AMERICAN OSTEOPATHIC ASSOCIATION

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September 27, 2019 *Submitted electronically via http://www.regulations.gov*

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1715-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations [CMS-1715-P]

Dear Administrator Verma:

As the leading national association representing more than 145,000 board-certified osteopathic primary care physicians, specialists, and medical students, the American Osteopathic Association (AOA) appreciates the opportunity to provide comments on the above-referenced proposed rule for calendar year (CY) 2020 and the accompanying Request for Information (RFI) published in the *Federal Register* on August 14, 2019 (84 FR 40482). The AOA is encouraged by many of the proposals in the rule, particularly CMS' efforts to reduce administrative burden and ensure appropriate payment for office/outpatient Evaluation and Management (E/M) visits, address the rising incidence of addiction to prescription opioids, and improve efficiency and usefulness of the Merit-based Incentive Payment System (MIPS). The comments below focus on the proposals most important to AOA members.

PROVISIONS OF THE PROPOSED RULE FOR THE 2020 PHYSICIAN FEE SCHEDULE

Technical Corrections to Direct PE Input Database and Supporting Files

For CY 2020, CMS is proposing to correct several inconsistencies in the direct practice expense (PE) database. The AOA supports CMS' acceptance of the StrategyGen report updating the direct PE inputs for supply and equipment pricing. We encourage CMS to continue to consider all pricing data, including invoices and other supporting evidence from specialty societies throughout the four-year transition period, and to develop an ongoing update process for supplies, equipment, and clinical labor staff cost per minute that would be open for public comment through the rulemaking process.

Methodology for the Proposed Revision of Resource-based Malpractice RVUs

In the rule, CMS solicits comments on its proposals to implement the fourth comprehensive review and update of malpractice (MP) RVUs for CY 2020. The AOA appreciates CMS' efforts to improve the data collection and methodology to develop MP premium data. In the absence of sufficient premium data for non-physician health care professionals, the AOA agrees with the RUC's recommendations for mapping Medicare specialty designations for speech language pathologist, psychologist, audiologist, physical therapist, occupational therapist, registered dietitian/nutrition professional and licensed clinical social workers. These clinician

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categories would be better aligned with the optometry specialty designation, for which valid premium data was collected for CY 2020 supporting a risk factor of 0.17 and annual premium rate of $1,539.

Minor Surgery and Major Surgery Premiums
For the major vs. minor surgery service risk groups, CMS proposes to combine minor surgery and major surgery premiums to create the surgery service risk group, which the agency claims will yield a more representative surgical risk factor. We agree with the RUC that there are methodological flaws in CMS' attempt to implement the new policy. Specifically, the definition of "minor" vs. "major" surgery is arbitrary and has led to undervaluation of certain specialties and codes. In addition, certain specialties and services are unfairly penalized as premium rates vary significantly within the specialty, and the physician work RVU shared by service risk type appear to be in error and need further explanation and review. For the 157 codes with a ZZZ global period and work RVUs lower than 5.00, the AOA supports the RUC's recommendation to change the assignment of the codes to major surgery. As CMS is aware, within specialties, physicians may subspecialize and perform very different services from other physicians in the same specialty. Therefore, it is imperative that data at this level result in different risk factors for those specialties defined as minor vs. major surgery.

Utilizing Partial and Total Imputation
The AOA disagrees with the proposed cross-walks for oral surgery (dentists only) to oral/maxillofacial surgery, certified nurse midwife to obstetrics/gynecology, pain management to interventional pain management, gynecologist/oncologist to obstetrics/gynecology, and sleep medicine to general practice. We agree with the RUC that these mappings are problematic and new mappings are needed for accuracy purposes of imputation of professional liability (PLI) premiums. We also agree with the RUC that it is inappropriate to map non-physician health care professionals and TC-only services to a physician specialty when there are no data to correspond to a CMS specialty. In such cases, the best solution is to collect comprehensive data for accuracy.

Technical Component (TC) Only Services
For CY 2020, CMS proposes to assign a risk factor of 1.00 for TC-only services, which corresponds to the lowest physician specialty-level risk factor, due to insufficient comparable PLI premium data for the full range of health professionals that furnish TC-only services. The AOA supports the RUC's recommendation to retain the current risk factors for TC-only services until comprehensive data is acquired, rather than assigning the lowest physician specialty-level risk factor to these services.

