National Alliance of Safety-Net Hospitals

July 10, 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 405, 412, 413, 417, 476, 480, 484, and 495; CMS-1735-P; RIN 0938-AU11; Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute-Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Attention: File Code CMS-1735-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 FY 2021 Medicare inpatient prospective payment system regulation that was published in the *Federal Register* on May 29, 2020 (Vol. 85, No. 104, pp. 32460-32975).

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

- Medicare DSH proposals
- The Medicare area wage index
- negotiated rate reporting
- Medicare bad debt policy
- Medicare graduate medical education policy
- CAR-T cell therapy payments

We address each of these issues individually below.

Medicare DSH

NASH is concerned about two aspects of how this year's proposed regulation addresses Medicare DSH payments to hospitals: the proposed reduction of the Medicare DSH uncompensated care pool and the manner in which CMS proposes calculating hospitals' uncompensated care.

The Medicare DSH Pool (Calculation of Factors 1 and 2)

The Medicare DSH uncompensated care pool is supposed to reflect what Medicare would have spent on Medicare DSH payments in the absence of the Affordable Care Act (Factor 1) adjusted for the change in

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the percentage of individuals without health insurance (Factor 2). NASH believes the effects of the COVID-19 outbreak require additional consideration in the calculation of both factors beyond what was considered in the proposed rule for FY 2021, which contemplates a $530 million reduction of the pool, to $7.8 billion.

First, the current public health emergency has led to many people putting off receiving health care: they have delayed seeing doctors and been prevented from undergoing non-emergency procedures. There is unquestionably a pent-up demand for such services, so NASH believes FY 2021 Medicare inpatient volume will rise significantly over that of recent years and that this influx of more patients receiving inpatient care during fiscal year 2021 will bring with it an increase in the amount of DSH payments that would have been made absent the changes in DSH policy brought about by the Affordable Care Act. Again, NASH believes this has led CMS to underestimate how much inpatient care hospitals will provide in FY 2021, which should be adjusted for in the calculation of Factor 1.

Second, the Medicare DSH uncompensated care pool is supposed to reflect the decline in the uninsured rate. For years after implementation of the Affordable Care Act the uninsured rate did, in fact, decline. That decline has ended: the uninsured rate has risen over the past two years and now, in the face of a public health emergency that finds people losing their jobs and losing their health insurance, that uninsured rate will continue to rise – as will the amount of uncompensated care hospitals provide. This means the uninsured rate will certainly be greater than the estimates on which the calculation of FY 2021's proposed Medicare DSH uncompensated care pool are based. This suggests a need to revise assumptions about uninsurance used to calculate Factor 2.

For these reasons, and because Medicare DSH uncompensated care payments are supposed to help hospitals with their uncompensated care costs, NASH urges CMS to increase, not to decrease, the Medicare DSH uncompensated care pool for FY 2021 specifically by adjusting the assumptions used to calculate factors 1 and 2 to reflect the effects of the COVID-19 pandemic.

Calculating Uncompensated Care (Factor 3) for FY 2021

Factor 3 represents a hospital's share (as estimated by the Secretary) of the total uncompensated care provided by all hospitals eligible to receive DSH payments. CMS has, in recent years, calculated Medicare DSH uncompensated care payments using an average of three Factor 3 calculations subject to a budget neutrality adjustment that modifies the average Factor 3 for each hospital to spend the appropriate amount for the fiscal year. CMS changed course, though, in FY 2020, choosing instead to calculate Factor 3 based on a single year's worth of data. There are two reasons why NASH believes CMS should return to using multiple years' worth of data. First, using multiple years smooths large annual fluctuations, and second, it strikes a needed balance between timeliness and accuracy.

Smoothing Annual Fluctuations

We continue to believe that a multi-year average is the most appropriate means of performing this calculation and protecting hospitals from stark annual fluctuations in payments. Without such protection, we believe hospitals' Medicare DSH uncompensated care payments will become unreasonably unpredictable. Our analysis of FY 2017 and FY 2018 data found that approximately 50 percent of hospitals reported increases or decreases in uncompensated care of more than 15 percent – and that some reported changes of more than 500 percent. These changes are large, and they can be increases or decreases. Simply put, reporting stable uncompensated care totals on the S-10 from one year to the next is uncommon. Only around one-third of DSH-eligible hospitals reported uncompensated care data that

changed less than 10 percent from 2017 to 2018. Thus, we believe using multiple years of data is necessary to mitigate large annual fluctuations and provide some stability and predictability to Medicare DSH uncompensated care payments.

