September 10, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

RE: CMS-1693-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

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 offer comments on the Centers for Medicare & Medicaid Services (CMS) Proposed Rule for the CY 2019 Medicare Physician Fee Schedule (PFS). Our comments center on three proposals:

1. The collapse of evaluation and management (E/M) payment rates and corresponding documentation changes;
2. Modifications to the appropriate use criteria program; and
3. Payment reductions for new drugs before average sale price data is available.

We are particularly concerned about the proposal to collapse payment rates for level 2 through 5 outpatient and office E/M visits into a single blended rate. While we deeply appreciate CMS’s sincere belief that this change would reduce the burden of documenting E/M visits and the need for audits based on the level of E/M visit billed, we believe there are a number of unanswered questions and potential unintended consequences that would result from the coding policies in the proposed rule. Specifically, we fear it could hurt physicians and other health care professionals in specialties that treat the sickest patients, as well as those who provide comprehensive primary care, ultimately jeopardizing patients’ access to care. **As such, we oppose finalization of the proposal at this time.** Instead, we believe CMS should further engage physicians and other health professionals with expertise in defining and valuing codes, and who also use the office visit codes to describe and bill for services provided to Medicare patients.

Our more detailed comments follow.
E/M PAYMENT AND DOCUMENTATION CHANGES

Under the existing coding structure, providers may use either 1995 or 1997 E/M documentation guidelines to code and bill one of the five levels of E/M visit codes. The codes are comprised of three key components: (1) history of present illness; (2) physical exam; and medical decision making. If counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter, providers can use the duration of the visit to select the appropriate E/M level. The medical community for many years has expressed concern that these E/M documentation guidelines are burdensome and outdated.

CMS has responded to these concerns in the proposed rule by including several proposals to modernize the documentation and coding requirements and reduce their complexity, administrative burden, and payment variability. AzHHA very much appreciates the Agency’s attention to the challenge that the E/M coding process presents to physicians and other stakeholders involved in the Medicare coding and billing process. However, as mentioned above and detailed below, we believe that the inclusion of the rate collapse with these documentation and coding changes will have a detrimental effect on certain specialties, service providers, and by extension Medicare beneficiaries.

The rule proposes to pay a single blended rate for the level 2 through 5 E/M visits for established patients and separate blended rate for new patients. As a corollary to this proposal, CMS proposes to require providers to meet only those documentation requirements currently associated with a level 2 E/M visit, subject to some exceptions. (CMS indicates that providers may continue to choose and report the level of E/M visit they believe to be appropriate.)

Collapsing four rate tiers into one tier essentially eliminates the role of coding by disconnecting fees from the resources needed to provide the service—potentially violating the statutory requirement that fees should be based on the relative resources used to provide each service approved for payment. Payment is the same whether the physician takes ten minutes to treat a patient with a sore throat and no other symptoms or 35 minutes to treat a patient with multiple serious chronic conditions, who is taking multiple medications, and presenting to the physician with recent onset of disorientation and unsteadiness. The proposal simply incorporates too wide a range of patient severity into a single rate, rather than taking into account the knowledge, time and risk associated with caring for the sickest patients.

Specialists such as geriatricians, neurologists, endocrinologists and rheumatologists must spend more time during office visits to evaluate and treat their different patient populations. The same holds for many oncologists and primary care practitioners who treat patients with multiple chronic illnesses. These providers will be disadvantaged by the proposal.

The proposed rule attempts to mitigate this disadvantage and the potential payment instability that results by creating several HCPCS G-code add-ons for specified specialties. However, our members tell us that these add-on codes are not sufficient enough to make up for the proposed decrease in payment rates for level 4 and 5 visits and to ensure continued access to care for the
sickest Medicare beneficiaries. Moreover, these add-on codes will add back complexity to the coding and billing system that CMS is attempting to address.

Our greatest concern is the perverse financial incentives created by the proposed rule. While professionalism would dictate that a physician would not change his or her practice based on changes in payment rates, it simply not financially sustainable for a physician to continue to spend 30 or 35 minutes with a complex patient when the payment rate is reduced by one-third or more. This will undoubtably impact quality of care because such time is often needed to evaluate and treat complex patients. Loss in per-visit revenue will incentivize volume, potentially requiring patients to return for multiple visits, increasing inconvenience and copays for Medicare beneficiaries. At the extreme end, we would expect some physicians to discontinue taking on new Medicare patients—further compounding access to care challenges.