Low Volume Service Codes
In regards to low volume service codes, CMS is soliciting comment on use of a list of expected specialties for CY 2020, instead of the claims-based specialty mix for low volume services (fewer than 100 allowed services in the Medicare claims data), which also includes no volume services, and apply overrides for both the PE and PLI valuation process. The AOA urges CMS to work with the RUC to ensure that the list of expected specialties is correctly and consistently applied for the low volume service-level overrides each year.

Updates to the Geographic Practice Cost Indices (GPCIs)
The AOA endorses equity in reimbursement for rural physicians as part of the strategy to increase the availability of quality health care in rural areas. As CMS conducts its statutorily required three-year review of the GPCIs under the Medicare Physician Fee Schedule (PFS), we urge CMS to ensure that indices used to calculate physician wage and PE GPCIs, particularly for non-urban localities, are accurate and up-to-date. Certain rural states like Montana and South Dakota are facing a GPCI reduction next year due to the expiration of the 1.0 work floor mandated by the Balanced Budget Act of 2018, which extended the floor through the end of 2019. Many other state localities will also see reductions due to changes in the PE GPCI and updated PLI GPCI data. The AOA encourages CMS to work with Congress to set a minimum GPCI to permanently extend

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certain adjustments for cost of practice, especially in frontier states that tend to have more patients in medically underserved areas.

Potentially Misvalued Services Under the PFS
The AOA fully supports and endorses the recommendations and comments of the RUC regarding potentially misvalued services. CMS modified recommendations for 91 codes, which the majority of the RUC unanimously approved. We urge CMS to reinstate the RUC recommendations for the potentially misvalued services as part of the 2020 PFS final rule.

Payment for Medicare Telehealth Services under Section 1834(m) of the Act
Starting in 2020, CMS is proposing to expand the list of Medicare covered telehealth services by adding three new HCPCS codes (GYYY1, GYYY2 and GYYY3) to describe face-to-face visits for treatment of patients with substance use disorder (SUD). The AOA supports the addition of the proposed new HCPCS codes, as telehealth services allow physicians to expand their reach beyond the office and provide timely care to patients in distant and rural areas that lack sufficient access to addiction treatment.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act removed the originating site and geographic limitations for telehealth services furnished on or after July 1, 2019 for individuals diagnosed with substance use disorder (SUD) or a co-occurring mental health disorder. The SUPPORT ACT also allows for SUD telehealth services to be furnished at any telehealth originating site (other than a renal dialysis facility), including a patient's home. These changes were adopted in the CY 2019 PFS final rule. To promote use of SUD services available via telehealth, upon annual update of the list of covered telehealth services payable under the PFS for CY 2020, the AOA urges CMS to clearly identify these and other services that no longer require originating and geographic restrictions.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)
In accordance with the SUPPORT Act, CMS is proposing to develop opioid treatment programs (OTPs) for opioid use disorder (OUD). The OTP would provide bundled monthly payments for an episode of care using medication-assisted treatment (MAT) and non-drug treatment to cover counseling, individual and group therapy, toxicology testing, development of a treatment plan, care coordination, and education to help patients manage their condition at home. To develop OTPs, CMS is proposing to create a definition, establish new enrollment policies, and create 19 new HCPCS codes (GXXX1-GXX19) with geographically adjusted payment rates that vary by medication and length of treatment.

The AOA commends the efforts and actions CMS has taken to develop an effective solution to combat the opioid epidemic. The severity of prescription opioid addiction has reached epidemic proportions in the U.S. and it is imperative that steps are taken at a national level to address the public health crisis. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2016 than in 1999.[1] We encourage our members to maintain current knowledge of prescribed addictive substances with a high potential for abuse and employ caution with appropriate prescribing and monitoring strategies. We urge all members of the osteopathic profession to participate in the prevention and rehabilitation of persons suffering from substance

[1] Seth P, Rudd R, Noonan, R, Haegerich, T. Quantifying the Epidemic of Prescription Opioid Overdose Deaths.American Journal of Public Health, March 2018; 108(4),e1-e3.

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use disorder and the disease of addiction. As such, we fully support the proposal to implement a new benefit category under the Medicare program for OUD treatment services furnished by OTPs. We also support the proposed definition for OUD treatment services, including services furnished via telecommunications technology as clinically appropriate, and the proposed bundled payment approach for services furnished in OTPs. The AOA urges CMS to move forward with finalizing the OTP policy proposals.

