AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

September 27, 2019

VIA ELECTRONIC MAIL

regulations.gov

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1715-P, CY 2020 Physician Fee Schedule (PFS) Notice of Proposed Rulemaking

Dear Ms. Verma:

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Calendar Year (CY) 2020 Physician Fee Schedule (PFS) proposed rule. Our organization is the policy voice of five Seventh-day Adventist affiliated health systems that include 89 hospitals and more than 300 other health care facilities in 15 states.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. Due to the difference among our hospitals and their geographic locations, our comments provide an objective and sound policy voice that work for health care as a whole.

Specifically, we offer comment to CMS on the following issue areas within the PFS proposed rule:

- Evaluation and Management (E/M) Payments
- Merit-based Incentive Payment System (MIPS)
- MIPS Value Pathways (MVPs)
- Review and Verification of Medical Record Documentation
- Medicare Coverage and Bundled Episode of Care for Opioid Use Disorders (OUD)
- Care Management
- Medicare Shared Savings Program (MSSP)
- Advanced Alternative Payment Models (APMs)
- Stark (Self-Referral Law) Advisory Opinion Process

Evaluation and Management (E/M) Payments

In the CY 2019 PFS rule, CMS finalized a proposal to collapse E/M office visit levels two through four into one. Beginning in CY 2021, this new level will receive a single blended payment rate if the proposal explained below is not finalized. CMS noted that this policy would help reduce provider administrative burden by removing certain documentation requirements needed to bill for different E/M levels. However, in the comment period and after the CY 2019 PFS rule was finalized, CMS received feedback that this policy could inappropriately incentivize multiple, shorter visits for less complex patients.

In response to stakeholder feedback, CMS now proposes to again change its policy on E/M office visits and replace it with a new reimbursement method. The new proposal would retain the original five E/M levels of coding for established patients and remove the first level only for new patients, as that coding level is determined by histories and exams. Instead of a blended payment rate, CMS proposes to adopt a new payment rate that would be assigned to new CPT add-on codes (99202-99215 or 99XXX) for E/M office visits levels one through five. These new codes would allow clinicians to choose the E/M visit level based on time or medical decision-making. The use of histories and exams, which are currently used to determine the E/M coding level, would only be required if medically necessary. Additionally, new code descriptors, prefatory language and an interpretive guidance framework (issued by the Joint American Medical Association (AMA) Current Procedural Terminology (CPT) Workgroup) would be adopted. These changes would be implemented on January 1, 2021.

AHPA supports the proposal for the new E/M visit payment modifications. However, we are concerned of the potential impact this policy would have on certain specialties. According to CMS' analysis, the proposal will have a negative impact on certain specialists, such as ophthalmologists, and positively impact primary care physicians. While we support increased payments for primary care, we urge CMS to proceed with caution so that the reduced payments to specialists do not jeopardize access to care.

Merit-Based Incentive Payment System (MIPS)

Changes to the Cost Category

In accordance with the Bipartisan Budget Act of 2018, CMS proposes to incrementally reduce the weight of the quality performance category and increase the weight of the cost performance category under MIPS. The weight of the quality category would *decrease* by 5 percent each year until it reaches 30

percent in 2022. Starting in 2022, the cost category would *increase* by 5 percent each year until it reaches 30 percent in 2024.

AHPA does *not* support increasing the weight of the cost category by 5 percent. Before increasing the weight of this category, we recommend that the comparative data that CMS provides to all MIPS participants include more granular cost and utilization data. Although we understand that this is a mandate, providers have not received the information that is necessary for them to improve the cost measures. Currently, CMS' feedback reports do not include enough detail to inform providers about the interventions they should take to improve their quality scores. Sharing granular cost and utilization data within the feedback reports would give providers more insight about their performance.

