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June 28, 2021

Via Electronic Submission

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

RE: CMS-1752-P, 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

Dear Administrator Brooks-LaSure:

On behalf of our more than 470 member hospitals and health systems, the Texas Hospital Association appreciates the opportunity to provide comments on the above-referenced proposed rule for the Hospital Inpatient Prospective Payment System. These comments address CMS' proposals regarding the following issues:

- Organ Acquisition
- Medicare DSH
- MS-DRG
- Negotiated Charges

Organ Acquisition

Recommendation

THA strongly opposes CMS' proposal to reduce organ acquisition payments. We respectfully urge CMS to delay implementation of the transplant-related proposals until HHS conducts a comprehensive policy impact analysis including a focus on the proposal's potential repercussions for organ donation and procurement, and its effect on patient access to transplantation. Without a comprehensive approach, any reduction or withdrawal of Medicare funds would result in a disruption that could reduce the overall availability of organs nationwide for transplants to both Medicare and non-Medicare patients.

The proposed changes are estimated to reduce Medicare payments by \$46M/year to 20 tertiary care hospitals in Texas for their 55 transplant programs. This includes a reduction of \$5.8M/year in payments to three children hospitals in Texas.



Background

Organ acquisition costs are excluded from the MS-DRGs and instead are paid based on reasonable and necessary costs. In order for Medicare to more accurately pay its share of organ acquisition costs, CMS believes it is necessary to require that transplant hospitals /hospital based organ procurement organizations keep track of organs, the identity of the organ recipient, and whether that recipient is a Medicare beneficiary.

CMS is proposing that beginning FFY 2022, transplant hospitals and hospital-based organ procurement organizations must accurately count and report Medicare usable organs and kidneys and total usable organs/kidneys on their Medicare hospital costs reports. Medicare usable organs would include:

- organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage beneficiaries with a date of service after January 1, 2021);
- organs for which Medicare has a secondary payer liability for the transplant; and
- 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.

Medicare usable kidneys would include only kidneys transplanted into Medicare beneficiaries.

When a donor community hospital (a Medicare-certified non-transplant hospital) incurs costs for services provided to a cadaveric donor, it bills the OPO its customary charges (not reduced to cost) or a negotiated rate. CMS is proposing that 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.

In the proposed rule, CMS estimates a cost savings to Medicare of \$230 million in FY 2022. This differs radically from an analysis of transplant hospitals' FY 2019 cost reports, which estimates an aggregate loss of \$383 million to transplant hospitals for organ donation and procurement efforts. The forecast of donated organs that will be eliminated from "Medicare usable organs" under the proposal is a best estimate because there is no available mechanism for a transplant hospital to identify the ultimate recipient. That gap exists because the organ allocation process, which determines the transplant recipient, is independent of the organ procurement process.

Twenty-seven children's transplant hospitals across the nation would bear a loss of over \$28 million in the first year. This is because Medicare's coverage of children is almost exclusively limited to end stage renal disease patients so this policy would exclude cost-based reimbursement for non-renal organs: life-saving hearts, lungs, livers, intestines, or pancreas. Furthermore, while kidney transplants comprised 56% of all transplants at these hospitals, only

one-fourth of those were Medicare beneficiaries. These hospitals may experience further losses at the state level for State Medicaid agencies and Medicaid managed care organizations that use CMS' current formula in their reimbursement methodology.

Without Medicare's support for any other patients, transplant hospitals would expend considerable time and resources attempting to renegotiate contracts with all other payors. An effective date of October 1, 2021 does not give providers and payors the time needed to agree on and implement the transition – assuming insurers choose to do so. Smaller health insurers and privately funded employers may limit transplantation as a benefit to their members or employees rather than cover procurement expenses. We ask that CMS not impose these administrative and financial burdens that would increase transplant hospitals' expenses at a time when CMS is simultaneously proposing to drastically cut transplant hospitals' reimbursement. Transplant hospitals should be allowed to focus on their most precious responsibility-savings lives.

There is no established mechanism for transplant hospitals to cross-reference the organ's travels – nor is there a need to when the focus is on the patient in front of them. CMS' proposed policy would necessitate the development of a reliable, real-time, secure, navigable, HIPAA-compliant, national clearinghouse for transplant hospitals to access the new data requested by CMS for our cost reports. The clearinghouse would need to include verification and validation of recipients' Medicare status as ultimately measured by Medicare primary or secondary payments to the transplant recipient's hospital. An infrastructure of this magnitude and complexity could not be completed by any one hospital or stakeholder groupalone.

Under this proposal, costs incurred by a transplant hospital to increase our nation's organ supply would remain without reimbursement for an indeterminate duration of time and possibly receive no compensation at all. If the recipient's insurance policy does not include coverage for organ recovery costs, the recipient is covered by Medicaid, or the recipient is uninsured or underinsured, individuals would have no organ procurement coverage under this policy. This results in the hospital receiving no reimbursement for its efforts and be forced to absorb the loss. This would adversely and disproportionately affect transplant hospitals that serve a high volume of uninsured and/or high volume of Medicaid beneficiaries such as children's hospitals.