In the 2019 PFS proposed rule, CMS solicited public feedback on potential non-opioid alternatives for pain treatment and management. In response to the solicitation, we mentioned the AOA's advocacy efforts to help curb the nation's opioid epidemic, and suggested alternative pain management protocols using non-pharmacological alternatives, such as osteopathic manipulative treatment (OMT). We believe treating pain osteopathically is a viable solution for non-opioid pain management and are working with legislatures in various states to promote this therapeutic solution.

The AOA also worked with the Federation of State Medical Boards (FSMB) to include OMT as a non-pharmacological therapy in the "Guidelines for the Chronic Use of Opioid Analgesics." The guidelines were adopted as FSMB policy on April 30, 2017, and serve as a resource for state medical and osteopathic boards in assessing physicians' management of pain in their patients, and determining whether opioid analgesics are used in a medically appropriate manner. The AOA would like to reiterate the effectiveness of OMT for pain management, and encourages CMS to reconsider it as a non-opioid alternative as part of its OTP.

Adjustment to Bundled Payment Rate for Additional Counseling or Therapy Services
While we support the proposals to pay for OUD treatment furnished in by an OTP, we agree that the payment bundle should be adjusted through adoption of add-on HCPCS code GXX19, in order to account for instances in which effective treatment requires additional counseling, group or individual therapy, to be furnished for a particular patient that substantially exceeds the amount of time specified in the patient's individualized treatment plan.

Cost Sharing
To minimize barriers to patient access to OUD treatment services, and to ensure that OTP providers receive the full Medicare payment amount for patient care, CMS is proposing to set the co-payment at zero for a time-limited duration (for example, for the duration of the national opioid crisis). The AOA opposes this proposal and urges CMS to establish a zero co-payment for the duration of the OPT. Lack of financial resources is a common reason patients suffering from OUD do not receive treatment for drug dependence. States with higher poverty levels and low-income patient populations, such as those dually eligible for Medicare and Medicaid, may not be able to afford a co-payment, and potentially forgo OUD treatment. Federally funded programs, such as the proposed OTP, must be an affordable option for recovering addicts. Imposing a co-payment could impose a significant barrier to vulnerable patient populations in need of help.

Bundled Payments Under the PFS for Substance Use Disorders
In addition to bundled payments for OUD treatment furnished in OTPs, CMS is proposing to create three new HCPCS codes (GYYY1, GYYY2 and GYYY3) to establish separate bundled payments for office-based OUD services provided by physicians and other health care professionals that are not part of an OTP. With the exception of MAT, the bundled payment would allow coverage for management, care coordination, psychotherapy and counseling activities. The AOA supports the proposal to create new payment codes for physician visits in the office setting. In doing so, primary care physicians wishing to treat patients for OUD would be able to integrate a comprehensive treatment plan into their clinical practice, thereby expanding the availability of care to patients in need of support.

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Physician Supervision for Physician Assistant (PA) Services
CMS is proposing to revise statutory physician supervision requirements for PA services in accordance with state law and state scope of practice rules governing medical direction and appropriate supervision. CMS intends for the proposed change to align regulation for physician supervision of PAs with that of nurse practitioners and clinical nurse specialists.

Although the AOA supports a team or collaborative model to healthcare delivery, we are concerned that authorizing independent practice of medicine by PAs, who do not complete comprehensive medical education, training and competency demonstration requirements that physicians do, could jeopardize the health and safety of frail and elderly Medicare patients who often have multiple chronic medical conditions. The AOA recommends that CMS maintain its current regulations on physician supervision for PA services, as the current regulations are consistent with the vast majority of state scope of practice laws.

We would also like to emphasize that under state scope of practice laws, only two states allows PAs to practice independently without any physician supervision or collaboration. Moreover, the Physician Assistant Education Association, which represents PA educational programs, stated in its "Optimal Team Practice Task Force Report" that they "[do] not support the elimination of legal provisions that require a collaborating physician for PAs" due to the potential negative consequences including harm to patients.[2]

While there are some PA state scope of practice laws that allow physician collaboration instead of supervision; they still require the PA to provide patient care largely within relationship with a physician, and within the context of a physician-led health care team. While we value the contributions of all health care providers to the health care delivery system, we believe that PA's education and training lacks the comprehensive and robust requirements needed to independently deliver primary care services to patients. That being said, the AOA firmly supports the "team" approach to medical care because the physician-led medical model ensures that professionals with complete medical education and training are adequately involved in patient care.

