



October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1736-P
P.O. Box 8016
Baltimore, MD 21244-8016

SUBMITTED VIA REGULATIONS.GOV

RE: Comments to Notice of Proposed Rulemaking entitled “Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Potential Revisions to the Laboratory Date of Service Policy; Proposed Overall Hospital Quality Start Rating Methodology for Public Release in CY 2021 and Subsequent Years; and Physician-owned hospitals.” (Vol. 85 Federal Register 48772, Aug. 12, 2020) (CMS-1736-P)

Dear Administrator Verma:

On behalf of the Arizona Hospital and Healthcare Association (AzHHA) and our more than 80 hospital, healthcare and affiliated health system members, thank you for the opportunity to provide input on the Centers for Medicare and Medicaid Services (CMS) Notice of Proposed Rulemaking regarding proposed changes to various aspects of the Medicare Program including the Hospital Outpatient Prospective Payment System (Vol. 85 Federal Register 48772, Aug. 12, 2020) (CMS-1736-P) (Proposed Rule).

AzHHA is Arizona’s largest statewide trade association for hospitals, health systems, and affiliated healthcare organizations. We represent short-term acute care, behavioral health, post-acute care, and critical access hospitals, as well as their affiliated clinics and staff. AzHHA is also contracted with the state of Arizona, the federal government, and private foundations to administer programs to improve quality of care, patient safety, and emergency preparedness. Our comments to the Proposed Rule are made in light of our commitment to ensure all Arizonans have access to quality, affordable healthcare.

Proposed Site-Neutral Payment Policies for Off-Campus Provider-Based Departments

The Bipartisan Budget Act of 2015 requires most services furnished in non-grandfathered off-campus provider-based departments (PBDs), except for dedicated emergency department services, to be paid under a payment system other than the Hospital Outpatient Prospective Payment System (OPPS).

In a previous rulemaking, CMS set payment for these services at 40% of the OPPS payment amount. CMS then expanded this payment methodology to hospital outpatient clinic visit services in grandfathered PBDs. For 2021, CMS is continuing these payment policies.

AzHHA and its membership believes that the continuation of these payment policies is threatening access to care, especially in rural and underserved communities where non-hospital based clinic services are not readily available. We are further concerned that the policies will undermine the ability of hospitals to adequately fund their 24/7 emergency standby capacity. Perhaps most significant, continuing the payment cut for grandfathered (excepted) clinic services undermines clear congressional intent and exceeds CMS's legal authority. As such, the American Hospital Association (AHA) is seeking a rehearing by the full U.S. Court of Appeals for the District of Columbia Circuit of the recent decision overturning a lower court's ruling in favor of AHA and plaintiff hospitals that invalidated the U.S. Department of Health and Human Service's (HHS) policy finalized in the CY 2019 rule to pay for clinic visit services in excepted PBDs at the "PFS-equivalent" payment rate of 40% of the OPPS payment amount.

Accordingly, we urge CMS to reverse the harmful policy of reducing payments for outpatient clinic visits in grandfathered PBDs.

Proposed Changes to Reimbursement for 340B Drugs

For over 25 years, the 340B program has helped hospitals to stretch scarce resources, provide access to care for more patients, and provide more comprehensive care to vulnerable communities. Pharmaceutical manufacturers participating in Medicaid agree to provide outpatient drugs to 340B entities at reduced prices. Covered entities include Disproportionate Share Hospitals, children's hospitals, and other safety-net providers.

Under Medicare, CMS generally reimburses separately-payable outpatient drugs and biologics based upon the Average Sales Price (ASP) of the drug/biologic as reported by its manufacturer plus 6%, regardless of whether the drug was purchased at a 340B discount price.

Based on the results of its Hospital Acquisition Cost Survey for 340B Acquired Specified Covered Drugs, CMS finalized a policy of reimbursing hospitals for separately-payable OPPS drugs at the

rate of ASP minus 22.5%. This has resulted in approximately \$1.6 billion in payment cuts.

In the Proposed Rule, CMS is proposing to pay certain 340B hospitals for drugs purchased through the 340B program at ASP minus 34.7%, plus the 6% add-on, resulting in a net payment of ASP minus 28.7%. This policy would further reduce payments for separately-payable OPPS drugs in the amount of \$427 million nationally in 2021.