CMS also proposes to add 10 condition and treatment-specific episode measures to the cost category. **We urge the Agency to consider that these measures may not generate enough reporting volume at the Tax Identification Number (TIN) level, which would affect their validity.** While AHPA supports CMS' efforts to improve the cost category, specialized measures with low reporting volume may impact providers' ability to meet the benchmarking criteria. **Due to this same validity issue, we also support CMS' proposal to modify the removal criteria of quality measures to include measures that do not meet the case minimum or reporting volume for two years. Additionally, we support CMS' inclusion of measures not available to all clinicians in the removing criteria of measures.**

Data Completeness Threshold

CMS proposes to raise the data completeness threshold from 60 percent to 70 percent in CY 2020. As stated in the CY 2018 Quality Payment Program final rule, CMS anticipated increasing the data completeness thresholds to increase the accuracy of clinicians' performance assessments. The incremental increases in the threshold would allow for individual MIPS eligible clinicians and groups to gain experience with the MIPS program.

AHPA believes that increasing the data completeness requirement to 70 percent would be difficult for health systems to reach. CMS states in the rule that the proposed 70 percent data completeness rate is lower than the average data completeness rate for individual clinicians, groups and small practices. However, these averages do not consider the rates of large health systems whose affiliated clinicians may use different Electronic Medical Records (EMRs). When clinicians affiliated to a health care system report together but use different EMRs, it becomes difficult to extract the data from different systems and aggregate it for reporting. **If CMS increases the data completeness threshold, we recommend that**

CMS make an exception for health systems due to the interoperability issues that they may face when aggregating data from different EMRs.

Opioid Treatment Agreement Measure

CMS proposes to remove the verification of the Opioid Treatment Agreement measure in the Promoting Interoperability (PI) program. Since its introduction in the CY 2019 PFS final rule, CMS has received feedback that this measure presents significant implementation challenges and does not further interoperability.

While AHPA commends CMS for its efforts to address the opioid crisis through the inclusion of the Opioid Treatment Agreement measure in the PI program, we support its removal. Since the definition of an Opioid Treatment Agreement varies widely between states and providers, the opioid treatment agreement measure has proven to be vague and duplicative, therefore resulting in increased administrative burden. As currently defined, the measure offers little clinical value to health care providers. For example, Opioid Treatment Agreements are not required to be created or maintained in a standardized, electronic format and ascertaining the legitimacy of paper agreements is often difficult. For these reasons, this measure should not be included in the PI program.

New Specialty Measures Sets

CMS proposes to add seven new specialty measures sets: Endocrinology, Nutrition/Dietician, Pulmonology, Chiropractic Medicine, Clinical Social Work, Audiology and Speech Language Pathology. The proposal to add these measure sets is due to CMS expanding the definition of the MIPS eligible clinician, which now includes physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals.

While we agree that the definition of the MIPS eligible clinician should be expanded, and that this should correspond with the inclusion of relative specialty measure sets, we are concerned about their proposed mandatory participation in MIPS. To participate in MIPS and report quality measures, clinicians must comply with a variety of requirements, such as using a certified EMR. Many of the newly eligible clinicians added in 2019 may find it difficult to meet the requirements of MIPS because they are often not in a group practice and do not have the resources to make the needed technology investments. Due to this reason, we urge the Agency to consider reclassifying the seven new eligible clinicians as "opt-in" eligible clinicians. We believe that the benefit of mandatory reporting does not outweigh the cost imposed on these clinicians to comply with the MIPS requirements.

MIPS Value Pathways (MVPs)

CMS proposes to transform the MIPS program by creating MIPS Value Pathways (MVPs). MVPs would create "bundles" or "tracks" that would allow clinicians to report fewer quality measures under the current MIPS framework. MVPs would connect measures and activities from the four MIPS performance categories into smaller, specialty-specific, outcome-based measure sets. CMS intends for this program to simplify MIPS and alleviate administrative burden by streamlining the measures being reported. Additionally, CMS anticipates that MVP participants would receive prompter feedback and more data in the reports that the Agency provides.

