WISCONSIN HOSPITAL ASSOCIATION, INC.

September 11, 2017

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

Re: CMS–1678–P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule (Vol. 82, No. 138), July 20, 2017.

Dear Ms. Verma:

On behalf of our more than 135 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 rule for calendar year (CY) 2018 hospital outpatient prospective payment system (OPPS).

WHA was established in 1920 and is a voluntary membership association. We are proud to say that we represent all of Wisconsin's hospitals. Our members include small, mid and large-sized hospitals, including many Critical Access Hospitals and several large 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.

340B Program

A cross-section of the hospitals we represent qualify for the 340B program and find it an essential component in their ability to help *"stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"* as Congress intended under Section 340B of the Public Health Services Act.

These 340B covered entities utilize 340B saving to further carry out these goals, including but not limited to:

- Programs to provide for low-cost prescription drugs for vulnerable patients
- Providing care for patients in need of behavioral health services (counseling, group therapy and medications)
- Program providing diabetic medications and supplies for over 1,000 low-income individuals

- Program providing discounted drugs for multiple diseases (cancer, end stage renal, Crohn's, Multiple Sclerosis and others)
- Providing clinical services to children with childhood cancers
- Providing free medication to children in need
- Providing a clinic for primary health care services and low-cost prescription drugs

These examples come directly from our smallest, rural hospitals to our large, urban Disproportionate Share Hospitals, and demonstrate the ongoing commitment 340B covered entities have to utilizing program savings to better serve Wisconsin patients and communities. Beyond this and consistent with program intent, 340B savings allow covered entities to have the *capacity* to provide more access to more services to patients.

CMS proposes in its CY 2018 OPPS rule to pay for separately payable, non pass-through drugs acquired through the 340B program at the rate of the average sales price (ASP) minus 22.5 percent. Currently these drugs are paid at ASP plus 6 percent. CMS estimates this proposal could decrease payments for Part B drugs by $900 million in 2018. The agency proposes to implement the policy in a budget neutral manner within the OPPS payment system through an increase in the conversion factor. However, it is also seeking comment on other options, including by using all or part of the savings to increase payments for specific services paid under the OPPS or applying the savings to other payment systems outside of the OPPS. Finally, CMS proposes to effectuate the policy through a modifier that would be applied to separately payable drugs that were not acquired through the 340B program.

WHA strongly opposes all aspects of the change in 340B policy and payments for our safety-net hospitals based on the following reasons:

- CMS lacks statutory authority to impose a payment rate for 340B drugs that so dramatically reduces payments to and effectively eviscerates the benefits of the 340B program for hospitals. This is certainly inconsistent with Congress's stated purpose in creating the 340B program.
- Medicare payment cuts of this magnitude would greatly undermine the 340B program. We believe this proposal will likely lead to reduced access to services and pharmaceuticals in various Wisconsin communities served by the 340B program. Again, this is contrary to the goal of the 340B program, which states that its purpose is to help qualifying covered entities *"stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."*
- We find it highly problematic that CMS proposes to then redistribute these dollars to other services or providers paid under the OPPS (budget-neutral) or use those dollars elsewhere (non-budget neutral manner). Again, CMS lacks statutory authority to do so, and WHA does not see how the agency can reconcile any of these options with the stated purposes of the original law. Further, CMS proposes hospitals use a modifier on the Medicare claim that would be reported with separately payable drugs that *were not*

acquired under the 340B program. Having such a modifier is administratively burdensome, costly to operationalize, and, for some hospitals, nearly impossible to implement. It also is at odds with the agency's commitment and active efforts to reduce regulatory burden for providers.

- Medicare beneficiaries, dually eligible Medicare beneficiaries included, would not directly benefit from lowered drug copayment amount. WHA believes they could actually see increases in out-of-pocket costs for other Part B benefits because of the proposed increase in the conversion factor.
- Rather than directly addressing the rising cost of pharmaceuticals, this proposal punitively targets 340B safety-net hospitals serving vulnerable patients, including those in rural areas.

WHA strongly objects to the proposed 340B changes. We urge CMS to remember that for more than 20 years, the 340B program has had a proven track record of decreasing drug costs for safety-net entities and expanding patient access to medical services. While some indicate the program has grown, this is directly linked to Congressional action. Further, it is important to remember the entire 340B program accounts for roughly 2.8% of the $457 billion in annual U.S. drug purchases, and does not cost CMS anything. We strongly urge CMS to pull this proposed policy back completely.

Medicare and Medicaid EHR Incentive Programs

Under the Medicare EHR Incentive Program, hospitals that fail to meaningfully use certified EHR technology are subject to significant Medicare reimbursement penalties. CMS regulations have made successful avoidance of penalties unnecessarily difficult, and many of the "meaningful use" reporting requirements entail investments and workflow disruptions that outweigh potential health care cost savings or improvements in outcomes.

