ALLIANCE of SAFETY-NET HOSPITALS

info@safetynetalliance.org
(703) 444-0989
safetynetalliance.org
21351 Gentry Dr, Ste 210, Sterling, VA 20166

September 12, 2022

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

Subject: CMS–1772–P - RIN 0938–AU82, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Attention: File Code CMS-1772-P

To Whom it May Concern:

I am writing on behalf of the Alliance of Safety-Net Hospitals ("ASH," formerly the National Alliance of Safety-Net Hospitals), a group of private community safety-net hospitals that serve economically disadvantaged and underserved communities, to convey to the Centers for Medicare & Medicaid Services (CMS) our views on the proposed calendar year 2023 Medicare outpatient prospective and ambulatory surgical center payment systems and other proposals published in the *Federal Register* on July 26, 2022, Vol. 87, No. 142, pages 44502-44843.

ASH would like to comment on four aspects of the proposed rule:

- the proposed update of outpatient and ambulatory surgical center rates
- site-neutral outpatient payments
- the 340B program
- prior authorization for facet joint interventions
- radiation oncology

We address each of these subjects individually below.

The Proposed Update of Outpatient and Ambulatory Surgical Center Rates

ASH appreciates CMS's effort to increase outpatient rates 2.7 percent in 2023 but strongly believes the proposed rate does not consider the serious challenges of rising health care delivery and labor costs.

Health care providers of all kinds have been hit hard by rising staffing costs, led by rising nursing costs. Perhaps more nursing positions than ever are currently occupied by contract nurses and the cost of these contract nurses has spiraled out of control. One study found that the hourly rates for contract nurses rose 213 percent between January of 2019, before the pandemic, and January of 2022, just a few months ago. While contract nurses are found less frequently in hospital outpatient departments than they are in hospitals themselves, staffing remains a serious problem – and a costly challenge – for hospital outpatient departments as well and those costs.

On top of all this has come an increase in the cost of doing business – inflation – to a degree not seen since the late 1970s and early 1980s. According to the Department of Labor, the annual inflation rate for the U.S. is 8.5 percent for the 12 months that ended in July of this year.

We understand the methodology CMS employs to calculate rate increases but believe that methodology has failed this year by not recognizing the true extent of the financial and medical challenges health care providers currently face and by not proposing an appropriate rate increase that reflects the severity of those challenges. Consequently, we ask the Secretary to exercise his authority to make exceptions and adjustments to implement a more appropriate rate increase.

Compounding the challenge posed by the inadequate market basket increase of 3.1 percent is the proposed 0.4 percentage point productivity adjustment that is subtracted from that increase. In theory the concept of adjusting payments for goods and services based on the ability of the providers of those goods and services to use technology and other means to provide those goods and services in a more efficient, less-costly manner is sound – but it is not applicable to all areas of endeavor. Despite many advances in health care technology, the delivery of care, and in this case the delivery of outpatient care, remains very much a hands-on endeavor: it cannot be automated, cannot be "off-shored," cannot be outsourced to lower-cost providers, cannot be delivered with greater efficiency through better use of information technology. In ASH's view, any productivity adjustment at all is inappropriate at this time. We recognize that the proposed productivity adjustment is required by statute, so we urge CMS to work with Congress to eliminate it – permanently. In the absence of that elimination we believe the final outpatient and ambulatory surgical rates should include an additional amount equal to the productivity adjustment so that adjustment will be offset 100 percent.

For these reasons ASH urges CMS to reconsider this year's proposed update in the face of the challenges its partners in serving the Medicare population face, the sacrifices they have made, and the obstacles they will encounter if they must enter a new year knowing that Medicare intends to provide nowhere near the resources they are counting on, that they need, to continue serving their Medicare patients. ASH recognizes that in other final payment rules this year CMS has done what it could to improve payments and for this we thank you, but we still urge CMS to take a different approach to determining a fair rate increase for outpatient and ambulatory surgical services for Medicare patients in the coming year.

Site-Neutral Outpatient Payments

Currently, CMS pays physician fee schedule-equivalent rates for hospital off-campus clinic visits.
In the proposed rule CMS calls for paying the full hospital outpatient department rate for care provided at rural Sole Community Hospital-based outpatient departments because it believes such a policy will help maintain access to care in rural communities. ASH supports this proposal; we believe the communities served by Sole Community Hospitals would greatly benefit from such a policy.

