National Alliance of Safety-Net Hospitals

October 5, 2020

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

Subject: 42 CFR Parts 410, 411, 412, 414, 416, and 419. RIN 0938-AU12. Medicare Program: Hospital Outpatient Prospective Payment and Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

Attention: File Code CMS-1736-P

To Whom it May Concern:

I am writing on behalf of the National Alliance of Safety-Net Hospitals (NASH) to convey to the Centers for Medicare & Medicaid Services (CMS) our views on the proposed 2021 Medicare outpatient prospective payment system regulation that was published in the *Federal Register* on August 12, 2020 (Vol. 85, No. 156, pp. 48772-49082).

NASH would like to bring to your attention our views on five aspects of the proposed regulation:

- outpatient rates
- the 340B program
- phase-out of the inpatient-only services list
- changes in the level of supervision for selected outpatient therapeutic services
- the physician-owned hospital exception

We address these issues individually below.

Outpatient Rates

NASH supports CMS's proposal to raise Medicare fee-for-service outpatient rates 2.6 percent in 2021 and thanks CMS for proposing this increase.

The 340B Program

NASH opposes CMS's proposal to reduce 340B payments to average sales price (ASP) minus 28.7 percent. This proposed reduction, even larger than the reduction CMS has proposed in recent years, is

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based on the results of a survey CMS conducted to identify the drug acquisition costs of 340B-covered entities. CMS also proposes, in the alternative, to continue its current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

NASH opposes this proposal on three grounds.

Congress Has Not Directed CMS to Make the Proposed Changes

The 340B program was created by Congress to help improve access to high-cost prescription drugs for low-income patients and to help put additional resources into the hands of qualified providers so those providers can do more for such 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. Only providers that care for especially large numbers of low-income patients qualify to participate in the 340B program. To date, Congress has not directed the executive branch to reduce payments to 340B providers that serve especially large numbers of low-income patients and did not direct CMS to introduce new policies that seek to reduce the federal government's commitment to serving low-income Americans.

HHS Has Recently Criticized Others for Attempting to Cut 340B

HHS's own recent actions suggest a strong level of support for the 340B program that the proposed regulation belies. In a September 21 letter to a pharmaceutical company about that company's attempt to circumvent established 340B policy and unilaterally deny 340B discounts to eligible providers, the Department of Human Services' (HHS) General Counsel wrote that

> …we believe that the timing of your pricing changes is, at the very least, insensitive to the recent state of the economy. Although the economy is rebounding at a record rate, the unemployment rates are still temporarily higher than at the beginning of the year due to COVID-19. Many Americans and many small business have had difficulty making ends meet.

After noting the outstanding financial performance of the pharmaceutical company in question, HHS's General Counsel went on to note that during that period of financial performance,

> …most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance.

These are the very providers that would be harmed by this proposed rule.

NASH agrees with HHS's General Counsel and observes that he sent that letter to the pharmaceutical company just two weeks ago. NASH also agrees with the HHS General Counsel's rationale for castigating the pharmaceutical company and believes CMS's actions on 340B should reflect this rationale by *not* reducing 340B payments so significantly at this time.

The Proposed Change is Based on Inadequate Data

In the proposed regulation CMS notes that it makes this proposal based on the results of a survey it conducted to identify the actual discounts 340B-covered entities receive. NASH would like to note that the survey in question was open to providers from April 24 through May 15, at the beginning of the pandemic – a time when, arguably, those providers had far more pressing matters to which to attend. The rate of participation in this survey was understandably low, with 38 percent of hospitals failing to respond at all and more than half of the responding hospitals doing so only through CMS's "quick survey" option.

This left CMS to draw conclusions based on an unrepresentative sampling of 340B participants. The survey also, it is worth noting, was built around hospitals' acquisition costs for their 340B-covered drugs even though Congress did not create the program to pay hospitals their acquisition costs; it wanted them to be able to purchase covered drugs at a discount below the reimbursement rate regardless of the payer and then to use the difference to do more to serve low-income patients. For these reasons, NASH believes this survey was fatally flawed and constitutes an inadequate basis for changing long-established policy.

Conclusion of 340B Discussion

On the web site of the Health Resources and Services Administration, which operates the 340B program, that agency writes that

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

Federal policy should enhance this program and help it achieve its objectives, not make it harder for low-income patients and the providers who serve them. The proposed regulation, however, would not help the program achieve its objectives and would, in fact, make it harder for low-income patients and the providers who serve them. In addition, because the proposed 340B cut is budget-neutral, it does not produce any savings for the federal government and only undermines Congress's desire to enable these hospitals to stretch scarce federal resources and help their low-income patients and communities. For these reasons, NASH urges CMS to withdraw the proposed payment reduction, and restore 340B payments to their 2017 level.

Phase-out of the Inpatient-Only Services List

CMS proposes phasing out the inpatient-only list, beginning with the removal of approximately 300 musculoskeletal-related services. NASH opposes this change.

NASH believes now is not the right time to make such a major change in such an important part of the health care delivery system. We are still in the midst of a pandemic and have not had time to step back and analyze what we have learned from the waivers and flexibilities CMS has extended to providers during this challenging period. Those lessons could greatly inform future changes in the health care delivery system. CMS cites the evolution and advancement of medical care and quality as its chief reason for eliminating the inpatient-only list, but the medical field has arguably seen its greatest change in outpatient care in just the last few months.

