National Alliance of Safety-Net Hospitals

September 26, 2019

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

Attention: CMS-1717-P

Subject: Department of Health and Human Services, Centers for Medicare & Medicaid Services; 42 CFR Parts 405, 410, 412, 416, 419, and 486; Office of the Secretary; 45 CFR Part 180 [CMS–1717–P]; RIN 0938–AT74; Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

To Whom it May Concern:

I am writing on behalf of the National Alliance of Safety-Net Hospitals (NASH) to convey our views on the proposed regulation governing Medicare payments for outpatient services for calendar year 2020 that was published in the *Federal Register* on August 9, 2019 (Vol. 84, No. 154, pp. 39398-39644).

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

- the price transparency proposal
- reimbursement for 340B-covered prescription drugs
- site-neutral payment policy
- updates of the inpatient-only list

We address each of these issues individually below.

The Price Transparency Proposal

NASH appreciates CMS's interest in fostering greater consumer awareness of the prices hospitals charge for their services and in facilitating price shopping among consumers for non-emergency "shoppable" outpatient services. Despite this, NASH believes the price transparency requirements presented in the proposed regulation reflect an imperfect understanding of how hospitals charge and are paid for their services, how patients find their way to doctors and hospitals, and how providers interact with health insurers. Most important, we do not believe the proposed requirements, even if implemented perfectly by

every hospital in the country by January 1, 2020, would be at all helpful to consumers shopping for the best prices for the outpatient care they need.

Problems Inherent When Listing Service "Prices"

Our first concern is that the proposed means of achieving price transparency for shoppable outpatient services, by requiring hospitals to post their gross charges (from their chargemaster) and their payer-specific charges (as negotiated with the insurers with which they work), does not reflect an adequate understanding of how hospitals work with insurers to charge for their services. Specifically:

- Hospitals do not bundle services the same way Medicare does and often bundle them differently with different insurers, creating apples-to-oranges comparisons that would be of little value to consumers – and that could even be misleading to consumers.
- Some private payers discount multiple surgeries in different ways.
- While Medicare pays for services using HCPCS codes, DRGs, and APCs, such codes often are not used as the basis for payments between hospitals and commercial insurers.
- Some insurers reimburse hospitals based on Medicare APCs, which include an entire logic of bundled or incidental codes, which means that the incidental code, when billed in another context, might be payable separately. Other private insurers might pay for the same services based on a percentage of a hospital's charges on a line-by-line basis.
- A few insurers' radiology payments bundle professional services into their payments to the hospital but most do not.
- Hospitals may charge for each item and service but each item and service is not necessarily associated with an HCPCS code, DRG, NDC, or APC, as the proposed regulation anticipates – nor do hospitals and insurers necessarily negotiate prices for each individual item and service.
- As a result of hospitals and insurers not necessarily negotiating prices for each individual item and service, this proposed regulation may be requiring hospitals to publish data that does not exist.
- Within individual DRGs or APCs, hospitals do not provide a standard set of items and services. Their standard services could differ from patient to patient, depending on patients' needs; from insurer to insurer, depending on the outcome of rate negotiations between individual hospitals and individual insurers; and from hospital to hospital, because such matters are not standardized, freeing hospitals to make their own decisions about how to set their prices and negotiate payments with insurers.
- Some insurers bundle the cost of implants and drugs into outpatient case rates while others do not, preferring hospitals to bill separately for those implants and drugs.
- Physician services may or may not be included by some hospitals in their standard service packages.
- Because private safety-net hospitals need to engage in more cost-shifting than the typical community hospital to compensate for the losses they incur caring for large numbers of uninsured and Medicaid patients, their commercial rates may be higher than those other hospitals. This could lead people to see these price differences and assume they would have to pay more for the services of such hospitals – which in most cases they would not. Thus, posting such prices without appropriate context could damage the very private safety-net hospitals that society has a great stake in protecting.

The Underestimated Cost of Posting Hospital Prices

In the proposed regulation, CMS estimates that posting the required information should take hospitals approximately 12 hours and cost them about $1000 in staff time. NASH believes this grossly underestimates the work involved in such an undertaking. One NASH member, for example, reports that in one calendar quarter of 2019 it interacted with 250 distinct insurers (including Medicare), and in the case of 41 of those insurers, that interaction involved just one patient. That means this hospital would need to post charge and price data for at least 250 insurers, a meaningful proportion of which have members the hospital only rarely serves.