Unfortunately, at the end of the day, the proposed rule may have little impact on the documentation burden that physician practices face. Because the proposal only affects CMS and Medicare claims and does not align with the CPT 4th edition code set, providers will continue to report codes as currently required for levels 1 though 5 for new and established patients, but for Medicare claims would submit these under one of two reimbursement levels. The limited documentation allowed for Medicare under the proposed rule would not support billing requirements for commercial payers. While commercial insurers will be free to follow CMS’s lead, there is no reason to believe they necessarily will. And, it is inconceivable to think all commercial payers would be able to make these types of changes by January 1, 2019—the effective date of the proposed rule. The result would be two separate documentation guidelines—one for Medicare and one for non-Medicare payers. This would create an operational nightmare for providers and undermine the intent of simplifying the documentation process.

In addition, reducing medical record documentation to the standard allowed under the proposed rule could have significant legal implications. If documentation is limited to time spent—with little additional clinical content—as allowed under the proposed rule, the treating physician and practice risks legal exposure. The core defense in medical malpractice cases is often based on provider notes in the medical record. Without these notes, defending an action is extremely difficult. While “note bloat” has become a significant burden for physicians, the proposed rule will not eliminate the medical-legal need to document certain additional information in the medical record beyond “time spent.”

Such documentation is also necessary to provide a more complete clinical picture of the patient. History of the present illness and diagnostic notes are critical to providing support for prescribed treatment plans. Documenting these is particularly necessary for patients who suffer from chronic illnesses and whose care is coordinated among multiple providers.

We also believe CMS may have underestimated the impact of the blended rate across specialties. While the table published in the proposed rule finds little variation in revenues across specialties, an analysis by the American Medical Association finds substantial variation. **We urge CMS to re-evaluate their estimate of the impact.**
Finally, our members are concerned about the proposed change to Modifier 25, which would reduce payment by 50 percent for the least expensive global procedure or visit that the same physician (or physician within the same group practice) furnishes on the same day as a separately identifiable E/M visit. We understand that it is CMS’s longstanding policy to reduce payment by 50 percent for the second and subsequent service furnished to the same patient by the same physician on the same day. However, the issue of multiple services on the same day of service was factored into prior valuations of the affected codes. The proposal also has significant impact on certain services, including chemotherapy, that may be an unintended consequence of changing the current practice expense methodology to accommodate the proposal.

With these concerns in mind, we urge CMS to not finalize the proposal to collapse the payment rates for levels 2 through 5 E/M visits and to require only the documentation necessary for a level 2 visit. While we appreciate CMS’s efforts to free providers from requirements to produce repetitive documentation, we do not believe the Agency has provided sufficient policy justification and data analysis to support the proposed approach. Instead, CMS should further engage physicians and other health professionals with expertise in defining and valuing codes, and who also use the office visit codes to describe and bill for services provided to Medicare patients, on alternative policy options that would truly reduce documentation burden, while fairly compensating providers for their time.

Having said this, the proposed rule does include a number of proposals that would reduce the administrative burden associated with excessive E/M documentation requirements, and which could be decoupled from the proposed E/M payment collapse. These proposals would help streamline documentation requirements, improve workflow, and reduce “note bloat.” We urge CMS to adopt that the following proposals included in the proposed rule:

1. Changing the required documentation of the patient’s history to focus only on the interval history since the previous visit;

2. Eliminating the requirement for physicians to re-document information that has already been documented in the patient’s record by practice staff or by the patient; and

3. Removing the need to justify providing a home visit instead of an office visit.

APPROPRIATE USE CRITERIA (AUC) FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

The Protecting Access to Medicare Act of 2014 requires CMS to establish a program promoting the use of AUC for advanced diagnostic imaging that integrates AUC into the clinical workflow. Beginning Jan. 1, 2017 payment may be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable AUC.
CMS took initial steps to implement the AUC program in the CY 2016 PFS rule by defining AUC and specifying the process for developing them. These initial procedures were refined in the CY 2017 and CY 2018 PFS rules, with CMS adopting a voluntary period from July 2018 to December 2019 for early adopters of AUC to report limited consultation information on Medicare claims forms. CMS also finalized a delayed start date of Jan. 1, 2020 for AUC consultation and reporting requirements, but determined that 2020 will be an “educational and operations testing year,” during which CMS will pay claims regardless of whether they contain information on the required AUC consultation.

Section 1834(q)(4)(B) of the Social Security Act requires that payment for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system may only be made if the claim for the service includes certain information about the AUC consultation. CMS specified in the CY 2018 PFS final rule that this requirement applied only to “furnishing professionals.” However, CMS is now proposing to require AUC consultation information to be reported on all claims – from both furnishing professionals and facilities – paid under applicable payment systems. **AzHHA opposes this proposal because it increases the regulatory burden on furnishing facilities while not targeting the outlier ordering professionals that are the source of the problem and for whom the AUC program is designed to apply.**

The proposed AUC requirements will introduce new data-reporting variables into the flow of information needed for hospital billing, which will be extremely difficult to capture given the variety of pathways through which hospitals receive data-reporting information. It will require major system and operational changes at a high cost of compliance for a program that aims to regulate ordering professionals who practice outside of the institution’s control—-institutions that are already required to demonstrate the medical necessity of the services they provide.

