Submitted Electronically

September 20, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8011
Baltimore, MD 21244-1850

Re: *Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System and Quality Reporting Programs (CMS-1695-P), July 31, 2018*

Dear Mrs. Verma:

The Florida Hospital Association (FHA), on behalf of its more than 200 member hospitals and health systems, welcomes the opportunity to comment on the proposed rule from the Centers for Medicare & Medicaid Services (CMS) entitled "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System and Quality Reporting Programs, etc." published in the *Federal Register* on July 31, 2018. The proposed rule would revise the hospital outpatient prospective payment system (OPPS), the ambulatory surgical center (ASC) payment system, and quality reporting requirements for specific providers. In this letter, we are submitting comments on the following proposals:

- Reduction in payments for clinic visit services in excepted off-campus departments;
- Reduction in payments for new families of services furnished in excepted off-campus departments; and
- Reduction in payments for 340B-acquired drugs in non-excepted off-campus departments.

Reduction in Payments for Clinic Visit Services in Excepted Off-Campus Departments
Citing "unnecessary" increases in the volume of clinic visits in hospital provider-based departments (PBDs), CMS proposes to pay for visits furnished in excepted off-campus PBDs at the same rate that they are paid in non-excepted off-campus PBDs. CMS proposes to pay for clinic visit (evaluation and management) services in excepted PBDs at the physician fee schedule-equivalent payment rate of 40 percent of the OPPS payment amount. This proposal would be implemented in a non-budget neutral manner, resulting in an estimated CY2019 cut to hospital payments under the OPPS by $760 million across the country and by more than $20 million for hospitals in Florida.

The FHA believes that this proposed policy misinterprets Congressional intent by proposing to reduce payment for services in excepted off-campus PBDs that Congress explicitly protected from site-neutral cuts in Section 603 of the Bipartisan Budget Act of 2015 (BiBA). In the proposed rule, CMS cites the Medicare Payment Advisory Commission (MedPAC) March 2018

Report to Congress as saying, "A large source of growth in spending on services furnished in hospital outpatient departments (HOPDS) appears to be the result of the *unnecessary* shift of services from (lower cost) physician offices to (higher cost) HOPDS." Note the use of the word "unnecessary" in the CMS quote from the MedPAC report – which does not appear in the actual report issued in March 2018. MedPAC references a shift in site of care, but not that the shift is *unnecessary*. By citing a reference that is not factual, CMS bases their justification on the increase in clinic visits as being *unnecessary* but does not substantiate that this increase in volume is in any way inappropriate.

Blaming increases in OPPS expenditures on the *unnecessary* shifting of services from physician offices to PBDs ignores other factors outside of hospitals' control that are driving increases in these expenditures. This includes the skyrocketing costs of pharmaceuticals, particularly chemotherapy drugs; the impact of Medicare policies, such as the two-midnight policy and the readmissions penalty program; new and costly technology not found in physician offices; and the fact that physicians frequently refer Medicare beneficiaries to PBDs for critical services they do not provide in their offices.

Reduction in Payments for New Families of Services Furnished in Excepted Off-Campus Departments

Under current site-neutral payment policy, an excepted off-campus PBD may expand the type of services it furnishes and will receive the full OPPS rate for such services. However, in the proposed rule, CMS expresses concern that this policy incentivizes hospitals to purchase additional physician practices and add those physicians to an existing excepted off-campus PBD, in a manner that CMS believes is inconsistent with the intent of Section 603.

In this rule, CMS proposes that if an excepted off-campus PBD begins to offer a new service from a clinical family for which it did not previously furnish and bill during a baseline period, defined as November 1, 2014 though November 1, 2105, the new service would no longer be a covered outpatient department service. Instead, it would be a non-excepted service and paid under the physician fee schedule at 40 percent of the OPPS amount. According to the proposed rule, CMS would require that, as a condition of outpatient payment eligibility, excepted off-campus PBDs ascertain the clinical families from which they furnished services during the baseline period.

This policy would penalize PBDs that expand the types of critical services they offer and prevent them from caring for the changing needs of their patients and communities. Essentially, CMS' proposal would serve to "freeze in time" an excepted PBD, thereby harming innovation and denying the evolution of evidence-based medicine. It is notable that CMS does not share any claims-based or other supporting evidence that demonstrates that excepted off-campus PBDs are taking advantage of the current policy, even though CMS had previously indicated that it would monitor service line expansion in excepted off-campus PBDs. It should be noted that many of the services listed in the detailed families of services are not payable in a physician office setting and can only be provided in a hospital setting, whether on or off-campus.

