National Alliance of Safety-Net Hospitals

November 27, 2019

William N. Parham, III
Director, Office of Office of Strategic
Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: Document Identifier CMS-10709

Subject: Department of Health and Human Services, Centers for Medicare & Medicaid Services; Document identifier CMS-10709; Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Mr. Parham:

I am writing on behalf of the National Alliance of Safety-Net Hospitals (NASH) to convey our views on the Department of Health and Human Services' agency information collection notice published in the *Federal Register* on September 30, 2019 (Vol. 84, No. 189, pp. 51590-51591).

NASH and the nation's private safety-net hospitals oppose the proposed collection of data involving the section 340B prescription drug discount program for three reasons:

- we oppose CMS's continued efforts to reduce 340B reimbursement to eligible hospitals;
- the proposed data collection would be exceptionally burdensome; and
- we disagree with attempting to address a matter still being litigated

The 340B program is a vital resource in enabling private safety-net hospitals to serve their low-income communities, and we address below our individual objections to this proposed information collection.

NASH Opposes CMS's Continued Efforts to Reduce 340B Reimbursement to Eligible Hospitals

NASH recognizes that the proposed data collection is a response to a federal court decision that the Centers for Medicare & Medicaid Services (CMS) cannot reduce 340B payments to providers in the absence of data on the costs hospitals incur acquiring 340B-covered drugs (among several other reasons). NASH, however, opposes any attempt to reduce 340B reimbursement to eligible hospitals.

The 340B program was created by Congress to enable hospitals (and other providers) that serve low-income communities to maximize their resources when working to serve those communities. The program helps improve access to high-cost prescription drugs for low-income patients and helps put

additional resources into the hands of qualified providers so those providers can do more for their low-income patients: provide more care that their patients might otherwise not 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. This was the purpose of the 340B program when Congress created it in 1992 and Congress has not modified that purpose since that time. NASH believes that through this proposed data collection CMS is seeking to exert authority it does not have to demand of providers information to which the agency is not entitled.

The Proposed Data Collection Would be Extremely Burdensome

NASH also opposes the proposed data collection because the steps CMS has proposed for collecting data for a program that does not even formally fall under its purview would be extremely burdensome.

In the proposed notice, CMS calls for asking 340B providers to supply their average acquisition cost data for more than 400 HCPCS codes and 1100 national drug codes (NDCs). For a given quarter, hospitals could easily need to account for tens of thousands of units of data. No less burdensome would be the extensive calculations the information collection request would require of hospitals to prepare for potentially hundreds of NDCs. CMS is asking hospitals to calculate average 340B prices for all NDCs paid under 400-plus HCPCS codes, which would require hospitals to average the prices together for all the NDCs mapped to the HCPCS codes – which can be dozens of NDCs for a single HCPCS code – and to convert NDC purchase units to HCPCS dosage units.

CMS also is asking hospitals to identify each provider-based department at which a relevant drug was administered. This would be extremely burdensome because most hospitals do not track data this way and would need to run numerous reports out of their billing systems and electronic medical record systems to back into where the drug was administered that generated the charge for the HCPCS code. It also is not clear what information CMS seeks to collect on provider-based departments.

NASH disagrees strongly with CMS's estimate that it would take 340B-eligible hospitals 48 hours to respond to the survey and collect the proposed data. To the contrary, our members believe it would take far more than 48 hours, cost far more than CMS estimates, and result in a corresponding and unfortunate reduction in the additional services these hospitals can afford to provide to their communities because they must spend so much time and so much money responding to the proposed data request.

NASH Disagrees With Attempting to Address a Matter Still Being Litigated

Twice now CMS has reduced 340B payments to eligible hospitals and twice now federal courts have rejected CMS's authority to apply that reduction. Despite this, CMS recently proposed and adopted the very same proposal a third time. The federal courts' rulings in this matter, at least so far, have been based on several considerations; CMS's lack of data on providers' acquisition costs for 340B drugs is by no means the only reason the courts have rejected CMS's 340B payment reduction proposal. NASH believes CMS should not attempt to implement piecemeal responses to the court's decisions until the litigation is concluded.

NASH also is concerned that at the very same time that CMS is attempting to introduce new data collection in response to one aspect of the court's concerns about the program, it is not devoting sufficient attention to another aspect of the court's ruling. Specifically, the court directed CMS to develop a methodology for reimbursing 340B hospitals for the payments it illegally withheld from them for the past two years (and will illegally withhold for them for a third year) while CMS continues to appeal its latest defeat in court. NASH believes it is inappropriate and ill-timed for CMS to focus on collecting data that

would address only one narrow aspect of the court's objections to its 340B payment-reduction attempts while at the same time it continues to systematically deny to 340B-eligible hospitals the full benefits that Congress directed that they receive nearly 30 years ago and stubbornly refuses to pursue development of a plan the courts ordered to compensate providers – and the communities they serve – for the benefits it has denied them for the past two years.

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The 340B program is an essential tool in the efforts of private safety-net hospitals to serve the low-income residents of the communities in which they are located. It gives them additional resources that translate into additional services, additional outreach, and additional care for people who otherwise lack the means to gain the care they need. The changes CMS has proposed – changes the courts have rejected – would detract from these efforts and hurt people. We see no value in implementing new information collection processes to support a policy change that the courts have steadfastly rejected and that would hurt people who have the least ability to help themselves – the very people the 340B program was created to help.

For the reasons outlined above, NASH urges CMS to withdraw its proposed information collection request and focus instead on reimbursing 340B-eligible hospitals, and the low-income communities they serve, for the resources they have been denied for the past two years. We appreciate your attention to this request and welcome any questions you may have about the views we have expressed.

Sincerely,

Ellen Kugler, Esq.
Executive Director

About the National Alliance of Safety-Net Hospitals

The National Alliance of Safety-Net Hospitals advocates for adequate recognition and financing of private safety-net hospitals that serve America's neediest communities. These private safety-net hospitals differ from other hospitals in a number of key ways: they serve communities whose residents are older and poorer; they serve patients who are more dependent on Medicare and Medicaid for health care; they provide more uncompensated care; and unlike public safety-net hospitals, they have no statutory entitlement to local or state funds to underwrite their costs. NASH's role is to ensure that when federal officials make policy decisions, they understand the implications of those decisions for these distinctive private safety-net hospitals. NASH 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. Until 2019 NASH was known as the National Association of Urban Hospitals, and its evolution into NASH reflects its members' recognition that private safety-net hospitals can be found serving communities not only urban but also rural and suburban across the country.