Moreover, due to the wide range of physicians’ levels of system capability, hospitals and health systems would likely be left to manually input AUC information. And, even if hospitals and health systems devise a system by which to capture AUC information, they have no way to report it. The electronic claim standard for institutional providers does not capture or have a placeholder for reporting the ordering physician’s national provider identifier. Even if the electronic institutional claim is modified, hospitals and health systems would still need to make large-scale and costly changes to interface with the modified claim standard.

The AUC program was intended to evaluate physicians who order advanced diagnostic imaging services, not hospitals and health systems. By shifting the burden of compliance to

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1 CMS has applied this policy when applicable imaging services are provided in specific settings – a physician’s office, hospital outpatient department (including an ED), an ambulatory surgical center, and any other provider-led outpatient setting as determined by CMS. In CY 2019 proposed rule, CMS proposes to add independent diagnosing testing facilities to the list of applicable settings to which AUC consultation and reporting requirements apply.
furnishing providers, the proposal could force hospitals and health systems to take dollars away from patient care. The proposal does not address the 5 percent of outlier ordering professionals whom the AUC program was intended to target, as it bears no connection to the physicians actually required to consult CDSMs. Congress intended the AUC program to serve as a way to educate physicians on the criteria they should follow for ordering advanced imaging. Yet this proposal does nothing to improve education nor dissuade bad actors from easily bypassing what the AUC rules intend. Ordering professionals could still simply select the code that indicates they consulted with the CDSM and automatically assign the coding for an advanced imaging order without altering their behavior or providing real proof of adherence to AUC requirements.

For these reasons, AzHHA recommends that furnishing facilities (hospitals and health systems) be exempt from reporting AUC requirements. We also recommend that CMS consider alternative methods of implementing this proposal that do not require reporting by furnishing professionals or facilities. For example, CMS could

- Modify the Merit-based Incentive Payment System quality score for ordering professionals to include a requirement that they demonstrate their use of CDSM tools, incentivizing providers to invest in CDSM tools, or
- Require a yearly attestation by ordering professionals that they consult CDSMs.

At a minimum, we urge CMS to include clear instructions in the final rule and in the Medicare Manuals that it is the responsibility of ordering professionals to include the necessary information on their orders. We further urge CMS to delay the Jan. 1, 2020 AUC implementation date to allow time for the Agency to determine and implement a methodology to identify outlier ordering professionals.

**PAYMENT FOR PART B DRUGS BEFORE AVERAGE SALE PRICE DATA IS AVAILABLE**

Currently, Medicare reimburses new Part B drugs for which average sales price (ASP) price data is unavailable during the first quarter of sales at the rate of 106 percent of wholesale acquisition cost (WAC). The WAC is the manufacturer’s list price and does not incorporate prompt-pay or other discounts. CMS proposes to reduce payment for certain new Part B drugs and biologicals from the rate of 106 percent of WAC to 103 percent of WAC. Specifically, the proposed reduction would apply to drugs and biologicals where ASP price data is unavailable during the first quarter of sales and in circumstances when Medicare Administrative Contractors (MAC) determine pricing for new drugs that do not appear on the ASP pricing files. CMS states that this proposal is consistent with a recommendation included in the fiscal year 2019 President’s Budget Proposal and the Medicare Payment Advisory Commission’s (MedPAC) June 2017 Report to Congress.

AzHHA opposes this approach because it would unfairly shift the burden for the high list prices imposed by drug manufacturers onto hospitals and physicians. Further, with the Medicare two percent sequestration still in effect, payment for drugs and biologicals would effectively be reduced by far more than proposed by CMS. We are concerned that
such a significant reduction in payment could negatively impact the ability of some providers to afford these new WAC-priced drugs. It also would not account for the growing pharmacy overhead costs, including drug handling and storage costs, that the WAC add-on percentage was intended to cover.

Finally, we note that MedPAC proposed this WAC policy as part of a larger package of Part B drug recommendations, including a recommendation for improving ASP data reporting. Currently only drug manufacturers with Medicaid rebate agreements are required to report their ASP data and some manufacturers required to report ASP data fail to do so in a timely manner. The Commission’s June 2017 report proposed a policy to require all Part B drug manufacturers to report ASP data and give the Secretary the authority to apply penalties to manufacturers who do not report required data. AzHHA supports efforts to improve ASP data reporting by manufacturers and encourages CMS to pursue this approach in order to ensure that timely and accurate ASP data is available for rate setting.

Thank you again for the opportunity to comment on the proposed CY 2019 PFS rule. Please feel to contact be at 602-445-4300 or djohnston@azhha.org if you have any questions.

Sincerely,

Debbie Johnston
Senior Vice President, Policy Development