[Letterhead of your hospital or hospital system]

September XX, 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 ***[name of your hospital or hospital system]****,* we appreciate 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 address CMS’s proposal regarding Medicare Part B payments for 340B hospitals.

***[As a 340B hospital]***, we strongly oppose CMS’s proposal to reduce Medicare Part B payments for drugs acquired through the 340B Drug Pricing Program. We urge the agency to withdraw its proposal for the following reasons:

* 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.
* Medicare payment cuts of this magnitude would greatly undermine 340B hospitals’ ability to continue programs designed to improve access to services – which is the very goal of the 340B program that Congress intended.
* CMS’s proposal would not directly benefit Medicare beneficiaries as it claims. In fact, seniors may end up paying *more* in co-payments under the proposal.
* Rather than addressing the real issue of the skyrocketing cost of pharmaceuticals, this proposal punitively targets 340B hospitals serving vulnerable patients, including those in rural areas.

**CMS Lacks Statutory Authority**

CMS lacks the statutory authority to impose a Medicare Part B payment rate for 340B drugs that results in such a dramatic payment reduction and 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 ASP plus 6 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’s Proposed Cuts Would Undermine the Congressionally-mandated Mission of 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.

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.”[[1]](#footnote-1) *[****Provide examples of how your hospital uses the 340B program to benefit your patients. Consider including examples such as providing free care to uninsured patients, medication management programs, free vaccines, lower priced prescription drugs and community health programs. If possible, include an example of a patient who has benefitted from your hospital’s participation in the 340B program – patients who received access to cancer treatment closer to home; a low-income patient who received prescription drugs at a reduced rate or free of charge; a person who received free treatment at one of your clinics or who is enrolled in one of your community health programs. Describe how these services would be negatively impacted by CMS’s proposal]***

As noted, 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, 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.[[2]](#footnote-2) ***[Consider adding your hospital or hospital system’s own financial information regarding OPPS outpatient Medicare margins and uncompensated care.]***

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. ***[Consider adding your hospital or hospital system’s own analysis of CMS’s proposal ASP minus 22.5% for all 340B drugs.]***

**Most Medicare Beneficiaries Would Not Directly Benefit from CMS’s Proposal**

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 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.[[3]](#footnote-3) Thus, CMS’s 340B payment reduction proposal would not directly benefit many Medicare beneficiaries, dually eligible Medicare beneficiaries included, as it so claims.

**Concerns regarding CMS’s Proposed Modifier for Non-340B Drugs**

In order 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 also is 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 we can possibly implement CMS’s proposed modifier accurately. That is, we 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 organization***,*** negatively impacting our ability to provide high-quality care to our 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.

Sincerely,

1. <https://www.hrsa.gov/opa/index.html> [↑](#footnote-ref-1)
2. AHA 2015 Annual Survey Data [↑](#footnote-ref-2)
3. MedPAC, June 2016 Databook, Section 3, p 27. [↑](#footnote-ref-3)