Off-campus PBDs must be able to expand the items and services that they offer to meet changes in clinical practice and the evolving needs of their patients and communities without losing their ability to be reimbursed under the OPPS. Given the rapid pace of technological advances in medicine, the treatments and services offered by PBDs today will inevitably evolve into newer,

innovative and more effective care in the future. CMS policy must not hamper access to innovative technologies and services. Nothing in BiBA requires that CMS treat expanded services in an excepted PBD in this way. CMS must ensure that patients continue to have access to the services they need at the facilities where they seek treatment.

Reduction in Payments for 340B-Acquired Drugs in Non-Excepted Off-Campus Departments

In CY2018, CMS finalized an OPPS policy to reduce payment for separately payable drugs and biologicals – other than drugs on pass-through payment status and vaccines – acquired under the 340B program from average sales price (ASP) plus six percent to ASP minus 22.5 percent. Because services furnished in non-excepted off-campus PBDs are no longer considered to be covered outpatient department services, 340B-acquired drugs furnished in these settings were not subject to this policy and so continued to be paid at ASP plus six percent in 2018.

In the CY2019 proposed rule, CMS expresses concern that the difference in the payment amount for 340B-acquired drugs furnished in excepted and non-excepted off-campus PBDs creates an incentive for hospitals to move drug administration services for these 340B-acquired drugs to non-excepted PBDs. For CY2019, CMS proposes to pay for separately payable drugs and biologicals (other than those exceptions noted above) acquired under the 340B program at a rate of ASP minus 22.5 percent when they are furnished by non-excepted off-campus PBDs.

We believe that this proposed reduction exceeds CMS' statutory authority – an issue that is currently subject to legal challenge. In making this proposal, CMS points to provisions in statute for services paid under OPPS as justification, but fails to recognize that, in its own rulemaking, CMS opted to merely use a percentage reduction in OPPS as a proxy for payment under the physician fee schedule. Thus, as stated by CMS, these services are no longer actually paid under OPPS. In addition, if this proposal were adopted, it is important to note that CMS does not propose to make this change in a budget-neutral manner as they did with 340B-acquired drugs in excepted off-campus PBDs.

For each of these provisions, it appears that CMS has misconstrued Congressional intent with its proposals to cut payments for hospital services provided in both excepted and non-excepted off-campus hospital PBDs. Congress clearly intended to preserve the existing outpatient payment rate for these PBDs in recognition of the critical role they play in their communities.

A recent letter to CMS from Sens. Rob Portman (R-Ohio) and Debbie Stabenow (D-Michigan) states that "In passing Section 603, Congress was clear in its intention to grandfather existing facilities, so that only new off-campus sites would have payments reduced, and as noted previously, while we share the goal of reducing our of pocket costs for our seniors, the proposed cuts to both HOPD [evaluation and management] services and to future serves from new clinical families threaten seniors' access to care in their own communities. Therefore, we ask that CMS ensure these facilities be treated as Congress intended and protected from the proposed cuts."

The proposals put forth by CMS will have the effect of impeding access to care for the most vulnerable Medicare patients. Recent studies have shown that patient severity for E/M clinic visits, as measured using weighted hierarchical condition categories (HCC) scores, is nearly 24

percent higher in PBDs than in physician offices. Not only do PBDs serve a higher percentage of patients who are dually eligible for both Medicaid and Medicare than physician offices, but they also serve a higher percentage of disabled patients. Physicians refer more complex patients to PBDs for safety reasons, as hospital departments are better equipped to handle complications and emergencies. Reflecting the increased complexity of the patients served in PBDs relative to those treated in physician offices, PBD patients are more likely to:

- Live in high-poverty areas;
- To be Black or Hispanic; and
- To receive care from a nurse in addition to a physician.

Finally, both excepted and non-excepted PBDs have more comprehensive licensing, accreditation, and regulatory requirements than do freestanding physician offices. Payments should reflect PBD costs, not physician payments. PBD payment rates, historically, were based on hospital cost report and claims data. In stark contrast, the physician fee schedule and its practice expense component are based solely on physician survey data.

We strongly urge CMS not to finalize these proposals and to provide payments that are adequate to cover the costs of providing care so that our member hospitals can continue to serve as the access point for quality care within their communities.

The FHA appreciates the opportunity to provide these comments for consideration in finalizing the OPPS rule for CY2019. We stand willing to work with CMS and other stakeholders in developing tools to provide meaningful, useful and valuable information to our patients and communities. If there are any questions, please do not hesitate to contact me at kathyr@fha.org.

Sincerely,

Kathy Reep
Vice President/Financial Services