In the proposed rule CMS also asks stakeholders if they believe other types of hospital should receive similar consideration, and ASH urges CMS to extend this change of policy to deemed Medicaid DSH hospitals as well.

We do so because access to care is no less a challenge in the communities served by these deemed DSH hospitals than it is in the communities served by many Sole Community Hospitals. ASH hospitals have learned from experience that geography is not the only barrier to access to care; the adequacy of payments to providers can be a barrier as well.

The communities in which these deemed DSH hospitals are located are characterized by especially large numbers of low-income, Medicaid-covered, dually eligible, and uninsured residents. Many of these residents are challenged by numerous social determinants of health beyond low income, lack of literacy or proficiency in English, long periods of unemployment, sporadic contact with the health care delivery system during their lives, inadequate food and housing, and more. Because so many of these residents are insured by Medicaid, physicians often find it economically unfeasible to establish medical practices in those communities because Medicaid pays providers so poorly in the vast majority of states. More often than not, doctors practice in areas with higher proportions of privately insured patients whose insurers pay them much better than Medicaid. Paying full hospital outpatient department rates to deemed DSH hospitals for hospital off-campus clinic visits can help level an inherently unlevel playing field, offering a potentially powerful inducement for physicians to practice in communities with larger numbers of Medicaid patients than they might otherwise have considered. In this regard, paying full hospital outpatient department rates to deemed DSH hospitals for hospital off-campus clinic visits is every bit as essential, as critical to access to care, as making full payments to physicians providing outpatient care in areas served by Sole Community Hospitals. If the purpose of paying full hospital outpatient department rates for hospital off-campus clinic visits to Sole Community Hospitals is to improve access to care in communities that currently have limited access to care, then making those same payments for deemed DSH hospital off-campus clinic visits would fulfill the very same objective: to enhance access to care in medically vulnerable communities. For these reasons, ASH encourages CMS to extend its proposal to pay full hospital outpatient department rates for care provided at Sole Community Hospitals to deemed DSH hospitals as well. We believe the communities served by Sole Community Hospitals would greatly benefit from such a policy change and we believe the communities served by deemed Medicaid DSH hospitals would, too.

The 340B Program

In the proposed rule CMS acknowledges the recent Supreme Court decision rejecting its current policy of varying reimbursement rates for 340B-eligible hospitals. The agency explains that the timing of the decision left it without sufficient opportunity to develop a new payment proposal reflecting this decision in time for publication of this proposed regulation, so in lieu of such a response it proposed the current rate of average sales price (ASP) minus 22.5 percent for drugs and biologicals acquired through the 340B program while clearly conveying that this proposal was a placeholder until it could develop a proposal that reflected the Supreme Court decision.

Now that some time has passed and CMS has had an opportunity to explore this issue and its response to the court's decision, ASH – in response to CMS's request that stakeholders offer their own views on how the federal government should pay for 340B prescription drugs and compensate program participants for the payments they have lost over the past five years – recommends a three-part approach to remedying this problem:

1. Revert to previous Medicare policy of paying ASP plus six percent for 2023 regardless of whether a drug was acquired through the 340B program.
2. Repay promptly all eligible hospitals the difference between ASP plus six percent and what they were actually paid for drug claims as a result of the overturned policy for calendar years 2018-2022.
3. Hold hospitals harmless for the overruled policy for calendar years 2018-2022.

ASH would like to take this opportunity to share our rationale for this recommendation – a recommendation we believe is shared by many hospitals.

The Supreme Court recognized that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." Despite this, for five years CMS's policy deprived 340B hospitals of payments even as hospitals across the country struggled to care for their patients and communities amid a once-in-a-century pandemic. Under these circumstances we believe prompt repayment is essential.

We believe the survey of 340B acquisition costs that CMS undertook in 2020 was defective and should not be used to set future payments or to delay or deny repayment for calendar years 2021 or 2022. That survey does not comport with the law and was never relied upon by CMS as the basis for continuation of its unlawful policy. It is not a fair, proper, or legal basis for the delay or denial of repayment.

In the past, CMS raised the possibility of invoking "budget neutrality" to retrospectively recoup funds from hospitals that received them because of the policy the Supreme Court has now overturned. CMS should not penalize hospitals for its own past mistakes. We believe retrospective recoupment would be illegal and impossible to implement as a practical matter. Most of the money hospitals received was spent during the pandemic, a crisis that even today is causing hospitals to struggle financially and clawing back that money now would only further put patients and communities at risk.