AHPA commends CMS for trying to reduce the administrative burden placed on providers. We believe that this proposal would be beneficial to small provider groups and specialties reporting under the MIPS program. **However, AHPA recommends that CMS make the MVPs optional instead of mandatory as their adoption would be significantly burdensome for large health systems with provider groups of different specialties.** For health systems, having the same reporting requirements simplifies reporting on behalf of all eligible clinicians, and MVP tracks would introduce more variability into the process. If specialists were mandated to participate in different MVP tracks, it would increase the reporting burden that health systems would face despite the reduced number of measures being reported. Therefore, the MVPs should be an option that individual and specialty providers can choose, but not replace the MIPS program.

AHPA further recommends that CMS first implement the MVPs as a pilot program to determine how successful participants can be in this model. Testing the MVPs would help inform the development of different pathways and evaluate the administrative burden the change may have on providers.

Review and Verification of Medical Record Documentation

CMS proposes allowing physicians, physician assistants and advanced practice registered nurses to verify, with a date and signature, medical information recorded by residents, nurses, students or other medical team members. This policy departs from the current practice, which requires providers to redocument the medical information. Under the proposal, the provider must still be present and participate in the medical services, and this participation must be reflected in the medical documentation.

AHPA supports the proposal to allow verification, rather than redocumentation of medical records. AHPA supports CMS' position that the verifying provider must still be present and involved in the services and that allowing verification should not influence the minimum documentation needed to justify medical necessity. This proposal would decrease provider burden and allow for additional time to be spent on patient care.

Medicare Coverage and Bundled Episode of Care for Opioid Use Disorders (OUDs)

In accordance with the SUPPORT Act, which established a new Medicare Part B benefit category for OUD treatment, CMS proposes new regulations for coverage and payment for services in Opioid Treatment Programs (OTPs). CMS also proposes to establish bundled payments for the overall treatment of OUDs, including management, care coordination, psychotherapy and counseling activities. In addition to the creation of a bundled payment, CMS seeks comments on patient stratification, Medicaid cost-sharing and coverage for Medication Assisted Treatment (MAT).

AHPA commends CMS for considering the unique needs of patients with OUD and the providers who assist them in accessing treatment. AHPA supports the creation of a bundled episode of care for the treatment of OUDs. However, in order to capture the needs of diverse patient populations and improve the effectiveness of such bundle, we offer the following recommendations:

1) **Create a separately billable code specific to pregnant women with OUDs.** Treatment for OUD among this population tends to be significantly more complex and involves additional resources beyond the episode of care described by the base code. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) endorses pharmacotherapy for treatment of OUD during pregnancy, since MAT outweighs the risk of continued opioid use to the mother and child.[1] SAMHSA also identifies peer support and patient education focused on the specific needs of pregnant women as interventions for mothers presenting with OUD. Furthermore, for this patient population, a stratification may be appropriate if CMS finalizes the proposal to treat OUD with MAT in the emergency department as a separately payable service.

[1] SAMHSA, Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants (2018).

2) **Provide guidance on codes used for polypharmacy.** While the proposed rule offers codes specific to OUD, in practice, it can be difficult to distinguish which addiction-related issues are specific to opioids as opposed to a non-opioid drug. Preliminary research has indicated that 7.5 percent of adolescents engage in polysubstance abuse[2] and that 7.8 percent of adults use two or more illegal drugs annually.[3] AHPA recommends that if, during an initiating visit for a non-opioid substance use disorder, it is also discovered that a patient has an OUD, that visit suffice as an initiating visit for the OUD bundle.

3) **Provide higher payments for patients with more complex needs who require more intensive services and time to treat.** This could be done by risk-adjusting payments to account for factors such as the presence of multiple comorbidities or the complexity of treating more complex populations, such as pregnant women**.** As noted by CMS, the Agency could also provide separately billable codes to describe additional resources involved in furnishing OUD treatment services.

4) **Adopt a method to evaluate the efficacy of the proposed changes and identify any adverse consequences.** It would be prudent for CMS to assess the outcomes of the proposals since it is unclear whether there may be unintended results based on these changes. We believe these bundled payments would be applicable for the treatment of a potentially high number of patients; however, we also anticipate that the actual number of patients who undergo comprehensive services is likely to be reduced by acquisition barriers and recidivism. For these reasons, AHPA encourages continuous evaluation and improvement of the proposed bundled payments.

