NAUH
NATIONAL ASSOCIATION OF URBAN HOSPITALS

September 8, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Subject: Medicare Program Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (42 CFR Parts 46 and 419, CMS-1678-P, RIN 0938-AT03)

Attention: CMS-1678-P

Dear Administrator Verma:

I am writing on behalf of the National Association of Urban Hospitals (NAUH) to convey to the Centers for Medicare & Medicaid Services (CMS) our views on the draft regulation for the Medicare outpatient prospective payment system that describes how CMS proposes paying for Medicare-covered outpatient services in 2018. This regulation was published in the *Federal Register* on July 20, 2017 (Vol. 82, No. 138), pp. 33558-33724).

NAUH wishes to focus its comments on CMS's proposal to implement major changes in the 340B Drug Discount Program. NAUH opposes this proposal on policy grounds.

The Purpose of the 340B Program

The purpose of the 340B program is to put additional resources in the hands of providers that care for especially large numbers of low-income patients so those providers can do more for such patients: provide more care that their patients might not otherwise be able to afford, offer more services that might otherwise be unavailable to such patients, and do more outreach into communities consisting primarily of low-income residents – communities that would otherwise be medically underserved.

This purpose is stated clearly on the web site of the Health Resources and Services Administration, with operates the 340B program.

> The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

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The 340B Program is Well-Targeted

The benefits of the 340B program consistently reach the patients for whom they are intended: low-income individuals being treated by providers that care for especially large numbers of low-income patients. Those providers include safety-net providers such as federally qualified health centers, critical access hospitals, sole-community hospitals, black lung clinics, Ryan White HIV/AIDS Programs, and others. Also among them are the country's private, non-profit urban safety-net hospitals, such as those represented by NAUH. These hospitals, and the patients they serve, benefit enormously from the 340B program.

The Impact of the Proposed Changes

Changing the 340B program in the manner proposed in this draft regulation would have devastating consequences for many 340B-eligible hospitals – and, more important, for the low-income patients those hospitals serve and the low-income communities in which those patients reside. The proposed changes constitute a fundamental change in the program's rationale and objectives and would be highly redistributive: they would take resources away from the safety-net providers for which they were intended, including private, non-profit urban safety-net hospitals and the low-income patients they serve.

This redistribution would be considerable. CMS estimates that the proposed changes would reduce outpatient prospective payment system spending for separately payable 340B-covered drugs by roughly $900 million. The American Hospital Association, however, estimates that the impact would actually be nearly twice as great: approximately $165 billion.

Such redistribution would effectively undo the policy objectives underlying the 340B program, and in so doing, it would at least partially undo the years of progress the 340B program has helped bring about. It would be harmful to urban safety-net hospitals and harmful to the especially large numbers of low-income patients those hospitals serve.

Concerns About the Methodology Underlying the Proposed Changes

The proposed changes in the 340B program come on the heels of a 2015 analysis by the Medicare Payment Advisory Commission (MedPAC) that called for a closer look at the program and offered recommendations for changes. NAUH has reservations, however, about the methodology both MedPAC and CMS employed in reaching their proposed changes in 340B payment rates. Both showed shortcomings in estimating 340B-covered drugs' acquisition costs and both suffered from their inability to identify which drugs were purchased through the 340B program within Medicare claims data. CMS, we believe, has incorrectly assumed that all separately payable drugs billed by 340B-eligible hospitals through Medicare Part B were actually purchased at 340B prices, which is not the case. The California Hospital Association, for example, estimates that hospitals in that state purchase only about two-thirds of eligible prescription drugs at 340B reduced prices.

NAUH also disagrees with the methodology CMS employed to determine how to reduce 340B payments. Its proposed changes, it is worth noting, do not reflect MedPAC's recommendation: MedPAC recommended reducing 340B payment rates by 10 percent of applicable drugs' average sale price. This is very different from this proposal, which would reduce payments to 22.5 percent less than the average wholesale price.

The Regulatory and Administrative Burden of the Proposed Change

NAUH would like to note that at a time when there is great interest in reducing the regulatory burden on businesses, this proposed rule would increase that burden instead. Most hospitals employ tracking and replenishment software to account for their use of 340B drugs and to replenish their stock of such prescription medicines as needed. Complying with the proposed regulation would require the modification of this software, at considerable cost to hospitals, and the use of manual compliance measures in the interim, thereby adding to the cost of the prescription drugs hospitals dispense to their low-income outpatients rather than reducing those costs. The new requirements would even apply to hospitals that do not participate in the 340B program, imposing additional costs of them without offering any benefits at all to those hospitals or their patients.

Alternative Uses of Possible 340B Savings

While NAUH appreciates that CMS proposes altering the 340B program in a manner that is budget-neutral and has asked stakeholders for suggestions on how to use the savings the proposed changes would produce, the simple reality is that virtually any change that might be envisioned or suggested will still end up taking money away from the hospitals with the greatest needs. These resources should continue to be invested in caring for low-income people and NAUH believes the 340B program remains an appropriate vehicle for that investment.

Conclusion

Changing the 340B program in the proposed manner and reducing Medicare 340B reimbursement so significantly would have a major, harmful impact on private, non-profit urban safety-net hospitals (and other safety-net providers), the low-income patients they serve, and the communities in which those patients reside. Urban safety-net hospitals use the additional resources afforded to them by the 340B program to provide additional services to the very individuals the program intends to serve, such as by offering new medical services that their communities need but that cannot be justified economically; by continuing to offer services that lose money for the simple reason that the low-income residents of their communities need those services; and by going out into the community and doing outreach and establishing clinics in areas with relatively few privately insured patients, doing so with the understanding that there is never a financial rationale for doing such a thing but that on occasion, and with the help of such supplemental assistance, need is more important than a financial rationale.

The proposed changes in the 340B program would threaten to undo at least some of the good work safety-net providers have done in recent years to serve more low-income people more effectively by depriving those safety-net providers – including urban safety-net hospitals – of some of the vital resources that made that good work possible. For this reason, the National Association of Urban Hospitals asks CMS to withdraw its proposal to change the terms of the 340B Drug Discount Program.

About the National Association of Urban Hospitals

The National Association of Urban Hospitals advocates for adequate recognition and financing of private, non- profit, urban safety-net hospitals that serve America's needy urban communities. These urban safety-net hospitals differ from other hospitals in a number of key ways: they serve communities whose residents are much older and poorer; they are far more reliant on Medicare and Medicaid for revenue; they provide far more uncompensated care; and unlike public safety-net hospitals, they have no statutory entitlement to local or state funds to underwrite their costs. NAUH's role is to ensure that when federal

officials make policy decisions, they understand the implications of those decisions for these distinctive urban safety-net hospitals. NAUH pursues its mission through a combination of vigorous, informed advocacy, data-driven positions, and an energetic membership with a clear stake in the outcome of public policy debates.

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NAUH appreciates the opportunity to present these comments to CMS and welcomes any questions you may have about the views we have expressed.

Sincerely,

Ellen J. Kugler, Esq.
Executive Director