September 8, 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 200 member hospitals and health systems, the Florida Hospital Association (FHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) proposed rule for calendar year (CY) 2018. Our comments will focus on CMS's proposal regarding Medicare Part B payments for 340B hospitals and the proposed removal of total knee arthroscopy (TKA) from the inpatient only list.

Medicare Part B Payments for 340B Hospitals. The FHA strongly opposes CMS's proposal to reduce Medicare Part B payments for drugs acquired through the 340B Drug Pricing Program. This program has been critical in expanding access to lifesaving prescription drugs to low-income patients in communities across Florida and the rest of the county. Cutting Medicare payments for hospital services in the 340B program is not based on sound policy. The proposed reduction does nothing to address the issue of skyrocketing drug costs, although this is used as an impetus for this proposal. Reducing payments to providers punitively targets essential providers across the country but does not reduce the cost they must pay for pharmaceuticals.

We urge the agency to withdraw its proposal due to (a) lack of statutory authority; (b) impact on the ability of 340B hospitals to continue programs designed to improve patient access to care; (c) impact on Medicare beneficiaries; and (d) addition of administrative burden on 340B providers while reducing reimbursement.

CMS lacks the statutory authority to impose a Medicare Part B payment rate for 340B drugs that results in such a dramatic payment reduction that it effectively eliminates the benefits of the 340B program. The agency's contention that it has specific statutory authority under subclause (II) of section 1395*l*(t)(14)(A)(iii) to reset the payment rate from average sales price (ASP) plus six percent to ASP minus 22.5 percent is contradicted by the plain and ordinary meaning of the text. It does not convey, as CMS asserts, the power to adopt a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would, according to the agency's own estimates, result in a reduction in payment to 340B hospitals of at

least $900 million. Moreover, the overall structure of the statutory section that contains the precise provision that CMS purports to rely on for this proposal reinforces the limited and circumscribed authority for the agency to set the payment rate. CMS's proposal is not the slight alteration to the payment rate permitted under the statute. Indeed, according to estimates by the American Hospital Association (AHA), CMS's proposal would reduce drug payments to 340B hospitals by $1.65 billion. It would effectively eviscerate the 340B program.

CMS states that one goal of its proposal is to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care." However, in reality, the proposal would do great harm to these hospitals that serve our most vulnerable citizens, undermining the purpose of the 340B program established by Congress. Specifically, it would undercut the 340B program's value as a tool for lowering drug prices and disrupt access to care for those in greatest need, including low-income Medicare beneficiaries. Nationwide, 340B hospitals use the savings they receive on the discounted drugs and reinvest them in programs that enhance patient services and access to care, as well as provide free or reduced-price prescription drugs to vulnerable patient populations.

Congress created the 340B program to permit hospitals that care for a high number of low-income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Many 340B hospitals are the lifelines of their community, and the discounts they receive through the 340B program play an important role in allowing these organizations to care for patients. However, many of these facilities are financially vulnerable. In 2015, one out of every four 340B hospitals had a negative operating margin. While hospitals overall had negative Medicare margins, 340B hospital margins are even worse. Specifically, 340B hospitals paid under OPPS had total and outpatient Medicare margins of negative 18.4 percent and negative 15.4 percent, respectively. CMS's proposed cuts would make these hospitals' financial situations even more precarious, thus putting at great risk the programs they have developed to expand access to care for their vulnerable patient populations.

Part of CMS's rationale for proposing a reduction in payment for Part B drugs acquired under the 340B program is that the agency believes the proposal will reduce Medicare beneficiaries' drug copayments when seeking care from 340B hospitals. However, this is not accurate. The majority of Medicare beneficiaries coming to 340B hospitals do not pay their own copayments. According to a Medicare Payment Advisory Commission (MedPAC) analysis, 86 percent of all Medicare beneficiaries have supplemental coverage that covers their copayments, of which 30 percent have their copayments paid for by a public program, such as Medicaid, or by their Medigap plan. Thus, CMS's 340B payment reduction proposal would not directly benefit many Medicare beneficiaries, dually eligible Medicare beneficiaries included, as it so claims.