Care Management

Non-Complex Care Management

CMS proposes to adopt two new HCPCS G-codes to describe additional time spent performing non-complex chronic care management:

- GCCC1 would capture the initial 20-minutes of clinical staff time directed by a physician or other qualified health care professional for chronic care management services.

[2] Conway, K., et al., Prevalence and Patterns of Polysubstance Use in a Nationally Representative Sample of 10th Graders in the United States (2013).
[3] Han, B., et al., Medical Multimorbidity and Drug Use Among Adults in the United States (2018).

- GCCC2 would capture each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional for chronic care management services. CMS seeks comments on whether they should limit the number of times this add-on code can be reported in a given service period for a beneficiary.

AHPA supports the addition of these two codes as we believe they would help to better capture time spent with patients on care management. We recommend that CMS allow for GCCC1 to be billed once a calendar month and for GCCC2 to be billed up to three times in the same billing month. This would allow the health care professional to spend telephonic time with the beneficiary reviewing the care plan and putting into place specific personalized goals and tasks to help the beneficiary. Many beneficiaries experience multiple issues, such as socioeconomic or behavioral issues, that significantly impact treatment and patient outcomes. It often takes multiple people from the clinical team to work with the beneficiary to identify those issues and provide potential solutions. Identifying the root cause of a beneficiary's issues can require multiple communication touch points with the patient across the course of treatment. Additionally, medication reconciliation and review are one of the major requirements for chronic care management and this alone can take up to 30 minutes a month if there are multiple medications that need to be reviewed. Limiting the billing of HCPCS code GCCC2 to only once a month would impede the ability of providers to identify and support the socioeconomic needs (e.g. food security, transportation assistance) of non-complex beneficiaries.

Principle Care Management (PCM) Services

CMS proposes to adopt new coding (HCPCS codes GPPP1 and GPPP2) and payment for PCM services. This includes care management services for a single, serious chronic condition. Patients would be eligible for PCM services if they have only one chronic condition that is expected to last between three months and a year or until the death of the patient. It would involve a condition that had led to a recent hospitalization and/or places the patient at significant risk of death, acute exacerbation/decompensation or functional decline.

AHPA supports the adoption of these codes as they would assist in providing appropriate care management to individuals with chronic conditions. To improve the utilization of these codes, we recommend limiting the documentation requirements to only include the patient's care plan. Additionally, the provision of Open Door Forums and guidance on the use of these codes would help to educate providers and encourage their use.

Medicare Shared Savings Program (MSSP)

To ensure the quality of care for assigned patients, the MSSP program currently consists of 23 measures across four domains that participants must report on. Accountable Care Organizations (ACOs) must meet a quality performance standard to qualify for shared savings. In the CY 2020 PFS proposed rule, CMS recommends the following changes to the current measure set:

- Remove the ACO 14 – Preventive Care and Screening Influenza Vaccination quality measure.
- Add the ACO 47 – Adult Immunization Status quality measure.
- Revert the ACO 17 – Adult Immunization Status and ACO 43 – Ambulatory Sensitive Condition Acute Composite quality measures to pay-for-reporting.

AHPA believes that the proposed changes will have a minimal impact on reporting quality measures. For this reason, we support the above proposed changes.

CMS also seeks input on how the MSSP quality scoring approach can be aligned with the MIPS quality category. CMS believes that the different methodologies in the two programs create potential conflicts for MIPS eligible clinicians participating in an ACO. For example, ACOs are allocated up to two points for quality measures according to where their performance falls relative to the benchmark. In contrast, each MIPS quality performance measure can receive three to 10 points depending on how it compares to established benchmarks. Due to the differences in the programs' quality measure sets, clinicians can achieve very different scores. This strains provider resources as participants must decide which methodology to use and prioritize in order to maximize their performance. For this reason, CMS proposes to replace the MSSP quality score with the MIPS quality performance category score. It also proposes to simplify MIPS by implementing a core measure set and seeks comment on how the MIPS quality score can be used to adjust the shared savings and losses under MSSP.

