nasH
National Alliance of Safety-Net Hospitals

September 17, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Attention: CMS-1753-P

Subject: 42 CFR Parts 412, 416, 419, and 512; 45 CFR Part 180; CMS-1753-P; RIN 0938-AU43; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

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 calendar year 2022 Medicare outpatient prospective payment and ambulatory surgical center payment systems regulation that was published in the *Federal Register* on August 4, 2021 (Vol. 86, No. 147, pp. 42018-42360).

In this letter we address five aspects of the proposed rule: health equity, the section 340B prescription drug discount program, hospital price transparency, proposed changes in the inpatient-only procedures list, and the extension of flexibilities related to the COVID-19 public health emergency.

Health Equity

In the proposed rule CMS seeks stakeholder comment about various matters that touch on health equity issues, and in particular, on the use of data, and the stratification of data, to promote health equity and improve health care quality in outpatient settings.

Before addressing these concerns NASH believes it is important to describe the role of community safety-net hospitals in the American health care delivery system.

Role of Safety-Net Hospitals

The communities private safety-net hospitals serve typically are characterized by significant health disparities driven in large part by inequities in the resources that have been invested in those communities over the years. Community safety-net hospitals often are older facilities that have aging medical equipment, lower operating margins, and smaller endowments. As a result of these inequities, these communities face significant health challenges. The role of safety-net hospitals is to work with their communities to address these health inequities. Because they primarily serve Medicare and Medicaid patients, these hospitals are paid less than other providers that serve more privately insured patients,

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which is one of the most important reasons community safety-net hospitals often lack the resources of other hospitals.

Despite these many challenges, safety-net hospitals are constantly testing new ways of doing a better job of serving their communities. To make these efforts more effective, these hospitals need the federal government to empower them financially to serve all of their patients, including their Medicare patients, which means that if and when new data collection and analysis reveals problems that need to be addressed, they need the federal government to work in partnership with them to address those challenges. Data collection and stratification can help, but they only identify problems; working to solve the problems such efforts identify requires federal leadership, and a major aspect of that leadership needs to be addressing the inequities in resources these hospitals experience that have helped lead to the health care disparities in the communities in question.

It is from this perspective that NASH responds to aspects of the proposed 2022 Medicare outpatient prospective payment system rule that address health equity.

Data Collection

In the proposed rule CMS has solicited comments on current data collection practices and the relative interoperability of hospitals' data collection methods. To engage in some of the enhanced support services described above, community safety-net hospitals have dealt with demographic data collection challenges constantly over the years and have come to understand that collecting data is not always the simple, straightforward endeavor some might hope it to be. Identifying at-risk populations and those who are vulnerable to long-time inequities in the health care system can be a very sensitive undertaking.

It is important for hospitals to be sensitive to and respectful of patient concern about possible disclosure of certain information. It also is important to try to avoid creating a stigma associated with separate practices or collections for certain individuals. Safety-net hospitals are hospitals first and foremost and for care to be effective, trust between patients and caregivers is essential. Finally, it is important to recognize that clinicians are working to care for patients and documentation of issues unrelated to clinical matters often requires the dedication of additional staff.

While NASH supports efforts to identify and address health inequities and the collection of data to better understand these inequities, we urge CMS to make any data reporting associated with such undertakings as simple as possible to minimize stress on the patient and cost to the provider. NASH is particularly concerned about especially burdensome new data-reporting requirements, which can become a distraction from the work safety-net hospitals do – that is, caring for their patients. NASH would welcome an opportunity to work with CMS to ensure that any new data collection meets these objectives in a way that is not burdensome to patients or providers yet is useful for enacting policies to better address patient needs.

Data Stratification

In general, NASH supports the concept of applying CMS's two disparity methods to stratify the performance results in the hospital outpatient setting, similar to the method used in the Hospital Readmissions Reduction Program but is concerned about the nature of the comparisons that might be made with this data. Like with the revised Readmissions Reduction Program, NASH believes it is essential that data not be compared across all hospitals, that comparisons should be among hospitals that care for similar types of patients in communities facing similar challenges. Without this distinction, the data would not account for the greater challenges some hospitals face in caring for their communities.

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To make the potential new outpatient data stratification a truly useful tool in the pursuit of health equity, CMS also must commit resources and an accompanying effort to work with hospitals to make improvements that move toward greater health equity if the data shows quality problems or quality inequities. NASH believes that those institutions facing the greatest challenges should receive the greatest assistance.