Accordingly, we recommend that CMS revise § 410.74(a)(2)(iv) to require that a PA "performs the services in a health care team led by a physician and in accordance with state law and regulations governing physician assistants in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed." This amended language would ensure that the statutory physician supervision requirement for PA services at § 1861(s)(2)(K)(i) of the Social Security Act are met.

Review and Verification of Medical Record Documentation
Starting in 2020, CMS proposes to establish a general principle to allow the physicians, PAs or advanced practice registered nurses (APRN) who bill Medicare Part B directly to review and verify, rather than re-document, information entered into in a patient's medical record by physicians, residents, nurses, students or other members of a medical team.

The AOA urges CMS to establish a general principle to allow physicians who furnish and bill for their professional services to review and verify documentation previously entered by members of a medical team. The proposed documentation amendments align with CMS' Patients Over Paperwork initiative to reduce unnecessary administrative burdens for physicians and streamline the health care system. We also agree with CMS that this general principle should be applied to teaching physicians.

[2] Physician Assistant Education Association OTP Task Force. "Optimal Team Practice: the Right Prescription for All PAs?" May 8, 2017. Available at: https://paeaonline.org/wp-content/uploads/2017/05/PAEA-OTP-Task-Force-Report_2017_2.pdf

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Care Management Services
In 2011, the CPT Editorial Panel and the RUC led the effort to appropriately describe and value care management services. Around this time, physicians and their staff were already engaging in non-face-to-face services that, while uncompensated, were critically important to their patients. CMS now recognizes what physicians knew then, that care management services provide patients with higher quality care and save the Medicare program money by reducing hospital readmissions and emergency room visits.

To pay for the newly created care management services, CMS is redistributing money away from other important physician services. The AOA agrees with the RUC that CMS must find alternatives to account for the savings for care management services, and to offset the cost of coverage of the new Principal Care Management (PCM) code. The AOA encourages CMS to inform Congress that positive updates to the Medicare PFS conversion factor are critical to expand care management services, while maintaining the integrity of the valuation within the RBRVS.

Transitional Care Management (TCM) Services
CMS is proposing to revise billing requirements for TCM (CPT codes 99495 and 99496) services by allowing the codes to be billed concurrently with other services by the same practitioner, and seeks comment on whether any overlap would occur if the same or a different practitioner reports the services.

Although current CPT guidelines prohibit a physician or other qualified health care professional who report TCM codes from billing Home and Outpatient International Normalized Ratio (INR) Monitoring Services (93792, 93793), Interpretation of Physiological Data (CPT Code 99091), Prolonged E/M Without Direct Patient Contact (CPT Codes 99358, 99359) and Complex Chronic Care Management (CPT Codes 99487, 99489) during the time period covered by the TCM codes, the AOA supports CMS' recommendation to allow billing of other services by the same practitioner, and urges CMS to immediately begin working with the CPT Editorial Panel and the RUC to align reporting rules and identify which codes overlap or duplicate TCM services.

CMS also noted in the proposed rule that the current payment amount for TCM codes were contributing to low utilization of services. For CY 2020, CMS proposes to adopt RUC recommendations to increase the work RVU for CPT code 99495 from 2.11 to 2.36, and to increase the work RVU for CPT code 99496 from 3.05 to 3.10. CMS also proposes to accept the RUC's PE input recommendations for these codes. The AOA participated in the 2018 RUC survey of the TCM codes as part of a regular RUC review for new technologies and services, and supports the RUC's recommendations, as well as CMS' efforts to increase the utilization of TCM services.

Chronic Care Management (CCM) Services
In order to improve payment accuracy for CCM services, CMS also proposes to adopt two new G-codes (GCCC3 and GCCC4) in lieu of existing complex CCM codes (99487 and 99489) and replace the current non-complex CCM code (99490) with two new G-codes (GCCC1 and GCCC2) to allow practitioners to bill additional increments of time when required in certain cases. CMS requests comment on whether to implement G-codes to expand the CCM codes for CY 2020 or wait for anticipated changes to CPT in 2021.

CMS also proposes to clarify the language describing the comprehensive care plan required for CCM codes to include new elements for cognitive and functional assessment, environmental evaluation, caregiver assessment and interaction and coordination with outside resources, practitioners and providers.

The AOA agrees that the CCM codes need refinement; however, we believe that CMS should work with the CPT Editorial Panel to create CPT codes, rather than create temporary G-codes. It is administratively burdensome for physicians and their staff to transition back and forth between CPT and G-codes. The CPT Editorial Panel is considering an application for new add-on codes for CCM in September 2019 for publication

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in the 2021 CPT code book. Clarifications regarding the patient care plans are also part of the proposal to the CPT Editorial Panel.