AHPA commends CMS for trying to streamline the MSSP and MIPS programs to help alleviate the administrative burden placed on clinicians. **AHPA recommends that the proposals have optional participation for providers.** For example, allowing participants to choose to report MIPS for an ACO measure set would help increase flexibility. This is especially true for large health systems with multiple groups participating in different programs, such as the MSSP.

AHPA also supports creating a streamlined core measure set for the MIPS program. However, changing measure sets or measure reporting processes requires EMR vendors to quickly implement the changes. Historically, some hospitals and providers have struggled with their EMR vendors making the changes necessary for quality reporting. **For this reason, AHPA recommends that CMS provide resources and support to EMR vendors to update their systems when there is a regulatory change.** This would help make changes to programs, such as MIPS, less resource intensive for eligible clinicians.

Alternative Payment Models (APMs)

Current policy excludes Partial Qualified Participants (QPs) from the MIPS reporting requirements, which prevents some eligible clinicians from receiving a positive payment adjustment for an APM. Beginning with the 2020 Qualified Participants (QP) performance period, CMS proposes to determine QP status through only the TIN/ National Provider Identifier (NPI) combinations through which a clinician attains QP status, rather than across all a clinicians' TIN/NPI combinations. Additionally, CMS proposes to modify the evaluation for marginal risk for other payer arrangements by basing the calculation on *average* marginal risk rather than the *lowest* marginal risk.

AHPA supports the proposal to modify how QP status is determined because we believe it would expand payment incentives to more clinicians. As a result, the expanded incentives would likely increase the participation in APMs. AHPA also supports the change for the evaluation of the marginal risk rate. We believe that this change would help protect participants from potentially catastrophic losses and undue financial burden that may arise from market factors.

Self-Referral Law (Stark) Advisory Opinion (AO) Process

CMS proposes modifying the Stark AO process and guidelines in order to improve such process and make it more accessible to stakeholders. CMS proposes changes to the formal bases of rejection for AO review, the types of entities that can rely on a favorable advisory opinion, and the imposition of sanctions. These substantive changes are accompanied by technical modifications to fees and timelines for issuing opinions. CMS also seeks input on a longer-term proposal to consider hypothetical fact patterns for Stark AO review.

AHPA commends CMS for its proposed approach to modernizing and making the Stark AO process more useful to providers and health systems. We believe that adopting many of these proposals will facilitate a better understanding of how to comply with the complex provisions of Stark

law. We support finalizing the proposals in this section of the rule to the extent that they are part of a broader strategy to expand the types of AOs CMS reviews.

More Flexibility for CMS to Consider Advisory Opinion Requests

CMS proposes that it may reject AO requests if, after consultation with both OIG and DOJ, the course of action is the same or substantially the same as a current investigation or proceeding involving a governmental entity and that such an opinion would interfere with the investigation or proceeding. CMS believes that the current regulation is too restrictive and unnecessarily limits CMS' flexibility to issue timely guidance to requestors engaged in or considering legitimate business arrangements. Currently, CMS only requires that the course of action be the same or substantially the same as a matter under investigation or a proceeding involving a government entity in order to issue a rejection.

While we appreciate CMS' attempt to further limit the bases under which it can issue a denial of a request under 42 C.F.R. § 411.370(e)(2), AHPA encourages CMS to further relax the regulations to fulfill the intent of the AO process. Stark violations can involve lengthy investigations and litigation, precluding other parties seeking guidance from receiving timely AOs that could prevent further violations. By maintaining this degree of discretion, it remains unlikely that the Agency will issue more AOs.

Hypothetical Fact Patterns

Currently, CMS rejects AO requests that present a general question of interpretation, pose a hypothetical situation or involve the activities of third parties. CMS seeks comments on whether the Agency should expand the AO process to include hypothetical fact patterns or general questions about interpretation.