In addition, nothing in federal law requires or even permits CMS to claw back funds to achieve budget neutrality. The law governing the outpatient prospective payment system makes clear that budget neutrality applies prospectively, not retrospectively, so we believe CMS lacks the legal authority to recoup past payments to achieve budget neutrality and are aware of no relevant instance in which CMS has even tried to recoup prior outpatient prospective payment system payments. It should not try doing so now.

CMS exempted a number of 340B hospitals from its recently overturned policy, including rural sole-community hospitals, free-standing children's hospitals, and free-standing cancer hospitals. These hospitals would be highly vulnerable to claw back, yet at the same time it would be impossible to fairly implement a budget neutrality policy if these entities were not subject to the same recoupments as other hospitals. No hospitals should be subject to claw backs based on a policy that the highest court in the land has overturned.

In the proposed rule, CMS states that it "fully anticipates" restoring payment to 340B hospitals at a rate of ASP plus six percent for separately-payable drugs. In undoing the agency's overturned policy, CMS is proposing a new budget neutrality adjustment to the outpatient prospective payment system conversion factor to account for this increase in payment. We are concerned that the agency's calculation of this adjustment is incorrect and will result in further underpayment to hospitals. These payments are critical for hospitals to cover the costs of caring for our Medicare patients. A recent report by the Medicare Payment Advisory Commission (MedPAC) found that hospitals' Medicare margins were negative 8.5 percent in 2020 even after accounting for federal relief during the pandemic. Hospitals simply cannot afford further underpayments. Consequently, we urge CMS to correct the proposed adjustment to ensure that the appropriate amount is added back into the 2023 outpatient payment system conversion factor and no hospital is underpaid.

When CMS first implemented the recently overturned 340B payment policy in 2018 it required certain hospitals to report the modifiers "JG" and "TB" on drug claims to identify separately-payable claims. Because CMS anticipates abandoning the current 340B payment policy, we urge it to end this requirement.

ASH appreciates CMS's recognition that it must restore payments to 340B hospitals for 2023 in light of the Supreme Court's decision and we urge the agency to ensure no further harm to hospitals by repaying 340B hospitals promptly for the money they are rightfully owed and not seek to recoup any funds from hospitals that were paid as part of a policy that the courts have now definitively rejected.

Prior Authorization for Fact Joint Interventions

CMS is proposing to add a new category – fact joint interventions – to the list of services that would require prior authorization with the goal to control "unnecessary increases" in volume of certain covered outpatient department services. ASH does not support additional services that require prior authorization and urges CMS to recognize that there will continue to be increases in all outpatient service categories as advances in medical technology and research allows for more procedures to be safely and successfully performed in the outpatient setting. This should not be the single motivating factor for CMS to institute new prior authorization requirements and obstruct patients' access to care. Prior authorization requirements often cause delays in patients' ability to receive timely, medically necessary care and impose additional administrative burden on providers.

As first line treatment options are exhausted, coupled with patient and provider reluctance to use prescription pain medications, facet joint injections under image guidance have become a valuable tool in diagnosing and treating chronic pain. Further, treatment of facet joint pain is a beneficial non-drug option. CMS 2021 claims data reveals facet joint interventions are used for patients with the diagnosis of drug therapy used to treat pain, including long term use of aspirin. While most healthy individuals can safely take pain relief medicines like nonsteroidal anti-inflammatory drugs such as ibuprofen and celecoxib, long-term use of some drugs can have significant side effects. This minimally invasive procedure can provide patients with pain relief for months after injection. ASH urges CMS not to finalize the proposal to require prior authorization for facet joint interventions because this option for safe and effective pain relief needs to remain readily available to patients.

Radiation Oncology

During the COVID-19 public health emergency, the relaxation of direct supervision requirements for the administration of radiation therapy was helpful. From a quality and patient safety perspective, however, ASH does not believe this flexibility should be retained when the public health emergency ends. In our view, radiation therapy should only be administered with a radiation oncology physician physically present at the time of its delivery.

* * *

ASH appreciates the opportunity to submit these comments and welcomes any questions you may have about them.

Sincerely,

Ellen J. Kugler, Esq.
Executive Director