Future Data Reporting Requirements

CMS has solicited comments on the future possibility of facility data collection, on the day of service, of a minimum set of demographic data using standardized and interoperable electronic health record standards. NASH recognizes that CMS will need data: data to identify health inequities, data to identify challenges, data to identify hospital performance, and data to drive resources to address those challenges. Before CMS begins to introduce new data collection, NASH urges the agency to carefully review the data it already collects and make every effort to ensure that it does not duplicate any current data reporting requirements. If the agency chooses to require hospitals to submit additional data, NASH requests that such additional requirements not be overly burdensome and that this new data be collected uniformly among all hospitals. CMS also must consider the patient sensitivities surrounding this type of data, as discussed above. It is vital that safety-net hospitals continue serving as a trusted ally for patients in these vulnerable communities rather than another government entity probing them for personal and at times embarrassing information.

The Section 340B Prescription Drug Discount Program

In the proposed rule CMS calls for maintaining the current payment rate for 340B-covered drugs at average sale price minus 22.5 percent for certain separately payable drugs or biologicals, with rural sole community hospitals, children's hospitals, and prospective payment system-exempt cancer hospitals not being subject to this reduced payment formula.

NASH opposes CMS's proposal to continue reimbursing hospitals for 340B-covered drugs at average sales price minus 22.5 percent. 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 – like community safety-net hospitals – 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 like community safety-net hospitals that care for especially large numbers of low-income patients qualify to participate in the 340B program. Congress has not asked the executive branch to reduce payments to 340B providers, nor did it mandate that CMS introduce new policies that seek to reduce the federal government's commitment to serving low-income Americans. CMS's own recent actions suggest a strong level of support for the 340B program that the proposed regulation belies: for the past year the agency has been at odds with pharmaceutical companies that are unilaterally denying 340B discounts to eligible providers and has come to the 340B program's defense.

The 340B program is vital for the low-income individuals 340B-qualified hospitals serve. It is an essential tool that enables community safety-net hospitals to help medically vulnerable individuals, many of whom have long been subject to health care inequities.

For these reasons, NASH urges CMS to restore 340B payments to their 2017 level of average sale price plus six percent.

Hospital Price Transparency

Beginning on January 1, 2019, CMS required hospitals to post standard charges for all items and services in a machine-readable format. Beginning on January 1 of this year CMS added to this requirement, compelling hospitals to make public gross charges and payer-specific negotiated charges for all items and services and gross charges and payer-specific negotiated charges for 300 shoppable services. CMS now proposes increasing the civil and monetary penalties for non-compliance.

NASH opposes CMS's proposal to increase the penalties for non-compliance with hospital price transparency requirements for several reasons.

First, NASH believes that patients should have access to the financial information they need to make informed decisions about their medical care, however we continue to question the value of the information this approach to transparency will give our patients. While we agree that patients want to know more about hospital costs, we believe what they want to know is not the overall cost of an episode of hospitalization but the out-of-pocket costs they can expect to incur when they are hospitalized. The data CMS now requires hospitals to post publicly requires far more than is needed to get that answer. In addition, data reporting requirements are confusing, occasionally ill defined, and sometimes impossible to meet.

Second, we are concerned about the timing of this proposal, coming as it does less than a year after the latest transparency requirements were introduced and in the midst of a COVID-19 public health emergency that we suspect CMS thought was winding down at the time it wrote and released this proposed regulation. Community safety-net hospitals and other hospitals find themselves once again in the middle of a daily battle against the pandemic, fighting disease, shortages of resources, staffing problems, and more. Finding a qualified IT professional is especially difficult. Now is not a good time to devote extra internal resources – money, staff, and time – to meeting the transparency requirement when our beds are once again filling with COVID-19 patients.

Third, while we respect CMS's intention to implement its transparency requirements, we do not believe increasing financial penalties for non-compliance is a productive way to foster greater compliance. Aside from potentially exacting an enormous financial toll on hospitals – and especially on community safety-net hospitals, which have far more limited resources than the typical hospital and in many cases are struggling to survive amid this pandemic – the challenge at hand for hospitals not currently in compliance is as much about understanding the transparency requirements as it is about willingness to comply with them. CMS first should engage in a more concerted effort to educate hospitals about the data they are expected to make public – and the form in which they must do so.

For these reasons, we respectfully request that CMS withdraw the portions of the proposed rule that call for increased penalties for failing to comply with its hospital cost transparency requirements. We also recommend that CMS form a workgroup that consists of its own staff and hospital representatives to tackle anew the question of what data best meets consumers' needs and how it can be made publicly available in a useful, accessible manner while not being overly burdensome for hospitals.