NASH is especially concerned about a premature shift of some procedures from an inpatient to an outpatient setting because of the potential financial implications for the health care safety net. Private safety-net hospitals like those that belong to NASH, and other safety-net hospitals similar to them, provide a wide range of services to communities whose residents are predominantly low-income and rely heavily on government – Medicare and Medicaid – for their health insurance, if they have insurance at all. Such hospitals also support emergency services, laboratory services, and diagnostic imaging services and care for medically complex patients. To serve such communities effectively, these safety-net providers often offer services that lose money: services like neonatal intensive care, substance abuse treatment, behavioral health care, and more. They offer these services for one simple reason: because the communities they serve need them and no one else will offer them.

This comes at a cost: hospitals that provide services they know will lose money do so because of their role in the health care safety net, but they recognize that they can only do so if they can offer other

services for which they receive fair and competitive reimbursement. Outpatient surgery, provided in the hospital, is one of those services. If safety-net hospitals lose the ability to continue providing these services because outpatient facilities underprice them they will lose their ability to offer services for which they can be fairly and competitively reimbursed. And one thing is clear: the vast majority of independent ambulatory surgery centers are as far from a safety-net hospital as possible. They provide no emergency care, no laboratory or imaging services available to community physicians; they have few if any beds; they have little staff, if any, on site when they are not operating; they care for few Medicaid patients and even fewer uninsured patients; they care only for patients with simple, relatively easy-to-treat conditions and never care for patients with complex or multiple medical conditions; and they never, ever provide a service that does not promise a handsome return. Before CMS takes steps to encourage this kind of behavior, which would benefit the owners of such facilities at the expense of entire communities, NASH encourages the agency to take a closer look at the implications of phasing out its inpatient-only services list for safety-net hospitals and the communities in which those hospitals are located. NASH also urges CMS to solicit stakeholder input and prepare a report on the anticipated consequences of eliminating the inpatient-only list. NASH urges CMS to solicit input from clinicians on whether it is or is not safe to provide care without the additional supports that a hospital setting affords and on a process for identifying possible procedures that might safely be removed from that list.

Changes in the Level of Supervision for Selected Outpatient Therapeutic Services

NASH supports CMS's proposal to change – that is, to reduce – the level of supervision required for selected Medicare-covered outpatient therapeutic services. The trend has been moving in this direction for some time and now, with the experience of the various waivers and flexibilities extended to providers by CMS during the COVID-19 pandemic, we appear to have learned that the level of supervision for certain services can be reduced without risking harm to patients. While NASH encourages CMS to monitor the impact of such a policy change carefully to determine if it proves to be appropriate or goes too far – or not far enough – in some circumstances and for some medical conditions, NASH encourages CMS to move forward with this proposal.

The Physician-Owned Hospital Exception

While the Affordable Care Act did not allow for the creation of new physician-owned hospitals, it permitted two types of physician-owned hospitals – "applicable hospitals" and "high-Medicaid hospitals" – to expand if they met certain criteria. For high-Medicaid hospitals, such expansion was limited to 200 percent of their number of existing beds and such high-Medicaid hospital expansion could be undertaken only on such hospitals' existing main campuses.

That conclusion was the result of CMS's original interpretation of the Affordable Care Act. Now, CMS has concluded that this interpretation was not correct and proposes to end the 200 percent limit on expansion and to end the requirement for high-Medicaid hospitals that such expansion must only be on a hospital's existing main campus. While NASH recognizes that CMS may have such authority, it does not believe it is a good idea to remove the requirement that expansion beds be located on the existing facility's main campus.

NASH believes the high-Medicaid definition was created to ensure that facilities dedicated to treating a high percentage of low-income individuals in their communities could add more beds to meet future growth in demand and that Congress intended for these high-Medicaid hospitals to be eligible under the same terms as so-called "applicable facilities." Eliminating the prohibition on increasing beds at an off-site location, especially when combined with the proposal to remove the cap on bed expansion, could result in unintended use of the exception. Since the criteria for the exception are limited only to the point

in time at which the hospital submits an application, there is no assurance that such a hospital would continue its commitment to caring for Medicaid patients in the future. Nothing would necessarily prevent such an applicant, for example, from opening a new campus in a more affluent area where the need to serve the Medicaid population is not as great. Worse, nothing would prevent that same hospital, once it expanded to that new, more affluent area, from closing its original high-Medicaid hospital. This would reflect a fairly common strategy many hospitals have employed over the years of taking their good name and moving their facilities to new locations where they can have a more favorable payer mix – that is, more commercially insured patients and fewer Medicaid and uninsured patients.

In addition, since approval for the exception appears to involve no actual commitment to establish those new beds, it appears the proposed rule would permit any qualifying facility to apply to increase its excepted bed count by, say, 10,000 beds and then hold onto that exception, along with the ability to use it at a new campus, in perpetuity. This would risk turning privately owned high-Medicaid facilities into valuable commodities in the form of physician-owned hospitals that have "super" exceptions to the physician self-referral rule in the form of largely unrestricted growth and the practical ability to relocate into new communities. It might even constitute a financial incentive to sell a physician-owned high-Medicaid hospital to an entity that is not at all interested in caring for Medicaid patients.

Although CMS may have the administrative discretion to eliminate the parallel terms of the exception, NASH believes continued parity between both types of exceptions is in the best interest of good public policy and therefore urges CMS to withdraw this proposal.

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The National Alliance of Safety-Net Hospitals appreciates the opportunity to share our views on the proposed Medicare outpatient prospective payment system regulation with CMS and welcomes any questions you may have about the ideas we have presented in this letter.

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 are more dependent on Medicare and Medicaid for revenue; 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.