Given the strict liability of the Stark statute, AHPA strongly supports expanding the AO process to address hypothetical fact patterns and issues of interpretation. This change would recognize that the Stark Law and the Anti-Kickback Statute (AKS) are different. The Stark Law is a payment statute and the AKS is a criminal statute. While it is understandable that the OIG does not want to provide guidance on hypothetical situations related to enforcement of a criminal law, CMS does not have the same justification regarding the payment statute. Providing AOs for Stark Law hypothetical questions will provide needed clarification for providers. We also believe that this would help reduce confusion as well as the administrative burden placed on health providers trying to navigate the complexity of Stark law. If CMS is concerned that this change could significantly increase the volume of AO requests, the Agency could institute guardrails, such as imposing additional fee requirements, for the review of AO requests.

Additionally, CMS clarifies that an AO must "relate to" rather than "involve" an existing relationship. **AHPA supports this clarification as it would incrementally increase the breadth of acceptable AO requests, which would improve the utility of the AO process.**

Timeline for Issuing AOs

CMS proposes to shorten the existing 90-day timeframe for issuing AOs to a 60-day timeframe. CMS is also considering an expedited pathway for requestors that seek an AO within 30 days of the request, for which the requester would be charged $440 an hour to process the request.

Given how quickly major business transactions can occur in today's health care landscape, AHPA supports the shortening of the review period for AO requests. We also encourage the adoption of a 30-day expedited process to review AO requests, as this would be a reasonable option for providers wanting an AO within an abbreviated timeframe.

Individuals Who Can Rely on AOs

CMS proposes to modify the current regulation at 42 C.F.R. § 411.387(a) to 1) make a favorable AO binding on the Secretary and 2) expressly allow requesting parties, as well as individuals and entities party to the arrangement under consideration, to rely on the opinion. Under current practice, CMS has precluded legal reliance on AOs by individuals or entities that were not part of the AO request.

AHPA agrees that the current preclusion is unduly restrictive and supports the proposed expansion of individuals who can rely on a favorable AO. This modification would reduce confusion and enhance the utilization of the AO process. **For these reasons, we also support the modification of 42 C.F.R. 411.387(c) that would allow individuals and entities to rely on non-binding guidance on the application of self-referral law.** These proposals maximize the ability of health care entities to innovate and form beneficial business arrangements. They may preclude otherwise avoidable litigation over lawful arrangements and promote better use of the AO process.

Fees for the Cost of AOs

To further align the Stark AO process with the OIG review process, CMS proposes eliminating the $250 initiation fee for an AO, while adopting a $220 hourly fee to prepare an AO. CMS believes that this amount reflects the costs incurred by the Agency in processing an AO request.

AHPA supports the elimination of the $250 initiation fee as this would remove a minor disincentive to submitting a good faith request for review. However, we urge the Agency to conduct further

analysis before implementing the $220 proposed hourly fee. While shortening the review time for AO requests may require additional resources from CMS, it is still uncertain whether the proposed change would lead to an increase volume of AO requests. If CMS decides to issue AOs on hypothetical facts and shortens the timeline for review, AHPA would support the fees as they would accommodate an increased volume and shorter turnaround. Currently, the proposed rule is unlikely to increase volume to the extent necessary to begin collecting fees in a departure from current CMS practice.

Veracity of Facts in AO Requests

Although current law allows CMS to rescind or revoke an AO after it is issued, CMS has never rescinded an AO. The Agency seeks comments on whether it should retain a more limited right to only rescind an AO when there is a material regulatory change or new facts that warrant reconsideration.

AHPA supports this policy change as it would enhance the reliability of Stark AOs and encourage the utilization of the AO process. The change would reassure providers that the process will result in an AO they can rely on the long-term. This technical change also aligns with the desirability of improving the efficacy of the AO review process.

Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact me at Carlyle.Walton@AdventHealth.com or Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AdventHealth.com.

Sincerely,

Carlyle Walton, FACHE
President
Adventist Health Policy Association