To identify which drugs are 340B and which are non-340B, CMS would require hospitals to report a modifier on the Medicare claim that would be reported with separately payable drugs that ***were not*** acquired under the 340B program. Implementing CMS's proposed modifier would be administratively burdensome, costly to operationalize, and, for some hospitals, nearly impossible to implement. It is also at odds with the agency's commitment and active efforts to

reduce regulatory burden for providers. For example, CMS's approach is the exact opposite of how a number of state Medicaid agencies administer their Medicaid rebate programs to prevent duplicate discounts on 340B drugs. To accurately collect rebates, some state Medicaid agencies identify 340B drugs with a modifier or their National Drug Code (NDC) code so that if the modifier or NDC code is not on the claim, the drug is eligible for a Medicaid rebate. CMS's proposal is the exact opposite, and it will add confusion and complexity to an already complicated system.

In addition, we have significant concerns about whether 340B hospitals can possibly implement CMS's proposed modifier accurately. That is, they would have to put the modifier onto the claim at the time service is rendered, or go back and retroactively apply it, thus delaying the submission of the claim. In particular, this would be difficult in mixed-use areas, such as emergency departments, catheterization laboratories and pharmacies, where both 340B eligible patients and non-340B patients are served.

In conclusion, we believe that CMS's proposed reduction in Medicare Part B payments for 340B drugs will put significant financial pressure on our members**,** negatively impacting their ability to provide high-quality care to Medicare beneficiaries and communities at large. We urge CMS to abandon the 340B drug payment proposal and redirect its efforts toward direct action to halt the unchecked, unsustainable increases in the cost of drugs.

Removal of Total Knee Arthroscopy from Inpatient Only List. The FHA opposes the removal of total knee replacement (TKA) from the inpatient only list. We do not believe it is clinically appropriate and are deeply concerned that it will put the success of the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payment for Care Improvement (BPCI) programs at risk. Shifting the less medically complex Medicare TKA patients to the outpatient setting would increase the risk profile of the remaining inpatient Medicare TKA population. This would thus inhibit an accurate comparison within the bundling programs when evaluating hospitals' actual expenditures versus their historical target prices – thus negatively impacting a provider's performance under the program. The same concerns exist for the potential removal of partial hip arthroplasty and total hip arthroplasty from the inpatient only list and we urge CMS to not make this change in the future.

TKAs remain complicated, invasive surgical procedures. While they may be successfully performed on an outpatient basis for non-Medicare individuals, we do not believe it is appropriate for the Medicare population. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which will make even a simple procedure more complicated. In addition, spinal anesthesia is often used for TKAs and waiting for full sensation to return can take hours. Finally, pain management, particularly in the immediate postoperative period, remains a challenge. Management of postoperative pain is best controlled in the inpatient setting.

As it pertains to both CJR and BPCI, as the agency notes, shifting the less medically complex Medicare TKA population to the outpatient setting would increase the risk profile of the inpatient Medicare TKA population. This would, in turn, create an apples-to-oranges comparison within bundling programs when evaluating hospitals' actual expenditures versus their historical target

prices. Performance under the programs would be inappropriately negatively impacted, potentially to a large degree.

If CMS moves forward with this proposal, however, they should evaluate including outpatient TKA in the CJR and BPCI programs. To do so, it could, for example, reimburse for this procedure at the outpatient APC rate, but substitute the relevant inpatient Medicare-Severity Diagnosis-Related Group (MS-DRG) rate when calculating a participant hospital's actual episode spending. To ensure a level playing field, CMS also would need to specify that TKA could only be performed in an HOPD – not in an ASC. Many additional considerations also would need to be evaluated, such as which quality measures would apply to participant hospitals and whether there would be sufficient information on the outpatient claim to assign the appropriate MS-DRG (i.e., the Major Joint Replacement with Major Complications MS-DRG vs. the Major Joint Replacement without Major Complications MS-DRG).

We appreciate the opportunity to provide these comments on the proposed CY2018 outpatient rule. If there are any questions, do not hesitate to contact me at kathyr@fha.org or via phone at (407) 841-6230.

Sincerely,

Kathy Reep
Vice President/Financial Services