Balancing Timeliness and Accuracy

NASH also believes using multiple years of data is the best way to balance the need to use accurate and audited data while also reflecting the most current data available. One of the keys to accurately calculating hospitals' Medicare DSH uncompensated care payments is the quality of the data hospitals report on their cost reports' S-10 worksheet. NASH has advocated rigorous auditing of this data for years, and two years ago CMS initiated such auditing – something NASH appreciates very much. At this point, however, significant numbers of DSH-eligible hospitals still have not had their S-10 data audited; meanwhile, a number of hospitals tell us they have already been audited more than once. This lack of auditing may help account for NASH finding, as noted above, that about 50 percent of hospitals reported increases or decreases of more than 15 percent in uncompensated care from FY 2017 to FY 2018, with some hospitals reporting variances of more than 500 percent.

Such findings heighten the need for CMS to complete auditing data from the remaining DSH hospitals as soon as possible – especially in light of the changes in the uninsured rate and the amount of inpatient care hospitals provide that can be expected in the next year. We believe these additional audits will help improve future data submissions as hospitals gain experience with the S-10 worksheet and auditors' interpretations of the S-10's instructions and the manner in which individual hospitals have interpreted those instructions.

In addition, we also ask CMS to establish a program of regular, periodic, and timely data review by implementing a system for flagging troublesome data and performing desk audits of and applying adjustments to that data, as needed. Through such efforts, CMS can ensure that limited Medicare DSH uncompensated care resources reach the hospitals actually providing true uncompensated care. Our proposal (described below) assumes implementation of such a process.

Our Proposal

Due to limitations of data reported in 2016, which was a transition year in the instructions for the S-10 and not subject to widespread auditing, last year NASH proposed to CMS a three-year phase-in that would avoid using 2016 S-10 data while also giving CMS time to expand audits and improve the quality of the available data for use in future periods. We now propose a two-year phase-in to accomplish those same goals using a three-year average of data.

- Year one (FY 2021) would be a 50/50 blend between a hospital's Factor 3 used to calculate its 2020 Medicare DSH uncompensated care payment and the Factor 3 derived from that hospital's 2017 data. Meanwhile, during FY 2021 CMS would engage in audits of the 2018 data of hospitals projected to receive DSH that still have not undergone an S-10 audit and establish a process to identify suspect data and perform preliminary reviews of 2019 data as it is reported.

- Year two (FY 2022) would consist of an equally weighted blend of hospitals' audited 2017 and 2018 data and preliminarily reviewed 2019 data.

Each year thereafter, CMS and its contractors would continue to perform audits and reviews while rolling forward the three-year average, adding the latest year of data to the calculation and dropping the oldest

year of data. The result will balance timeliness and accuracy while also maintaining year-over-year stability.

Puerto Rico hospitals, Indian Health Service and Tribal hospitals would continue to receive a Factor 3 based on low-income insured days from FY 2013.

Medicare Area Wage Index

NASH objects to the manner in which CMS proposes changing the Medicare area wage index and also to CMS's continued implementation of a change introduced in the current (2020) fiscal year.

First, in the proposed rule CMS calls for introducing changes in wage index labor markets to reflect changes in Core-Based Statistical Area definitions published by the Office of Management and Budget. Doing so would affect the calculations of individual hospital wage indexes, Lugar hospitals, and out-migration adjustments. To help hospitals adjust to these changes, CMS proposes implementing a five percent cap on hospitals' wage index-associated losses from 2020 to 2021, with this cap to apply to wage index losses of all hospitals regardless of the reason for the loss.

While NASH appreciates CMS's willingness to try to protect hospitals from the immediate and damaging impact of this change, we believe the proposed five percent cap on losses for one year is not enough. We believe five percent is too great a reduction to suffer in a single year, and there are wage areas that would suffer such significant reductions of their wage index adjustments that the five percent cap represents less than half of the anticipated losses of hospitals in those areas. Some hospitals, moreover, can expect to suffer even greater reductions next year. With this in mind, we ask CMS to limit individual hospitals' potential losses to just three percent, rather than the five percent proposed, and to extend this lower limit to a second year instead of just one to give hospitals a fairer chance to adjust to this unexpected proposal.

Second, NASH wishes to convey its continued opposition to the implementation of the FY 2020 change in wage index adjustments that arbitrarily increases the wage adjustments of hospitals in the lowest quartile of wage adjustments and pays for the changes this produces with a budget neutrality adjustment to the standardized amount. While NASH recognizes that there may be valid reasons to believe the federal government needs to do something to increase Medicare payments to hospitals in certain low-wage areas of the country, CMS has not pointed to any unfairness in how wage index adjustments are calculated or suggested that hospitals not in the lowest quartile have done anything untoward to gain those higher adjustments. This is a funding matter, not a formula matter, and NASH continues to believe that CMS should not take money away from some providers to benefit others without a policy basis for doing so. Instead, NASH urges CMS to work with Congress to secure new funding with which to assist hospitals in the lowest quartile of wage index adjustments and to restore the associated payment reduction to all hospitals.

