National Alliance of Safety-Net Hospitals

March 2, 2020

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-3427, CMS-10709, CMS-10631 and CMS-10466
OMB control number 3209-0002

Subject: Department of Health and Human Services, Centers for Medicare & Medicaid Services; Document identifier CMS-3427, CMS-10709, CMS-10631 and CMS-10466; Agency Information Collection Activities: Submission for OMB Review; 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' proposed information collection notice published in the *Federal Register* on February 7, 2020 (Vol. 85, No. 26, pp. 7306-7308).

NASH appreciates the changes the Centers for Medicare & Medicaid Services (CMS) has made since its November 2019 information collection notice on the same subject (Document Identifier CMS-10709, published in the *Federal Register* on September 30, 2019 (Vol. 84, No. 189, pp. 51590-51591, and in particular, the steps it has taken to reduce the administrative burden on hospitals. Nevertheless, NASH and the nation's private safety-net hospitals continue to 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 very 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

21351 Gentry Drive, Suite 210, Sterling, VA 20166
Phone: 703-444-0989
www.safetynetalliance.org

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 very burdensome. While we appreciate that in this latest notice CMS proposes reducing some of the burden associated with this data collection – making reporting on national drug codes (NDCs) optional and clarifying that hospitals do not need to include information about which of the many hospital-based departments under their purview dispensed the drug – NASH continues to find this data request unacceptably burdensome.

In particular, in the proposed notice CMS calls for 340B providers to supply their average acquisition cost data for more than 400 HCPCS codes. For a given quarter, hospitals could easily need to account for thousands of units of data. The survey not only requires hospitals to compile and report the costs of the drugs they acquired in the given time period in the quantity and packaging in which they acquired it but it also mandates the standardization of data submission across all hospitals. It would require many hours of administrative staff time to reference the HCPCS crosswalk files and determine the appropriate purchase units CMS has in mind for each drug.

Even with the proposed reduction in the data that would need to be reported, NASH disagrees strongly with CMS's estimate that it would take 340B-eligible hospitals only 48 hours to collect the required data and respond to the survey. CMS's suggestion that responding to the survey would take still take 48 hours, as previously projected, is curious in light of the significant changes the agency has proposed in the data to report and suggests there is little hard evidence or analysis underlying the 48 hours estimate. As it is, NASH 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, last year CMS 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 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.