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October 5, 2020

Via electronic submission
<http://www.regulations.gov>

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1736-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: CMS-1736-P, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.

Dear Ms. Verma:

On behalf of our more than 465 member hospitals and health systems, including rural, urban, children's, teaching and specialty hospitals, the Texas Hospital Association appreciates the opportunity to provide comments on the above-referenced proposed rule for the Hospital Outpatient Prospective Payment System.

The following summary reflects THA's comments on CMS' proposals regarding hospital payment and quality initiatives.

1. Medicare Wage Index
2. Physician Owned Hospitals
3. Inpatient Only List
4. Prior Authorization
5. Supervision of Outpatient Therapeutic Services
6. Site-Neutral Payments for Off-Campus PBDs
7. 340B Program

1. Medicare Wage Index

Unfortunately for nearly thirty years, the wage index has disadvantaged hospitals located primarily in Southern and rural parts of the country. Due to required budget neutrality, hospitals located in the most affluent areas of the country have been able to steadily increase their Medicare payments at the expense of hospitals in areas where critical care is often

needed the most. Currently hospitals in those areas can be paid almost three times as much for doing the same work as our hospitals causing rural hospital closures and forced consolidation. This was never the Congressional intent.

The problem continues to grow worse each year. Declining Medicare payments have forced our hospitals to further cut both costs and services resulting in a downward spiral. If no reforms are taken, the wage index will continue to contribute to fewer rural hospitals and poorer health outcomes. The influx of additional Medicare payments to struggling, primarily rural hospitals, will allow these hospitals to increase their employee wages and help to break the cycle of downward wage pressure that has resulted in progressively lower wage index values. This will help rebalance the current large disparity in Medicare payments and bring them more in line with Congress' original intent.

CMS noted that many comments from the Wage Index RFI in the proposed FFY 2019 IPPS rule reflect "a common concern that the current wage index system perpetuates and exacerbates the disparities between high and low wage index hospitals." Also mentioned was the concern over the rural floor calculation allowing a limited number of hospitals to manipulate the system to achieve a higher rural floor for the state. This was done at the expense of other states leading to increased wage index disparities.

For FY 2021 CMS began to raise the wage indexes of low wage hospitals between FY 2021 and FY 2023. As it was adopted to be in effect for a minimum of four years in order to be properly reflected in the Medicare cost report for future years. For FFY 2021 CMS continues to increase the wage index for low wage index hospitals. Hospitals with a wage index value in the bottom quartile of the nation would have that wage index increased by a value equivalent to half of the difference between the hospital's pre-adjustment wage index and the 25th percentile wage index value across all hospitals. CMS will continue to offset these increases in a budget neutral manner by applying a budget neutrality adjustment to the national standardized amount.

The COVID-19 emergency has strained hospital resources and has severely impacted their ability to continue operations as prior to the PHE. Many hospitals made the difficult decision to temporarily or permanently reduce wages. As a result, depressed wages represented in the wage data during the PHE stand to lower the hospital wage index adjustment for certain areas.

Recommendations:

- **Rather than applying a national budget neutrality adjustment to the standard amount, CMS should allocate additional funds to cover the additional payments;**
- **As originally proposed last year CMS should reduce the AWI for those hospitals above the 75th percentile. These funds can be used to increase the AWI for those hospitals falling below the 25th percentile;**
- **Ensure the budget neutrality adjustment factor is not applied to those hospitals falling below the 25th percentile; and**
- **Proactively address the COVID PHE impact on hospital wages and their wage indexes by excluding wage index data collected during the PHE from calculation of area wage indexes.**

2. Physician-Owned Hospitals

The physician self-referral (Stark) law prohibits physicians or their immediate family from referring patients to hospitals where the physician or an immediate family member has an ownership or investment interest, subject to certain exemptions. The ACA limited the use of some of these exemptions by imposing a ban on self-referral to new physician-owned hospitals. Specifically, the ACA allows existing POHs to continue operating subject to several conditions and apply to CMS to expand if they meet certain requirements. The law prohibited any new physician-owned hospitals from billing Medicare or Medicaid as of Dec. 31, 2010.

In this rule, CMS proposes to remove certain restrictions on the expansion of POHs that qualify as “high Medicaid facilities.” A high Medicaid facility is one that (1) is not the sole hospital in a county; (2) has an annual percent of total Medicaid inpatient admissions that is greater than that of any other hospital in the county, with respect to each of the three most recent years of available data; and (3) does not discriminate against beneficiaries of federal health care programs and does not permit its physicians to do so. CMS says its current regulations on high Medicaid facilities impose undue burden on physician-owned hospitals and, to that end, it proposes to amend certain regulatory requirements.

CMS’ proposal includes:

- Allowing high Medicaid facilities to request an exception to the prohibition on expansion of POHs more frequently than once every two years.
- Removing the restriction that expansion of POHs may not result in the number of operating rooms, procedure rooms and beds for which the hospital is licensed exceeding 200% of the hospital's baseline number of operating rooms, procedure rooms and beds.
- Removing the limitation that expansion may occur only in facilities on the POH’s main campus.

CMS also proposes to revise the definition of “baseline number of operating rooms, procedure rooms, and beds” to clarify that a bed is included in this baseline number if it is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital.

In addition, CMS is considering eliminating community input in the review process for expansion of high Medicaid facilities and requests input on this topic.

Recommendation:

- **CMS should retain having the review process include community input**

3. Inpatient Only List

In recent years, the OPPI proposed rule has consistently removed several procedures from the inpatient-only (IPO) list each year. The IPO list specifies those procedures for which a hospital will be paid only when the procedures are provided in the inpatient setting due to the complexity of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. There are currently about 1,740 procedures on the list.