Another NASH member shared agendas for two meetings for relevant staff to discuss the price-posting requirements from the 2019 outpatient prospective payment system regulation. Those staff meetings, held in the fall of 2018 to address new requirements that were less demanding than those proposed for 2020, both involved 32 participants, many of whom were there to report on work already undertaken to meet the 2019 requirements and others who left the meeting with new assignments. This contrasts sharply with the proposed rule's assertion that compliance would require the participation of just one lawyer, one operations manager, one business specialist, and one computer systems administrator. This member's business services team, in fact, estimated that compliance with this requirement, if adopted as proposed, would necessitate the year-round services of two full-time employees.

This suggests that CMS has significantly underestimated the time and cost involved in posting the proposed information. This is a legitimate concern for hospitals – as it should be for CMS as well in light of its frequent, publicly articulated commitment to reducing the paperwork burden on health care providers so those providers can focus on providing care rather than on paperwork.

The Problem Posed by Sharing Proprietary and Confidential Information

The rates set between hospitals and insurers are not objective, universal measures: they are the product of careful, deliberate, and at times contentious negotiations between the parties. As a result of these negotiations, some hospitals gain more advantageous rates than others. As tempting as it might be for hospitals to learn if their competitors are doing "better" than they are in rate negotiations, it is more important to them to keep the results of their own negotiations confidential. Coca-Cola is not required to share its soft drink recipe with its competitors and NASH believes it would be inappropriate, and possibly even foster a form of collusion, to require hospitals to share so publicly their rate information – proprietary information – with their competitors. Doing so also could violate confidentiality agreements between the negotiating parties.

The Biggest Challenge: The Required Information is Not Useful

The underlying rationale for this price transparency proposal appears to be that if consumers have more information they will be more likely to make better, more informed health care purchasing decisions. In the case of this particular proposal, however, NASH believes that more information will not be better information and that it will not lead to better, more informed purchasing decisions.

Without question, NASH's biggest objection is that after all of the work hospitals would have to do to meet this proposed regulation's requirements and after all of the "shopping" consumers might do once such information becomes available, we are convinced that consumers will find this information to be of little value. In the experience of hospitals, the reality of this situation, as opposed to the theory underlying it, is that patients are not interested in whether the shoppable service they need "costs" $10,000 or $15,000 – not interested because they have health insurance and know they will not be paying that $10,000 or $15,000 cost. In the experience of hospitals, patients are interested only – *only* – in what their out-of-pocket costs will be, which means their co-pays and deductibles for the outpatient service in

question. In short, the "price" that this entire undertaking seeks to provide to consumers is not viewed by those consumers as a price at all and is irrelevant to them. This is comparable to a consumer purchasing a mattress with a list price of $3000 for a sale price of $1250. No one cares that the list price is $3000; all that matters is that the mattress can be purchased for $1250.

Instead, the overwhelming majority of patients who contact hospitals about costs prior to receiving outpatient services inquire only – *only* – about their anticipated out-of-pocket costs. Months can go by without patients referring to or asking about a hospital's charges or its prices, let alone about its chargemaster; in fact, the word "chargemaster" is unknown to the vast majority of health care consumers. NASH encourages CMS officials to spend a few days in a hospital billing office and sit with customer service representatives as they field calls from patients who are considering procedures or have procedures scheduled. When you do, you will find that these patients virtually never inquire about a procedure's price or cost; they are interested only in its *cost to them*, which is very different – and which will not be included in the vast amount of data this proposed regulation would compel hospitals to publish for consumer use. This has certainly been the experience of NASH members in California and Connecticut, where hospitals are already required to post extensive price and charge data on their web sites and where those hospitals tell us they seldom are asked by patients about their actual charges.

In the end, NASH believes, there are virtually no true "consumers" for this data at all, with the possible exception of competitors eager to learn if they are doing better, or doing worse, than nearby hospitals when negotiating rates with health insurers (or, for that matter, insurers eager to learn if they are overpaying or underpaying compared to other insurers). In the end, the time patients might spend visiting hospital web sites to research the cost of outpatient care and talking to hospital billing offices about their potential out-of-pocket costs would unquestionably be better spent talking to their insurers because those insurers, rather than hospitals, are more likely to have the answers to these questions and ultimately are the best source of information about the out-of-pocket costs patients can expect to incur when seeking medical care. This information is controlled and managed by insurers, not providers, so it is insurers that would be a more appropriate focus of CMS's laudable effort to provide information that would be relevant to consumers and help inform their health care purchasing decisions.

