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October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: Comments on Proposed Rule CMS–1736-P: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals Proposed Rule (Vol. 85, No. 156), August 12, 2020.

Dear Administrator Verma:

On behalf of our more than 150 member hospitals and integrated health systems, the Wisconsin Hospital Association (WHA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed FY 2020 rule related to the Medicare Program Hospital Inpatient Prospective Payment Systems.

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small Critical Access Hospitals, mid, and large-sized academic medical centers. We have hospitals in every part of the state—from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

Area Wage Index

The area wage index is designed to adjust payments based on local differences in labor costs. WHA has often noted concerns about manipulation of the Medicare Area Wage Index in the prospective payment system. CMS has echoed these concerns in recent proposed rules, noting that results of making the rural floor budget neutral on a national basis, as required by the Patient Protection and Affordable Care Act Section 3141, is that all hospitals in some states receive an artificial wage index that is higher than what the single highest urban hospital wage index would otherwise be. WHA has previously joined with associations in other states to garner support from Congress to address this patently unfair payment manipulation, which has specifically benefited hospitals in states on the east and west coasts and has been commonly referred to as the "Bay State Boondoggle."

WHA continues to support CMS exploring ways to restore fairness to the wage index in this and other rules. In this proposed rule, CMS would continue the policy from recent PPS rules aimed at increasing equity in the wage index calculation:

1. Increasing wage index values for low-wage hospitals in the bottom 25th percentile by adjusting downward the wage index for hospitals in the top 25th percentile.
2. Modifying the rural floor calculation as it relates to budget neutrality. Specifically, CMS would not take into consideration urban hospitals that reclassify as rural hospitals when calculating each state's rural floor.

WHA is generally supportive of these efforts to restore fairness to the wage index so long as they do not unintentionally exacerbate disparities for labor markets with naturally higher wages. However, even with these changes, we believe CMS needs to do more to bring fairness to the wage index calculation. As CMS has previously stated, the impact of the Bay State Boondoggle, that changed budget neutrality from a statewide calculation to a nationwide calculation, is significantly inflated wage indexes across particular states. This has come at the expense of other states and in a manner not intended by Congress when the wage index was originally created.

340B Prescription Drug Discount Program

HHS proposes to increase cuts to 340B hospitals for covered outpatient 340B drugs to a net payment rate of ASP minus 28.7%. It also seeks feedback on whether it should continue to employ the cuts first proposed in the 2018 OPPS rule of minus 22.5%. WHA is very concerned that HHS is proposing new cuts when a federal lawsuit challenging the legality of these cuts is still under review and the previous cuts had been determined to be unlawful prior to a successful appeal by HHS.

WHA continues to oppose these cuts at either level, noting that the savings hospitals receive in discounts from drug companies participating in the 340B program were designed to help hospitals "stretch scarce federal resources as far as possible." It is particularly troubling that CMS is proposing even deeper cuts during a pandemic that is already creating significant financial challenges for 340B hospitals that care for a disproportionate share of Medicaid and low-income patients. It is also worth noting that CMS is basing the data for the new payment cut off a survey hospitals were requested to respond to in the midst of this pandemic, making the survey information inadequate and incomplete.

Continued Site-Neutral Payment Cuts

Like the 340B cuts previously mentioned, site-neutral payment reductions to hospital outpatient departments (HOPDs) are another example of CMS acting unlawfully by going around Congress's clear statutes in attempting to implement a policy at the expense of hospitals. In the 2021 rule, CMS proposes to continue the prior policy of making payments for clinic visit services in grandfathered off-campus HOPDs at the physician fee schedule rate of 40% of the OPPS rate. WHA expressed its displeasure in prior OPPS rules and was joined by members of Wisconsin's Congressional Delegation in asking CMS to abandon this proposal that goes against the clear wishes of Congress. While CMS has cited unnecessary utilization, this contradicts past statements from CMS that recognized hospitals face a higher regulatory burden, serve sicker, more complex patients, must run 24/7 Emergency Departments, and thus face higher costs for which they are not adequately reimbursed.

WHA was relieved to see U.S. District Judge Rosemary M. Collyer rule in hospitals' favor initially in the lawsuit filed by the American Hospital Association, but like the 340B lawsuit, HHS has successfully appealed this decision at the present time. Given that this lawsuit is also under further appeal, and given that many of these hospitals are dealing with additional losses due to COVID-19, we strongly believe HHS should reverse this policy. It is important to note that many of these HOPDs were purchased by hospitals to help keep access to care in their local communities when independent physician practices were at risk of closure due to poor payor mixes and low rates paid by the physician fee schedule. Requiring HOPDs to accept these lower rates will again jeopardize the ability to sustain access to care where it is needed most.

Proposed Additional Prior Authorization Requirements

Continuing to cite its authority to control "unnecessary increase in the volume of services" under section 1833(t)(2)(F) of the Social Security Act and the regulations at 42 CFR § 419.83, CMS proposes to expand the prior authorization program it established in 2020 to two new service categories: cervical fusion with disc removal and implanted spinal neurostimulators by July 1, 2021.