Principal Care Management (PCM) Services
CMS is proposing to create two new G-codes (GPPP1 and GPPP2) to allow separate coding and payment for physicians providing PCM services for patients with a single high-risk disease. These codes would be reported for care management of a single chronic condition that may be managed by a primary care practitioner or specialists. The current CCM codes require patients to have two or more chronic conditions. CMS estimates an additional $125 million in annual spending for these services, offset by reductions to the Medicare conversion factor.

We believe this proposal warrants further consideration and discussion, and we urge CMS to work with the CPT Editorial Panel prior to implementation. The timing of the proposal is concerning, as CMS suggests to implement the time-based code at the same time as proposing an add-on code to be reported with each office visit code for a similar patient. In addition, there may be other codes that describe the work performed for these patients, including the office/outpatient E/M visit codes for new and established patients that were just revalued to include time spent three days prior and seven days following each office visit. It is important that the proposed PCM service be appropriately reviewed to avoid overlap with other services.

Transcatheter Aortic Valve Replacement (TAVR)
To recognize the evolving technology and site of service changes for TAVR procedures CMS is proposing to adopt the RUC-recommended work RVUs and RUC-recommended direct PE inputs for CPT Codes 33361, 33362, 33363, 33364, 33365, and 33366.

The AOA supports CMS' proposal to increase the work RVUs and direct PE inputs for TAVR family of codes as recommended by the RUC. The updated values will support the recent revisions CMS' has made to the National Coverage Decision (NCD) and expanded FDA indications for TAVR coverage.

Comment Solicitation on Opportunities for Bundled Payments under the PFS
In the proposed rule, CMS solicits feedback through a Request for Information (RFI) on the concept of bundling services, to the extent that principles, such as establishing per-beneficiary payments for multiple services or condition-specific episodes of care, can be applied within the statutory framework of the PFS.

We would like to remind CMS that several years ago, the RUC began using screening tools to identify services that are inherently performed together by the same physician on the same day of service under direction of the Relativity Assessment Workgroup. The screen started with services reported on the same date by the same physician 95 percent or more of the time with another service. The screen was then lowered for services reported together 75 percent or more of the time to capture more services to be bundled. After five iterations of this screen, the CPT Editorial Panel created code bundling solutions for approximately 340 services and the RUC submitted recommendations.

We agree that medical societies, in collaboration with the RUC, are best able to determine if opportunities exist for development of new CPT code bundles to describe an episode of care. Accordingly, the AOA recommends that CMS work with the CPT Editorial Panel on code concepts that arise from the comments to the RFI on bundled payments to ensure the established CPT process is followed.

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Payment for Evaluation and Management (E/M) Visits

a. Office/Outpatient E/M Visit Coding and Documentation

Effective for services starting January 1, 2021, CMS proposes to adopt the new coding, prefatory language, and interpretive guidance framework recommended by the CPT Editorial Panel for new and established patient office/outpatient E/M visits (99201-99215) to accomplish greater burden reduction and make the policies more intuitive and consistent with the current practice of medicine. Under the proposed framework, CMS would allow clinicians to choose E/M visits based on medical decision making (MDM) or time, and require history and/or exam for code selection only when medically necessary.

b. Office/Outpatient E/M Visit Revaluation (CPT codes 99201 through 99215)

For CY 2021, CMS would retain five levels of codes for established patient E/M visits (99211-99215), and delete 99201 reducing the level of codes for new patient E/M visits (99202 – 99205) from five to four. The level one visit (99211) would only describe or include visits performed by clinical staff for established patients. In addition, CMS proposes to eliminate the uniform payment rates previously finalized for levels two – four E/M visits (99202-99204 and 99212-99214) and allow separate payment for each code. Finally, CMS' proposal would adopt the RUC-recommended work RVUs for all of the office/outpatient E/M codes and the new prolonged service add-on code.

The AOA greatly appreciates CMS' proposals to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. We urge CMS to finalize the CPT codes, CPT guidelines, and RUC recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC. The AOA agrees that this new coding framework will relieve physicians of administrative burden when documenting E/M visits. We also request that CMS work with the medical community to urge Congress to implement positive updates to the PFS conversion factor to offset increases in the E/M visits.