Reimbursement for 340B-Covered Prescription Drugs

The 340B prescription drug discount 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 such patients: provide more care that their patients might otherwise not be able to afford, offer more services that might otherwise by 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.

In this year's proposed rule, CMS calls for reimbursing 340B-eligible providers at average sale price less 22.5 percent for 340B-covered prescription drugs. NASH strongly opposes this proposal.

For the past two years CMS also has reimbursed 340B-eligible providers at average sale price less 22.5 percent for 340B-covered prescription drugs, a break from past policy, which reimbursed eligible providers at average sale price plus six percent. This policy change was implemented even though Congress, which created the program, did not direct CMS to reduce payments to 340B providers that serve especially large numbers of low-income patients just to save money and certainly did not direct CMS to introduce new policies that seek to reduce the federal government's commitment to serving low-income Americans.

Shortly after implementation of the reimbursement reduction that took effect in calendar year 2018, various stakeholders sued CMS over the payment cut and the courts agreed with the stakeholders and rejected the cut. Despite the court's ruling, CMS did not restore payments to average sale price plus six percent but continued to pay average sale price less 22.5 percent even though the court rejected this payment.

Despite the court's rejection, CMS proposed the same payment cut for calendar year 2019: average sale price minus 22.5 percent. The stakeholders again sued and the courts again sided with stakeholders and rejected the payment cut. Despite this, CMS again did not restore payments to average sale price plus six percent but continues to pay average sale price less 22.5 percent even though the court had now twice rejected this payment.

In light of these continued rejections by the courts, NASH encourages CMS to restore 340B payments to their previous level of average sale price plus six percent. The courts have spoken and it is time to respect their verdict.

This leaves the question of how to reimburse providers for the revenue they lost when CMS continued to make essentially illegal underpayments for two full years, refusing to adjust its payments in the face of its losses in court – a question posed in the proposed regulation. NASH believes the best way, the only way, to repair the damage done to safety-net providers by two years of underpayments is to restore those payments retroactively through a one-time, lump-sum payment that compensates them for every underpaid claim, every under-reimbursed prescription drug during the two-year period during which CMS continued to pay eligible providers average sale price less 22.5 percent despite not one but two court rulings that it must not do so. These lump-sum payments, NASH believes, should be made in their entirety to all affected hospitals by the end of calendar year 2020. To do this, NASH urges CMS to identify the amount of individual hospitals' underpayments based on data hospitals have already submitted rather than requiring additional action by the injured parties.

As explained by the web site of the Health Resources and Services Administration, which 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.

Federal policy should enhance this program and help it achieve its objectives, not make it harder for low-income patients and the providers that serve them. NASH urges CMS to heed the federal government's own rationale for the program and restore 340B payments to their previous level.

Site-Neutral Payment Policy

In the proposed regulation, CMS calls for completing its two-year phase-in for paying for off-campus clinic visits at the same rates as the physician fee schedule even if those clinics are grandfathered. As a result, clinic visits to grandfathered, off-campus outpatient departments would be reimbursed at the site-neutral rate of 40 percent of the outpatient fee.

NASH continues to oppose the implementation of site-neutral payment policy for Medicare-covered outpatient services. Implementation of this policy is based on authority granted to the Secretary under §1833t)(2)(F) to "develop a method for controlling unnecessary increases in the volume of covered OPD services." NASH disagrees with the idea that reducing reimbursement for clinic visits is an appropriate method for controlling unnecessary increases in the volume of covered outpatient services. First, and most fundamentally, there has been no credible finding that Medicare is experiencing "…unnecessary

increases in the volume of covered outpatient services." Increased volume? Yes. Unnecessary increases? There is no evidence that this increase is unnecessary. In fact, the federal government for years now has pursued policies that seek to reduce hospital inpatient utilization and encourage the delivery of more care on an outpatient basis. If anything, increased outpatient utilization should be viewed as a sign that this effort has succeeded and should be further encouraged, not discouraged and suddenly viewed as "unnecessary" and punished.

