Texas Hospital Association

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Via electronic submission

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1716-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: CMS-1716-P, Medicare Program: Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Ms. Verma:

On behalf of our more than 450 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 Medicare Disproportionate Share payments, CC/MMC reclassifications, and payment for CAR T-cell therapy. This is the second of our two comment letters concerning this proposed regulation.

Medicare Disproportionate Share Payments

The ACA mandates the implementation of Medicare disproportionate share payments in order to address the reductions to uncompensated care as coverage expansion takes effect. The uncompensated care pool is to be distributed to hospitals based on each hospital's proportion of UCC relative to the total UCC pool for all DSH-eligible hospitals. With a growing number of uninsured in Texas, these payments are an important source of Medicare payments for our Texas hospitals. In FFY 2020, 199 Texas hospitals are estimated to receive approximately $1.3B in Medicare DSH payments.

Due to concerns regarding data variability and lack of reporting experience with Worksheet S-10, CMS has been using Medicaid and Medicare SSI days as a proxy for uncompensated care in Factor 3 since FFY 2014. In the FFY 2018 IPPS final rule, CMS again stated that it has been seeing an improving correlation between Factor 3 values calculated using data on uncompensated care from Worksheet S-10 and those calculated using data from the IRS Form 990. CMS began

to phase-in the use of data (charity care and non-Medicare bad debt expense) to calculate Factor 3 starting with FFY 2014 cost reports for DSH payments in FFY 2018.

For FFY 2020 CMS is proposing to utilize a single year of Medicare cost report data from the audited FFY 2015 S-10 Worksheet and to discontinue the three year averaging process for Factor 3. CMS is seeking public comment on whether FFY 2017 S-10 data should be used in lieu of the audited FFY 2015 S-10 data.

1. **We strongly support CMS' proposal to continue utilization of the S-10 data. The transition away from the use of Medicaid days and SSI data to determine uncompensated care payments was necessary and appropriate;**
2. **We support utilizing the most accurate data available;**
3. **We realize there is no perfect data year to use. Although use of the audited 2015 data is the best policy decision, an argument can be made to use the more current 2017 data; and**
4. **We support utilizing 2017 S-10 audited data for FFY 2021 IPPS payments.**

We received the following comments from our members concerning which data year to use.

Use of 2015 data

Advantages

- The 2015 data for the larger providers have already been scrubbed/audited
- The 2015 data was the most recent S-10 data that had any sort of meaningful MAC audit scrutiny. This helps ensure data integrity as any questionable data have been reviewed and verified

Disadvantages

- Audited hospitals may be conceptually disadvantaged when compared to hospitals that were not audited
- This is older data and does not reflect the revised S-10 instruction changes

Use of 2017 data

Advantages

- 2017 is a more current time period
- The S-10 instructions were not clear until the 2017 cost reports. There was a lot of confusion about certain fields. In September 2017, CMS issued transmittal 11 to clarify the instructions. Every hospital received a letter clarifying some of the data elements on S-10 and asking hospitals to either explain unusual data or to resubmit their data

Disadvantages

- As the data have not been audited, there will be data incongruities for this time period. There will be a lack confidence in the data until the data is audited
- Without an audit the data for some hospitals might be questionable and may severely distort the distribution of payments

Use of three year average

Advantages

- Use of the three year average was a stop-gap approach to provide a transition to a fairly major change
- A three year average provides some stability. It reduces fluctuations caused by using a single year of S-10 data

Disadvantages

- Bad principle to mix audited and unaudited data in developing the database
- If a provider has UCC dollars that are rapidly changing, it makes for a slow response. Using a three year average will hurt the newest of providers that don't have a full complement of data to report

CAR T-Cell Therapy

CAR T-cell therapy is approved by the FDA as the standard of care for some forms of aggressive, refractory non-Hodgkin lymphoma and for patients with relapsed or refractory acute lymphoblastic leukemia up to age 25. In addition, there are many ongoing trials for CAR T-cell therapy for other forms of blood cancers. Because this is a highly specialized, highly personalized treatment, CAR T-cell therapy is available at a limited number of cancer centers with specialized expertise in cellular therapies.

Currently CAR T-cell therapy is lumped into the MS-DRG for autologous bone marrow transplant (MS-DRG 16). **We encourage a new MS-DRG be created because the costs of the drugs and therapy are significantly higher.** The challenge in determining a weight for CAR-T therapy is that not all therapies have the same resource use as a patient's escalation of acuity is unpredictable.

There are risks of significant side effects with CAR T-cell therapy. If a patient does NOT have an adverse reaction to the therapy, the autologous grouper is similar to the intensity of clinical resources needed to provide the care. In cases with an adverse reaction, patients are admitted and require resources closer to the cost of those used for allogeneic bone marrow transplant (MS-DRG 14). It is impossible to determine at the time of infusion whether the patient will have

an adverse reaction. As more CAR T-cell therapies are approved and come to market, there will be an increased need to create a dedicated MS-DRG for CAR T-cell therapy.

Given that reimbursement by CMS is insufficient to cover the cost of Yescarta or Kymriah, and that hospitals are not sufficiently reimbursed for the cost of cell acquisition and preparation, hospitals are disincentivized to offer CAR T-cell therapy for Medicare patients. There had been a request to create a new MS-DRG specifically for CAR T-cell treatments, however CMS is not proposing this change for FFY 2020 due to the limited number of cases in which they are used.

The reimbursement hospitals receive from CMS is not their net reimbursement because of the costs incurred in paying other parties for specialized services that are part of the CAR T-cell therapy process. Even the 65 percent new technology add-on payment is insufficient because of the high cost for the drugs and therapy process. **CMS should consider modifying the NTAP for this therapy. More hospitals would be encouraged to offer this life-saving therapy if the NTAP were to be 100 percent of the cost of the drug and independent of the cost-to-charge ratio**.

CC/MCC Reclassifications

CMS proposes to change the complication and comorbidity severity levels of approximately 1,500 ICD-10 diagnosis codes. CMS' proposal runs contrary to their goal of eliminating overly burdensome and unnecessary regulations. **We do not support this proposal without additional transparency, clinical clarity, and analysis of multiple years of MedPAR files across provider types.**

CMS should analyze more than one year's worth of MedPAR data. Not all the DRGs selected for downgrade are clinically sound changes. These changes will impede accurate documentation of a patient's medical condition. Severity levels provide distinction for risk stratification and are necessary tools to capture the degree to which a patient's medical complexities should influence health care decisions made by providers, patients, family and caregivers.

A coding system that is too simple will impair the coordination and continuum of patient's health care. For example, transfers to post-acute care will be inefficient and potentially dangerous because severity levels will not reflect the clinical resources that a patient will be based on the reality of their condition. This will also have ramifications on coverage determinations such as IRF eligibility and SNF 3-day qualifying stay.

The switch from ICD-9 to ICD-10 was a collective step forward to improve granularity thereby improving medical decision-making and patient outcomes. The loss of granularity proposed by CMS will negatively impact research and patient care because inappropriately aggregated data runs the risk of providing misleading results.

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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