The proposed provisions would also undermine ongoing HHS' initiatives to transform how kidney disease is prevented, diagnosed, and treated within the next decade. CMS' FY 2022 budget highlights HHS' goal of 80 percent of new ESRD patients either receiving dialysis at home or receiving a transplant by 2025. The current reimbursement structure has been a primary factor in hospital and transplant leaders' ability to engage internal teams, partners, and the community to improve organ donation and access to transplantation.

Medicare DSH

Recommendation

THA opposes CMS' proposal to limit section 1115 patient days that hospitals may include in the Medicaid fraction of their Medicare DSH calculations. It is THA's belief that CMS lacks the authority under the Medicare Act to exclude certain section 1115 waiver days from the DSH calculation once CMS has approved the section 1115 waiver. CMS' proposal to limit allowable section 1115 waiver days by deeming as "eligible for Medicaid" only those section 1115 waiver days explicitly providing "inpatient hospital insurance coverage on that day" to individual patients conflicts with the Medicare Act, the congressionally ratified existing regulations, and recent court decisions. We urge CMS to abandon their proposed amendments to 42 CFR Section 412.106 (b)(4).

Background

CMS proposes to amend 42 CFR Section 412.106(b)(4) to limit the patient days associated with a section 1115 demonstration waiver that may be included in the computation of the Medicaid fraction of the Medicare Disproportionate Share Hospital adjustment:

"For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient . . . directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver."

The Proposed Rule focuses on two types of section 1115 demonstrations that CMS has approved but is nonetheless concerned are not sufficiently similar to traditional Medicaid benefits (1) uncompensated care pools and (2) premium assistance programs.

Neither the plain language of the Medicare DSH statute nor the plain language of the applicable regulations permit CMS to limit the section 1115 patient days that may be counted in the Medicaid fraction of Medicare DSH payment adjustment to waiver days that CMS believes are "comparable to traditional Medicaid benefits." Courts who have considered CMS's recent attempts to limit the section 1115 waiver days counted in the Medicaid fraction have found CMS' limitations unlawful.

In addition, CMS' proposal to limit section 1115 waiver days that may be counted to those resembling traditional Medicaid insurance runs afoul of the purpose of both the Medicare DSH payment statute (where the counting of Medicaid days serves only as a proxy for capturing the relatively higher costs associated with providing services to low income patients) and the section 1115 demonstration waivers, which by their very nature are experimental and differ from traditional Medicaid insurance.

The proposed 42 CFR 412.106(b)(4) would inappropriately reduce hospitals' capacity to provide needed care to low-income population after hospitals have legitimately relied on CMS' Section 1115 waiver approval.

MS-DRG

Recommendation

We <u>support</u> CMS' proposal to delay the application of the Non-CC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023. In addition, we support CMS' proposal for FY 2022 to maintain the current structure of the 32 MS-DRGs that have a three-way severity level split (total of 96 MS-DRGs) that would otherwise be subject to these criteria.

Background

In the proposed rule CMS states that "using the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, we analyzed how applying the Non-CC subgroup criteria to all MS-DRGs currently split into three severity levels would affect the MS-DRG structure beginning in FY 2022."

"Findings from our analysis indicated that approximately 32 MS-DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, we found that applying the Non-CC subgroup criteria to all MS-DRGs currently split into three severity levels would result in the deletion of 96 MS-DRGs (32 MS-DRGs × 3 severity levels = 96) and the creation of 58 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases. We refer the reader to Table 6P.1c for the list of the 96 MS-DRGs that would be subject to deletion and the list of the 58 new MS-DRGs that would be proposed for creation for FY 2022 under this policy if the Non-CC subgroup criteria were applied."

"In light of the public health emergency (PHE), we have concerns about the impact of implementing this volume of MS-DRG changes at this time, and believe it may be appropriate to delay application of the Non-CC subgroup criteria to existing MS-DRGs in order to maintain more stability in the current MS-DRG structure. Therefore, we are proposing to delay the application of the Non-CC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023, and proposing for FY 2022 to maintain the current structure of the 32 MS-DRGs that currently have a three-way severity level split (total of 96 MS-DRGs) that would otherwise be subject to these criteria."

Negotiated Charges

Recommendation

We <u>support</u> CMS' proposal to repeal their finalized policy requiring hospitals to report the median payer-specific negotiated charges for Medicare Advantage plans as well as a new market-based methodology for estimating the MS-DRG relative weights using these negotiated charges.

Background

"In FFY 2021, CMS finalized a policy that required hospitals to use the Medicare cost report to report "the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations ... payers, by MS-DRG" for cost reporting periods ending on or after January 1, 2021 as well as a new market-based methodology for estimating the MS-DRG relative weights, beginning in FFY 2024, which would be based on the median payer-specific negotiated charge information collected on the Medicare cost report."

"Due to comments received on the 60-day Paperwork Reduction Act revision request published on November 19, 2020, CMS is proposing to repeal both of the aforementioned policies while comments and alternative approaches are considered."

Thank you for your consideration of these comments. We look forward to working with you on these issues. Should you have any questions or comments, please email me at rschirmer@tha.org.

Sincerely,

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