Proposed Changes in the Inpatient-Only Procedures List

Last year CMS announced a three-year process to eliminate the inpatient-only procedures (IPO) list, starting with the removal of 298 services from that list. In response to stakeholder comment on this plan CMS now proposes halting elimination of the list and restoring the 298 eliminated services and codifying the criteria for future removals.

NASH agrees with CMS's proposal to halt the elimination of the IPO list and recommends that the agency continue to develop a safe and rational approach to shifting appropriate care to outpatient and ambulatory settings, especially in ways that might improve access and outcomes for patients.

NASH also agrees with restoring the 298 procedures to the IPO list in 2022 and with removing the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a three-year transition. In implementing this restoration, however, we urge the agency to consider the significant steps many providers have already taken to implement the policy finalized in last year's rule. Surgeries are scheduled in advance and there will be only a relatively short period of time between the finalization of this rule and the beginning of the calendar year during which these 298 procedures will return to the inpatient-only list. For this reason, we ask CMS to permit providers to bill for services provided in an outpatient setting after the implementation date of the rule if those procedures were scheduled prior to the rule's official implementation. In this manner, providers will be able to more effectively wind down the policies they implemented in response to last year's finalized rulemaking with minimal disruption to the lives of patients who are already expecting to receive care in an outpatient setting.

We also encourage CMS to take a closer look at the impact removing services from the list can have on beneficiary safety. We encourage CMS to develop criteria for removing procedures from the IPO list that clearly define when a given procedure can be done in an outpatient setting and when it is still appropriate for being performed in an inpatient setting based on a broader look at medical necessity, which can go beyond the clinical aspects of the procedure in question and be affected by the home environment and family, social, and community supports, or lack thereof, that patients undergoing outpatient procedures may face when they return home. Finally, NASH also urges CMS to study carefully the out-of-pocket financial impact on Medicare beneficiaries that could arise when moving procedures to outpatient settings – something that is especially important for the patients served by community safety-net hospitals because so many of those patients have limited financial means.

The Extension of Flexibilities Introduced in Response to the COVID-19 Public Health Emergency

Over the past 18 months CMS has introduced a number of flexibilities to help providers respond to the COVID-19 emergency – flexibilities to help patients suffering from COVID-19 and those who have found their access to their traditional sources of health care hindered by the effects of the pandemic. In the proposed rule CMS seeks stakeholder feedback on whether some of these flexibilities should remain permanent and is especially interested in the extent to which hospitals have billed for mental health services furnished to beneficiaries in their homes through communication technology, the anticipated demand for this kind of service in the future, and whether any changes are needed to accommodate such a shift.

In NASH's view, the increased use of telehealth since the start of the public health emergency has been very successful, producing high-quality outcomes for patients, enhancing patients' experience in the health care delivery system, and protecting access for individuals susceptible to infection. They have provided access to quality care when hospitals and outpatient facilities were not an option and have enabled isolated, sick people with limited access to care to get the care they needed. Even in non-pandemic times, access to care has often been an issue for the kinds of communities safety-net hospitals serve because so many residents of those communities lack transportation, child care, or other services they need to keep doctors' appointments. While certainly not the ideal circumstances for a policy roll-out, this expanded use of telehealth has filled a major void and proven its worth – for physical health programs and especially for behavioral health care.

In response to CMS's request for comment in the proposed rule, NASH members are providing mental health services to patients in their homes using communications technology and billing for those services. Because of the physical access-to-care challenges that many of the low-income residents of the kinds of communities safety-net hospitals serve, both providers and patients have found this approach to be useful and productive. As a result, community safety-net hospitals anticipate a continued demand for the delivery of mental health services via telehealth in the future, including beyond the end of the current public health emergency.

For these reasons, NASH urges CMS first, to preserve all of these flexibilities until at least the end of the calendar year when the current public health emergency officially ends; second, to initiate an in-depth examination, with stakeholder participation, to explore how the individual flexibilities worked and whether they are worth preserving or even extending; and third, to take definitive steps to make telehealth a permanent and important and more prominent fixture in the American health care delivery system.

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The National Alliance of Safety-Net Hospitals appreciates the opportunity to share our views on the proposed FY 2022 Medicare inpatient 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
Executive Director

About the National Alliance of Safety-Net Hospitals

The National Alliance of Safety-Net Hospitals advocates for adequate recognition and financing of community safety-net hospitals that serve America's neediest communities. These community 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 Community 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. Private community safety-net hospitals can be found serving communities urban, rural, and suburban across the country.