in the language from PRM 3105B, that CMS' current policy related to living organ donor complications is not specific to kidneys provided to Medicare beneficiaries. HFMA is concerned that the proposed rule only addresses complications related to living kidney donors, as emphasized above from 86 FR 25663. **The proposed rule is silent on how the agency will cover living donor complications for organs other than kidneys provided to Medicare beneficiaries. Therefore, we respectfully ask that CMS affirm that it will continue covering post-discharge complications related to living organ donation for all organs provided to Medicare beneficiaries. Otherwise, if the cost of post-discharge complications must be shouldered by the donor or other entities, HFMA is concerned that this will limit the availability of other organs amenable to living donation to Medicare beneficiaries.**

Given that the proposed rule is silent on an effective date for these changes HFMA assumes that CMS is proposing to make them effective retroactively. **If the agency does not address the issues described above related to items included in the Medicare Part A allowable standard acquisition charge and complications related to living organ donor complications, HFMA respectfully asks CMS to make the changes to its policies related to allowable pre-transplant charges and living donor complications effective October 1, 2021.** We strongly believe it is inappropriate for the agency to engage in retroactive rulemaking.

Proposals Requiring Donor Community Hospitals to Charge OPOs Reasonable Costs
Medicare-certified hospitals that are not transplant hospitals 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).

CMS alleges in the proposed rule 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. In response, CMS proposes to add § 413.418(b) in new subpart L, to specify that for cost reporting periods beginning on or after October 1, 2021, when a donor community hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered.

Based on conversations with member hospital transplant staff, HFMA found that community donor hospitals have negotiated rates with the OPO and therefore reimbursement for excised organs is not based on billing charges. Additionally, while HFMA appreciates CMS' concern, we note there is

opportunity cost incurred when a community donor hospital elects to use its operating room to excise cadaveric organs. Hospitals infrequently have operating rooms that sit idle, so when one is used for cadaveric organ recovery, it requires that a scheduled procedure be canceled or delayed. This cancellation or delay results in lost margin for the community donor hospital, which must be offset in the payment from the OPO for harvesting the organ. If CMS finalizes its proposal and caps community donor hospital payment from OPOs for excised organs to the procedure's cost, HFMA is concerned that it will decrease the number of viable recovered organs and ultimately reduce access to organ transplantation for both Medicare and non-Medicare individuals who are in need of this life saving procedure.

Therefore, HFMA does not support CMS' proposal to require community donor hospitals to bill OPOs the charges associated with excising an organ reduced to cost using the hospital specific CCR. If CMS believes this issue is widespread enough that it must address it, we ask that the agency:

1) Continue to allow community donor hospitals to negotiate standard acquisition charges with the OPOs.
2) Work with community donor hospitals to determine a reasonable margin that compensates them for the opportunity cost of using an operating room and related resources to excise cadaveric organs. Once this is determined, it will allow CMS to move to a reasonable cost reimbursement model that fully accounts for the opportunity cost of delayed or canceled procedures to allow for the OR time necessary for cadaveric organ recovery. This model should only be used when an OPO and a community donor hospital have not negotiated a standard acquisition charge.

HFMA believes taking these steps will mitigate the negative impact changes to community donor hospital organ acquisition will have on the availability of organs for transplantation.

Solicitation of Comments Regarding Surgeon Fees for Cadaveric Kidney Donor Excisions
The FFY 2022 proposed rule 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. **Based on conversations with HFMA's members the current limit of $1,250 is inadequate relative to the surgical, travel, wait times and ancillary transportation expenses incurred when recovering cadaveric kidneys. HFMA invites CMS to formally survey transplant programs to collect the data necessary to rebase payments for this service.**

Closing Gaps in Health Equity in Graduate Medical Education (GME)
CMS is proposing to make strides in closing gaps in health equity through the training and retention of physicians in underserved communities that have historically experienced workforce challenges. CMS proposes to implement sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA) 2021 which addresses the distribution of additional residency slots, adjustments to the FTE caps for hospitals facilitating rural training tracks and adjustments to the per resident amount and FTE count for hospitals that host a small number of residents for short duration. **Overall, HFMA supports the agency's effort to create additional Medicare funded residency training slots to address current and anticipated physician shortages.**

The Proposed Rule also outlines a requirement that data reported in the Intern and Resident System (IRIS) match the cost report the data it relates to. **HFMA does not negate the importance on consistent**

data sources, but request CMS delay the requirement to allow hospitals and MACs sufficient time to familiarize themselves with the new platform and address potential process issues that could result in unintended cost report submission errors.

In addition, HFMA recommends that CMS take into consideration the enormous impact that COVID-19 has had on the healthcare workforce. Physician retention, burnout, shortage, and delays in establishing new medical residency programs are just a few of many unprecedented disruptions hospitals have encountered during the PHE. **HFMA requests that CMS extend the five-year cap-building window for impacted hospitals by the length of the PHE plus the additional time needed to reach July 1, to align with the start date of the academic year when residency programs begin**.

The 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 FFY 2023. 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 areas designated as Health Professional Shortage Areas (HPSAs)

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

HFMA's members appreciate the agency's efforts to equitably and effectively distribute the new residency positions created by the CAA. However, we are concerned that CMS' proposed definition of Category Four is overly restrictive and would impose unintended limitations on physician shortages in certain areas.

CMS is proposing to adopt geographic HPSAs for primary care and mental health providers to identify hospitals that serve areas designated as HPSAs. Furthermore, the agency is proposing that hospitals that only have campuses or provider-based facilities in mental health only geographic HPSAs may only apply for positions for psychiatry residency programs. Additionally, as part of the qualification requirements under Category Four, in the residency program for which the hospital is applying, at least 50 percent of the residents' training time over the duration of the program must occur at those locations in the HPSA.