The list provides important patient safety guardrails and ensures that Medicare beneficiaries undergoing any of the procedures on the IPO list will receive inpatient care and monitoring, and its proposed elimination without appropriate or adequate clinical analysis threatens that safety.

In the CY 2021 proposed rule, CMS proposes to eliminate the IPO list in its entirety over a three year-period. CMS believes that the distinctions between the need for inpatient care and the appropriateness of outpatient care are becoming less clear as medical practices evolve and that physicians should use their clinical judgment, combined with the needs of the patient, to determine the best care setting for a procedure. Beginning with 2021, CMS proposes to remove 266 musculoskeletal services from the IPO list, with additional clinical families and specific services removed each year thereafter through 2024.

THA strongly opposes the proposed, arbitrary elimination of the IPO list as it would create inappropriate safety risks for Medicare beneficiaries, imposes administrative burdens on physicians and hospitals, increases the financial burden for beneficiaries, and erodes the value of Part A coverage.

Recommendations:

- **CMS strongly supports retaining the IPO list;**
- **CMS continue to follow its current procedures for considering whether a procedure should be removed as well as maintaining the IPO list;**
- **Until a procedure removed as part of the proposed elimination of the IPO list is determined by CMS to be safe and appropriate for Medicare beneficiaries in the outpatient setting, the exception from medical review should continue for that procedure;**
- **Oppose adding total hip arthroplasty to the ASC list in light of clinical concerns;**
- **Oppose eliminating the five exclusion criteria proposed for the ASC list; and**
- **If a procedure is determined by CMS to be safe and clinically appropriate for outpatient delivery, providers should be given at least two years to update their billing systems and gain experience with respect to the newly removed procedures.**

4. Prior Authorization

The CY 2020 OPSS final rule implemented new prior authorization requirements for five categories of covered outpatient department services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. The basis of these new requirements was CMS' belief that there were "unnecessary increases in the volume" of those services based on its review of claims data. In the CY 2021 OPSS proposed rule, CMS updated its analysis of claims data and determined that the overall rate of outpatient department claims increased each year between 2007 and 2018 by an average rate of 2.8 percent. It also determined that the average annual rate of increase in the Medicare allowed amount was 7.8 percent.

Based on CMS' analysis, the agency further determined that there were higher than expected increases for cervical fusion with disc removal and implanted spinal neurostimulator procedures. CMS believes that these increases exceed the average rate of increase in the number of Medicare beneficiaries and that there are no other factors that warrant increased utilization. Consequently, CMS proposes to require prior authorization for these services for claims on or after July 1, 2021.

Doing so will increase the burden on hospitals and health care providers, while at the same time delaying needed care for patients. These requirements run contrary to CMS' stated goal of reducing the regulatory burden hospitals face through initiatives such as Patients Over Paperwork. VHHA's members report that Medicare Administrative Contractors (MACs) are already unable to handle the volume of claims that require prior authorization. Adding additional procedures will only result in further delays.

As we have seen in the Medicare Advantage program, prior authorizations have resulted in delays to access to medically necessary services for patients and significantly increased administrative burdens for providers with no assurances of reimbursement, yet are still subject to recoupment, even after prior authorizations have been approved.

Recommendations:

- **THA opposes implementing prior authorization requirements for these procedures**
- **CMS should rely on existing processes to verify the medical necessity of these procedures**

5. Supervision of Outpatient Therapeutic Services

In the CY 2020 final rule, CMS changed the minimum level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision. However, non-surgical extended duration therapeutic services and pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services were not subject to the change.

For CY 2021, CMS now proposes to permanently establish general supervision as the minimum requirement for NSEDTS furnished on or after January 1, 2021. CMS also proposes to make the use of audio/video real-time communication technology for direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services permanent. However, CMS clarifies that the virtual presence using that technology would not be limited to mere availability but real-time presence throughout the performance of the procedure.

Recommendation:

- **CMS amend this proposal to allow for mere availability rather than real-time presence.**

6. Site-Neutral Payments for Off-Campus Provider Based Departments

For CY 2021, the agency continues to identify the Physician Fee Schedule as the applicable payment system for most clinic visit services and will set payment for most at 40% of the OPPS payment amount for both non-grandfathered (non-excepted) and grandfathered (excepted) provider-based departments (PBDs). THA continues to believe that the payment cut for hospital outpatient clinic visits threatens to obstruct access to care, especially in rural and other vulnerable communities, where these clinics provide convenient access to care.

Recommendation:

- **CMS should reverse its harmful policy of reducing payment for outpatient clinic visits**

7. 340B Program

For more than 25 years, the 340B program has provided safety net hospitals and other providers who treat a disproportionate share of low-income and uninsured patients with a vital drug discount benefit. The savings generated by the program enable hospitals to expand their services and benefit the communities they serve through a variety of programs

Despite ongoing litigation, CMS now proposes to further reduce payments to ASP minus 34.7 percent with a six percent add-on payment, for a net payment reduction of ASP minus 28.7 percent. CMS estimates that this proposal will result in an additional \$427 million payment reduction in CY 2021 alone.

CMS also proposes to continue its policy of extending the proposed payment rate to 340B drugs furnished in non-excepted off-campus hospital outpatient departments and applying it to biosimilar drugs and other drugs without an ASP that are purchased through the 340B program. For biosimilar drugs, CMS would pay the ASP minus 28.7 percent. For drugs without an ASP, payment would be at the wholesale acquisition cost (WAC) minus 28.7 percent if the WAC is available. If the WAC is unavailable, then payment would be at 63.09 percent of the average wholesale price (AWP).

Recommendation:

- **THA opposes further reductions in payments for 340B drugs**

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.



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