Negotiated Rate Reporting

In the proposed rule, CMS calls for requiring hospitals to report on their cost reports their median payer-specific negotiated inpatient services charges for Medicare Advantage organizations and third-party payers for any service package that hospitals are required to make public under the hospital price transparency final rule that can be cross-walked to an MS-DRG. This data then would become publicly accessible on the Healthcare Cost Report Information System (HCRIS) dataset.

NASH opposes this proposal for two reasons.

First, NASH is concerned that CMS's proposal to publicly report the results of confidential negotiations between hospitals and insurers would greatly interfere with free markets. Giving confidential, proprietary information to competitors and granting insurers unprecedented, inappropriate, unfair, and insurmountable leverage in their rate negotiations would hamstring hospitals that have already been forced to undergo unprecedented industry consolidation merely to maintain the negotiating leverage they are currently able to muster.

Second, NASH agrees with other provider groups in questioning CMS's legal authority to require such information – both as a requirement in general and its basis in the still-disputed hospital price transparency final rule. NASH recognizes that the question of authority is currently being litigated and encourages CMS to wait until both sides have exhausted their legal options before attempting to impose the proposed requirement.

For these reasons, NASH urges CMS to withdraw this proposal.

Medicare Bad Debt

In the proposed rule CMS calls for revising its Medicare bad debt policy by clarifying, updating, and codifying certain longstanding Medicare bad debt principles. NASH appreciates this attempt to create greater clarify but has several concerns.

NASH is concerned about the proposed retroactive applicability of the updated policy. Specifically, we believe it may not be appropriate in all cases. We also think some aspects of the proposed changes that are described as a codification of long-standing policy may actually be substantive changes.

For these reasons, and also because the health care industry has been almost exclusively consumed with addressing the current public health emergency and has not had the opportunity to give these proposed changes the attention they deserve, we respectfully request that CMS withdraw this proposal at this time and propose it again next year.

Graduate Medical Education Policy

CMS proposes changes involving teaching hospitals and residency programs that close, the residents who are affected by such closures, and the Medicare graduate medical education payments intended to support the training of those residents. NASH supports the proposed changes.

CAR-T Payments

In the proposed FY 2021 rule CMS announces its intention to remove the existing CAR T ICD-10 procedure codes (XW033C3 or XW043C3) from MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy) and assign them to a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). This new MS-DRG 018 represents a significant weight increase from MS-DRG 016. NASH appreciates CMS's continued focus on the reimbursement complexities of

this technology. NASH also supports CMS's decision to exclude cases that are part of clinical trials from the relative weight determination and also to pay these cases exclusive of the cost of the CAR T-cell product. We agree that CAR T-cell therapy is sufficiently different from other treatments to warrant its own MS-DRG.

The proposed increased DRG payment, however, does not sufficiently cover the product acquisition cost ($373,000) or consider other costs associated with inpatient care, such as nursing, diagnostic studies, room and board, and more. Medicare's reimbursement must be sufficient not only to cover the acquisition cost of the CAR-T therapy but also to cover the inpatient medical costs associated with administering these therapies.

In light of the low volume of CAR-T claims to date, NASH urges CMS to continue identifying claims to be included in the calculation of the relative weight. NASH also encourages CMS to continue collecting more data on the cost of treating patients with CAR-T therapy going forward to ensure accurate pricing of the therapy. Based on this need to collect more data, NASH recommends that CMS consider this new MS-DRG a transitional payment for CAR T-cell therapy.

NASH also believes that CMS's payment for this therapy should take into account factors such as a patient's burden of illness and comorbid conditions and complications associated with receiving these treatments. Patients receiving this therapy can often experience post-infusion complications, which is an additional financial cost to hospitals. NASH urges CMS to consider complication or comorbidity or major complication or comorbidity codes when evaluating reimbursement for CAR-T cell therapies as more clinical data becomes available.

NASH appreciates CMS's continued focus on this innovative treatment and ensuring that Medicare beneficiaries have access to CAR T-cell therapy.

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Finally, NASH urges the administration to extend the current public health emergency, first because we are still in the midst of the emergency and second, because many of the things hospitals are doing to support the response to COVID-19 have only been made possible because of the special flexibilities the administration and Congress have granted them in response to the current crisis.

The National Alliance of Safety-Net Hospitals appreciates the opportunity to share our views on the proposed 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 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.