Second, although similar outpatient services can be safely provided in more than one setting, CMS's conclusion that providing care in the more expensive setting is unnecessary presumes that patients who require these services have access to both types of settings. In reality, they often do not: many private safety-net hospitals that operate off-campus, provider-based departments do so because they are addressing a need in their communities. Rather than increasing the volume of unnecessary services, the payment differential enables safety-net hospitals to create access to necessary services in communities where these services would otherwise be unavailable in any setting. NASH asks CMS to stop this misguided drive to "throw out the baby with the bath water" by continuing to cut reimbursement for necessary outpatient department services just because there may be circumstances in which alternative settings might be available. The proposed regulation continues to take the site-neutral payment policy too far, and in so doing it ultimately could jeopardize access to vital forms of care for the residents of many low-income communities served by private safety-net hospitals.

This continued practice of reducing payments even to exempted hospital-based, off-campus facilities is harmful: harmful to those medical practices, harmful to the hospitals that own and operate those practices, and most of all harmful in the long run to many of the patients these practices serve. NASH continues to object to Medicare reimbursing non-excepted, provider-based physician practices at physician fee schedule rates. These rates fail to reflect the hospital-related costs associated with such practices – costs such as maintaining emergency departments, operating laboratories, offering comprehensive radiology services, complying with regulatory requirements not imposed on independent physician practices, and much more. These are valid costs that benefit entire communities, and further reducing these payments, as proposed in this regulation, would jeopardize major parts of the health care infrastructure that every community truly needs.

Finally, last week a federal court ruled that CMS's implementation of its site-neutral payment policy for Medicare-covered outpatient services exceeded the agency's authority. NASH understands that CMS may appeal this ruling, as is certainly its right, but we suggest that continued implementation of the policy be suspended until this matter is adjudicated.

Updates of the Inpatient-Only List

In the proposed rule, CMS proposes removing arthroplasty – acetabular and proximal femoral prosthetic replacement total hip arthroplasty with or without autograft or allograft – from the list of procedures and services that will be paid only under Medicare's inpatient prospective payment system. NASH objects to this change as it has been proposed. While we acknowledge that it may be possible to perform hip replacement on an outpatient basis on some patients under some circumstances, hip replacement is medically complex and invasive surgery – far more so than knee replacement, which has already been removed from the inpatient-only list. Complications can arise even in the most otherwise healthy of patients. Often, in fact, hip replacement is performed on an emergency basis, which can complicate both the procedure and recovery from it. The opportunity for full and safe convalescence is important: patients who have hip replacement on an outpatient basis and who end up needing post-acute care because of complications would not even, under this proposed rule, be eligible for Medicare-covered skilled nursing care because they spent less than 24 hours in a hospital. This could jeopardize their complete

recovery from serious surgery. In this respect, this proposed change is not in the best interests of the Medicare population. NASH suggests that before implementing this proposal, CMS address this problem through additional rule-making.

NASH also is concerned about how making hip replacement available on an outpatient basis could affect private safety-net hospitals that participate in the Comprehensive Care for Joint Replacement (CJR) and Bundled Payments for Care Improvement (BPCI) Advanced programs. These programs face the prospect of decreases in inpatient volume and the effect of such decreases on provider target prices, yet the regulation does not address how this would be addressed in the context of those programs. This, too, would benefit from additional rule-making before hip replacement is removed from the inpatient-only list.

NASH supports CMS's proposal to establish a one-year exemption from medical review activities for procedures removed from the inpatient-only list beginning with 2020. While a step in the right direction, more can and should be done to allow time both for provider education and to ensure that CMS and its quality review contractors are aligned on medical review guidance for providers.

In addition, NASH supports CMS's proposal to continue quality reviews of short-stay inpatient claims for procedures that have been removed from the inpatient-only list within the first year. Such claims will not be counted against a provider in the context of the two-midnight rule. We do not believe medical review guidance questions have been fully addressed and think additional time is needed for processing claims and for contractors to gain experience in medical review in this area before putting hospitals at risk for recovery audit contractor (RAC) referrals.

We appreciate that these procedures would not be eligible for referral to RACs for non-compliance with the two-midnight rule and RAC patient status review during their first calendar year of removal from the list but believe one year is not enough time. NASH urges CMS to consider the challenges that occurred when procedures were removed from the inpatient-only list in the past and give itself and contractors additional time to develop guidance that can be shared for stakeholder input prior to implementation.

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The National Alliance of Safety-Net Hospitals appreciates the opportunity to share our views on the proposed 2020 Medicare outpatient prospective payment system regulation with CMS and welcomes any questions you may have about the views we have expressed 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 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.