Although HFMA appreciates that the HPSA Physician Bonus Program and Category Four requirements under the Section 126 distribution requirements are similar, the situations surrounding these programs pose their own unique challenges.

The intent of the HPSA Physician Bonus Program is to encourage physicians to establish practices in HPSAs through increased Medicare payments. Similarly, the intent of requiring that at least 10% of the Section 126 slots be allocated to residency programs at hospitals that *serve* HPSAs is to address a

shortage of physicians in these areas. However, while it is relatively easy for a physician to establish a new practice in a specific geographic area, it is not feasible for a teaching hospital to create a new program within the geographic limits of a HPSA in order to secure additional residency slots. The agency must acknowledge the limited number of slots available through this distribution will not offset the costs associated with creating a new program within the geographic confines of a HPSA. Therefore, HFMA is concerned that given this narrow definition, few hospitals will qualify and apply for slots under Category 4 and an opportunity to increase access to care for individuals in underserved areas – as was Congress's intent – will be missed.

As CMS states in the proposed rule, hospitals outside of HPSAs provide much needed care to individuals who live in areas where the supply of physicians is insufficient to meet the demand. HFMA encourages CMS to expand its definition of a hospital that serves a HPSA to include proximate hospitals that support care shortages in underserved areas. **Therefore, HFMA respectfully requests the agency to expand the definition of hospitals that qualify for residency positions under Category Four to include those within ten miles of the border of the HPSA or expand Category Four to include population HPSAs rather than being limited to geographic HPSAs, which would satisfy PHSA section 332(a)(1)(A) and 332(a)(1)(B).**

CMS proposes to prioritize applications from qualifying hospitals that serve underserved populations using population based HPSAs. HFMA understands this to mean that all additional residency positions will be distributed to hospitals that qualify under Categories One through Four based on the population HPSA score of the area by the residency program for which each hospital is applying. Programs serving higher HPSA scores will receive higher prioritization. Like the use of geographic HPSAs, CMS proposes hospitals that only have main campuses or provider-based facilities in mental health only population HPSAs may only apply for position for a psychiatry residency program. Hospitals applying for residency positions for programs that do not serve HPSAs are not categorically excluded, but those applications would have the lowest priority.

As CMS discusses in the proposed rule prioritizing applications based on HPSA scores duplicates criteria that the agency is already mandated by Congress to consider as part of the application process. HFMA shares this concern and notes that Congress only mandated a minimum of 10% of the new residency positions be allocated to programs serving HPSAs, not 100% which is what CMS' scoring criteria implies. Therefore, using population based-HPSA scores to prioritize distribution of all new residency positions will make expanding residency slots for hospitals that are training over their cap, residency programs in rural areas and states with new medical schools or additional branches of existing medical schools a non-priority.

HFMA respectfully requests that CMS withdraw its proposal to use population HPSA scores to prioritize applications for additional slots. Not only does the proposal far exceed what Congress intended – to the detriment of its other priorities– when included in the prioritization of these newly created slots, it may be ineffective to address projections of long-term physician shortages.

As an alternative, the proposed rule discusses 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. **For the FFY 2023 distribution HFMA encourages CMS to use the alternative distribution methodology that prioritizes applicants for the additional slots created by section 126 of the CAA based on the number of categories the hospital qualifies for. For FFY 2024 and beyond, HFMA encourages CMS to**

develop an alternative scoring factor to prioritize applications for receipt of additional residency slots. We ask CMS to consider collaborating with teaching hospitals and exploring a methodology that gives priority to applications seeking to create or expand programs in specialties that have the highest projected future physician shortfalls.

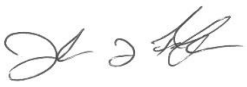
CMS anticipates that the 200 resident per year distribution will be oversubscribed leaving the agency without enough slots to distribute to teaching hospitals that may qualify. To make additional residency positions available to more hospitals each year, the agency proposes to limit the increase in the number of residency positions made available to each individual hospital to no more than 1.0 FTE each year.

HFMA understands that CMS would like to make additional residency slots available to as many hospitals per year as possible. However, from the perspective of a teaching hospital trying to build or expand a residency program this is impractical. The current proposed limit of 1 FTE per hospital per year makes it difficult to plan and build a program as there is no guarantee that the hospital will receive slots in subsequent years to support the new or expanded program. The residency program will face considerable uncertainty regarding the funding source as the slot awarded in its first year 2023 may impact the hospital's eligibility for subsequent distributions of residency slots and could limit the number of hospitals that are willing to add new or expand additional programs.

HFMA believes that CMS can address this uncertainty by modifying the limitation on the number of residency slots the agency distributes per year. **We respectfully recommend that instead of limiting a qualifying teaching hospital to one FTE per year and requiring it to reapply each year for additional slots for the residency program that the agency tie the number of slots allocated in response to an application to the duration of the residency program the teaching hospital is creating or expanding.**

HFMA looks forward to any opportunity to provide assistance or comments to support CMS' efforts to refine and improve the FY22 IPPS. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS and advisory groups. We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Senior Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



Joseph J. Fifer, FHFMA, CPA
President and Chief Executive Officer
Healthcare Financial Management Association

About HFMA

HFMA is the nation's leading membership organization for more than 70,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices,

accounting and consulting firms and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant and consultant.

HFMA is a nonpartisan professional practice organization. As part of its education, information and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices and standards.