AzHHA and its members oppose this proposed deepening of payment cuts for 340B drugs. These cuts would only serve to exacerbate the strain placed on hospitals serving vulnerable communities. The proposed cuts also conflict with Congress' intent for the 340B program. Finally, as this policy this would result in the continued loss of resources for 340B hospitals during a global pandemic.

AzHHA urges CMS not to finalize this proposal.

Proposed Changes to Inpatient-Only List

The Inpatient-Only List (IPO) specifies procedures and services that must be provided in an inpatient setting in order for a hospital to be reimbursed by Medicare. Services may be placed on the IPO List due to the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recover time or monitoring before the patient may be safely discharged. Currently, the IPO List includes approximately 1,740 services.

In the Proposed Rule, CMS would eliminate the IPO List over a period of three years, from 2021 through 2024. While AzHHA supports ensuring that the IPO List includes only those procedures that are inappropriate in an outpatient setting, AzHHA cannot support an arbitrary elimination of the entire IPO List. Eliminating the IPO List would compromise patient safety, increase administrative burdens for hospitals and physicians, and increase the financial burden for Medicare beneficiaries.

We are particularly concerned that this policy will result in increased admissions to hospitals from ambulatory surgery and other settings for procedures that result in complications that cannot be resolved in the ambulatory setting. This will cause additional financial hardship on patients and potentially expose them to longer lengths of stays. It is also unclear what impact this change will have on the recovery audit contractor process. Under the proposal, hospitals face additional exposure for procedures coming of the IPO List.

For these reasons, we strongly oppose elimination of the IPO List.

Proposed Changes to the Level of Supervision of Outpatient Therapeutic Services

The Proposed Rule would change, effective Jan. 1, 2021, the minimum level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services CMS would define direct supervision to include the virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. CMS clarifies that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. CMS adopted both of these changes in an interim final rule published March 31, 2020 for the duration of the current public health emergency. The proposed rule makes the changes permanent.

AzHHA has long supported easing requirements for direct physician supervision of therapeutic services that have a low risk of complication after initial patient assessment. We appreciate all the previous changes that CMS has made to ease direct supervision requirements, especially for rural hospitals, which face acute medical staffing shortages.

As such, AzHHA strongly supports CMS' proposal of making this policy permanent going forward.

Prior Authorization

CMS proposes to require prior authorization for an additional 2 categories of services: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. These services are often provided to give patients relief from chronic intractable pain.

The Social Security Act requires HHS to ensure that that OPPI reimbursements do not financially incentivize the use of opioids rather than non-opioid alternatives. AzHHA is concerned that CMS's proposed prior authorization requirements would be inconsistent with that mandate. Prior authorization requirements could significantly delay the provision of these services, leading to the patient taking opioids to control the pain.

Because prior authorization for these procedures would seem to incentivize the taking of opioids instead of non-opioid alternatives, AzHHA cannot support this proposal.

Hospital Star Ratings

CMS proposes making substantial changes to the hospital star ratings methodology in the Proposed Rule. As longstanding supporters of transparency, Arizona's hospitals believe that patients, families and communities should have valid, clear and meaningful quality information to help them make important health care decisions. Accordingly, AzHHA and our members generally support addressing the substantial flaws in the current star ratings methodology and commend CMS for proposing changes that attempt to address these flaws. Specifically, we concur with the AHA's concurrent, detailed comments on the specific methodology changes proposed by CMS.

Our support for many of CMS's proposed changes notwithstanding, we continue to question the basic concept of a single, overall rating of hospital performance. The measures included in the ratings were never intended to create a single, representative score of hospital quality. Furthermore, the ratings often do not reflect the aspects of care most relevant to a particular patient's needs. For example, a family may be interested in selecting the best hospital for cancer care, but there is only one such measures included in the current star ratings. In addition, there is vast variation in the type, scope and mix of services that hospitals provide.

For those reasons, we continue to encourage CMS to consider developing an alternative approach in which star ratings are done only by topic area such as patient safety, patient experience of care and cardiac care. This approach may increase the relevancy of ratings information to consumers and lessen the possibility of consumers receiving misleading information about quality.

Thank you for the opportunity to comment on the Proposed Rule. The health and well-being of our state and our nation is our top priority, and we look forward to continuing to work with you to serve that goal.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ann-Marie Alameddini".

Ann-Marie Alameddin
President and Chief Executive Officer
Arizona Hospital and Healthcare Association