WHA continues to oppose the OPPS prior authorization program as an unnecessary added burden and urges the agency to withdraw it. Furthermore, WHA does not believe HHS has established that the increase in volume for these services is "unnecessary." Oftentimes, increases in utilization of services occur due to advances in care and more widespread adoption of clinical judgement supporting a particular service to treat a condition. In this case, there appear to be medically necessary indications for both categories:

- The increase for implanted spinal neurostimulator utilization appears to be attributable to the national focus on the opioid crisis and providers being encouraged to substitute non-opioid pain management treatments.
- The increase in cervical fusion with disc removal appears to be attributable to the shifting of these services from inpatient to outpatient settings, due to its removal from the inpatient only (IPO) list.

Given that there appears to be good reason for the increase in these services, we urge HHS to continue to allow providers to use their clinical judgement and not establish an additional burdensome process that adds another bureaucratic layer for patients and providers.

Proposals to relax regulations on physician-owned hospitals, eliminate the inpatient only list (IPO) and add to the list of covered Ambulatory Surgical Procedures

WHA has consistently supported reducing regulations on hospitals and providers and instead allowing them to rely on clinical judgment to meet patient care needs. For this reason, we offer only wholesale comments on proposals by CMS to relax regulations on physician-owned hospitals, eliminate the inpatient only list, and add to the list of ambulatory surgical procedures.

While we understand the logic CMS is using for these changes, we urge CMS to thoughtfully consider the overall impact on our healthcare system these changes may have. It is important to recognize that hospitals care for the most vulnerable and most ill or medically complex patients even when certain care or procedures may be available in other settings. While we cannot fault CMS for allowing care to be sought in other settings that are clinically appropriate, CMS should also recognize the impact this may have on patient-mixes and provider revenues.

For instance, if these changes lead to cherry picking of easier patients or more lucrative services in other settings, hospitals may be left with worse patient-mixes. As patient care evolves, CMS must also realign payment for hospitals so that losses from government programs like Medicare and Medicaid are not exacerbated by these changes.

Hospital Quality Star Ratings

From the inception of the Overall Star Ratings, WHA has voiced concern about the complexity of the star rating method, the unreliability of the results, and the inability of our members to use these ratings in a meaningful way. The current statistical process is so complex there is no way for the hospitals to audit their own results for accuracy, making it impossible to appeal a rating. This is especially troublesome as payers and others are using these ratings for tiered contracting and other perhaps unintended uses.

WHA has a long history of public transparency and every hospital in the state voluntarily reports quality measures and summary ratings on a WHA website. We support ratings that both benefit the public and are useful to hospitals in driving their quality improvement work.

WHA is pleased that CMS has taken the feedback provided by hospitals, consumers, and other stakeholders to seriously consider the changes we have been asking for. In addition to the comments we are submitting in response to several of the proposed changes, **WHA recommends that CMS immediately suspend the 2021 refresh of the star ratings until any finalized changes to the methods have been implemented and a process is put in place to include an independent audit to ensure the changes are implemented correctly, in the future each time the method is changed and data is refreshed in January 2022.**

More specifically, WHA supports the following proposed changes to the star ratings method:

- **The Latent Variable Model process should be eliminated**. From the first, LVMs were a volume and accuracy burden for the SAS software used in the calculation method. Additionally, the LVM, measure loading, and Winsorization methods are very difficult to understand and explain to stakeholders – including patients and the public. This complexity also makes it hard for hospitals to replicate their results and identify quality improvement opportunities.
- **The Effectiveness of Care, Timeliness of Care, and Efficient Use of Care Groups should be combined into the single group Timely and Effective Care**. This change acknowledges the attrition of several measures from Hospital Compare and provides an additional opportunity for small and Critical Access Hospitals to reach minimum measure thresholds and be included in the program. Further, WHA supports assigning a 12% weighting value to this new measure group.
- **Applying Peer Grouping Based on Number of Measure Groups**. Since the beginning of the star ratings, WHA has commented on the implied homogeneity of hospitals in the star ratings system. Consumers, for whom the ratings were created, presume that all hospitals can be compared to each other, while industry stakeholders understand the implications of patient and service mix on the data and the star results. We believe that peer grouping may be a first step toward transparency that educates consumers more about the differences between hospitals and the complexity of comparisons.

WHA urges caution to CMS as they consider adopting the following proposed changes regarding Measure Group thresholds. CMS is proposing to eliminate Readmissions Measure Group as one of the outcome measure groups that hospitals could endanger some hospitals from meeting the measure group threshold for inclusion in the star ratings. The Mortality and Safety of Care measure groups include measures that are specific to Medicare populations and service lines. WHA urges CMS to keep the Readmissions Measure Group in the minimum threshold, do further study, and consider this change in future rulemaking.

Finally, WHA reminds CMS about the potential impact of Q1 and Q2 2020 quality data reporting exceptions on future years of star ratings. The extent to which the program is affected should be on the minds of CMS as they consider the current proposed changes, and those that will be deferred to future years.

WHA appreciates the opportunity to provide comment on this proposed rule.

Sincerely,

Eric Borgerding
President and CEO, WHA