Many of CMS's meaningful use reporting requirements in the Medicare and Medicaid EHR Incentive Programs are not experience-based and not shown to positively affect clinical outcomes, and they are scheduled to become even more burdensome when Stage 3 begins in 2018. Many of these reporting requirements do not have widespread acceptance, are new, and with respect to the patient engagement measures, put success largely outside of the hospital's and physician's control by making it contingent on the actions of patients. In its 2017 OPPS final rule, CMS seemed to acknowledge this reality by reducing the required performance thresholds for a wide variety of Stage 3 measures in the Medicare EHR Incentive Program for 2017 and 2018.

For these reasons, WHA recommends that CMS provide flexibility for hospitals and physicians reporting under the Medicare and Medicaid EHR Incentive Programs. Specifically, we recommend that CMS delay or cancel altogether Stage 3 of the EHR Incentive Program. At the very least, CMS should make permanent for the Medicare and Medicaid EHR Incentive Programs the temporary Stage 3 flexibilities finalized by CMS for the Medicare EHR Incentive

Program in the 2017 OPPS final rule. Further, WHA recommends that CMS establish a 90-day reporting period for every year of the EHR Incentive Program.

Direct Supervision

Hospital outpatient services have always been provided by licensed, skilled professionals under the overall direction of a physician and with the assurance of rapid assistance from a team of caregivers, including a physician, should an unforeseen event occur. However, in the 2009 OPPS final rule, CMS mandated a new policy for “direct supervision” of outpatient therapeutic services that was burdensome, unnecessary and potentially detrimental to access to care in rural and underserved communities. At the time, the policy required that a supervising physician be physically present in the relevant department at all times when Medicare beneficiaries were receiving outpatient therapeutic services. CMS characterized the new policy as a “restatement and clarification” of existing policy, instead of the new policy that it was, and hospitals, particularly small and rural hospitals and critical access hospitals (CAHs), found themselves at increased risk of unwarranted enforcement actions.

In response to hospital concerns, CMS has, since 2009, adopted several helpful regulatory changes to its supervision policy, including: allowing certain non-physician practitioners (NPPs) to provide direct supervision if they meet certain conditions, modifying the definition of direct supervision to replace physical boundaries within which a supervising practitioner must be located with a standard of “immediate availability,” and establishing an independent review process through which CMS can reduce the required level of supervision for individual services. In addition, from 2010 through 2013, the agency prohibited its contractors from enforcing the direct supervision policy. Congress has extended this enforcement moratorium every year since 2014, with the most recent enforcement moratorium having expired on December 31, 2016. **While these extensions of the enforcement moratorium have provided some relief, this annual reconsideration of a misguided direct supervision policy places CAHs and small rural hospitals in an uncertain position.**

In the proposed rule, CMS proposes to reinstate the enforcement moratorium for CAHs and small rural hospitals having 100 or fewer beds for 2018 and 2019, but not for 2017. The agency indicates that this time-limited moratorium is intended to give these hospitals more time to comply with the supervision requirements, as well as time to submit specific services for evaluation for a potential change in supervision level via the independent review process the agency established. **WHA supports CMS’s proposal to reinstate a moratorium on enforcement of its burdensome direct supervision requirement for outpatient therapeutic services provided in CAHs and small and rural hospitals; however, we urge the agency to make the enforcement moratorium permanent and continuous (i.e., without a gap in 2017).**

We believe that CMS’s overall policy on direct supervision has not been clinically warranted and restricts a hospital’s ability to effectively use their existing staff and provide needed access to care for Medicare beneficiaries. We further believe that CMS’s direct supervision policy is unnecessary and unworkable in CAHs and small rural hospitals because:

- CMS has not offered any clinical basis for its supervision requirements. In fact, the agency admitted that it had no evidence that patient safety or quality of care had been compromised in past years due to inadequate or ineffective supervision.
- As hospitals have set protocols to address safety and quality as required by Conditions of Participation, there is not a good rationale for CMS to impose stricter supervision regulations. Direct supervision is not a requirement for inpatient services when the patient is presumably more acutely ill, so to impose direct supervision for outpatient services is not clinically sensible.
- There continues to be shortages of health care professionals, particularly in rural areas. The direct supervision requirement exacerbates this and has the prospect of reducing access because of a requirement that, again, is clinically unnecessary.
- CMS's requirements severely restrict the ability of hospitals and CAHs to effectively use their existing resources to make supervisory assignments and leave them with limited options to comply. Although CMS asserts that its requirements may be met by assigning the responsibility for direct supervision to a physician of a different specialty from the services being supervised or to a NPP, the details of its policy effectively eliminate a hospital's or CAH's ability to do so. This is because CMS also requires that the supervising professional be authorized to actually provide the service they are supervising, according to their state license and hospital-granted privileges. This requirement is impractical, if not impossible, for many hospitals and CAHs to meet, due to severe shortages of specialist physicians in the community.

For all these reasons, WHA urges CMS to make its enforcement moratorium permanent and continuous for CAHs and small rural hospitals.

WHA appreciates the opportunity to provide comments to you as you develop your forthcoming final regulation. Should you have additional questions or if we can assist in other ways, please contact Jenny Boese, VP-Federal Affairs & Advocacy at 608-268-1816 or jboese@wha.org or me.

Sincerely,

Eric Borgerding
President & CEO