Regarding the RUC recommendations for PE inputs for these codes, CMS has declined to accept the desktop computer (ED021*, computer, desktop, with monitor*) used in examination rooms as a direct PE input that would be allocated for use for each patient for an individual service. CMS believes the desktop computer would be better characterized as part of indirect costs similar to office rent or administrative expenses. The AOA disagrees with CMS' interpretation, as the computer, whether a desktop or laptop, is an essential tool in documenting the E/M visit and entering the information into the EHR. Therefore, the AOA recommends CMS recognized equipment item ED021 (computer, desktop, with monitor) as a direct PE input.

c. Simplification, Consolidation and Revaluation of HCPCS codes GCG0X and GPC1X

CMS also proposes to consolidate the newly created add-on codes for primary care (GPC1X) and specialty care (GCG0X) complex cases into a single code by revising the descriptor for GPC1X and deleting GCG0X. If the previously finalized complexity codes were to be implemented in CY 2021, the codes would only be billable with levels two – four E/M visits. The proposed changes would allow the individual complexity code to be reported with all office/outpatient E/M visit levels.

The AOA seeks clarification on application of GCG0X to clearly define the types of visits that require additional resources. We support CMS' intent to ensure that physicians are adequately paid for those patients that require addition time and resources beyond the typical patient described in the valuation of office visits; however, CMS does not provide any specific assumptions regarding the projected utilization for this new add-on code.

d. Valuation of CPT code 99xxx (Prolonged Office/Outpatient E/M)

CMS further proposes to eliminate the new extended visit code GPRO1 that was previously finalized to reflect E/M services that require additional time. This code also would have been billable only with levels two – four

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E/M visits. Instead, CMS proposes to replace GPRO1 with an entirely new add-on CPT code (99XXX) for prolonged E/M visits that would be billable with all levels of E/M visits when total time is used for code selection, and when the time for level five E/M visits (99205 and 99215) are exceeded by 15 minutes or more.

In the proposed rule, CMS states that "CPT codes 99358, 99359 can be used to report practitioner time spent on any date (the date of the visit or any other day)." This interpretation is incorrect. These codes are not reported for time spent on the date of an office or other outpatient encounter (99202-99205, 99211-99215).

CMS further states that it is unclear if 99358 and 99359 can be reported in addition to or instead of the new 99XXX add-on code to describe extended time. The new CPT descriptor and guidelines in the prefatory language clearly state that 99XXX should be utilized for the extended time on the date of encounter and that 99358 and 99359 are NOT to be reported for this time: "(Do **not** report 99XXX in conjunction with 99354, 99355, 99358, 99359, 99415, and 99416). However, CMS believes based on its interpretation, that CPT codes 99358 and 99359 may need to be redefined, resurveyed and revalued, and seeks public comment on these codes. The AOA recommends that CMS work with CPT/RUC Workgroup on E/M to examine the codes and determine if the guidelines require further clarification.

g. Comment Solicitation on Revaluing the Office/Outpatient E/M Visit within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services

In light of the modifications to the office/outpatient E/M visits, CMS solicits comment on whether it is necessary to make systematic adjustments to other E/M services, such as home care, nursing homes, and hospice to maintain relativity between services.

While the AOA appreciates CMS' willingness to maintain relativity among the office/outpatient E/M visits and other E/M services, any adjustments should occur in tandem with input from the CPT Editorial Panel, the RUC and the respective medical societies to ensure the coding structure aligns with the same burden reduction modifications made for the office/outpatient E/M visits, and the documentation guidelines are consistent with E/M services in other settings.

OTHER PROVISIONS OF THE PROPOSED REGULATIONS

Medicare Shared Savings Program

CMS solicits comment on aligning the Shared Savings Program quality score with the MIPS quality performance category score, and aligning the Shared Savings Program quality measure set with proposed changes to the Web Interface measure set under MIPS per previously finalized policy.

In the rule, CMS acknowledges that aligning Shared Savings Program and MIPS quality measures could potentially create conflict in the scoring methodologies for these programs. However, the increase in quality measure reporting required by CMS, coupled with the variability of programs across CMS has become extremely complex and administratively burdensome for physicians. The AOA raised this concern in our comments on the Patients Over Paperwork initiative. Some programs require use of different measures to report the same clinical condition, further increasing burden with each program. A single methodology would minimize duplicative reporting and confusion in trying to understand different measure specifications. We urge CMS to bring into line the methodologies to evaluate quality performance under both programs to enable MIPS and ACO participants to better focus on improving patient care and outcomes.

For performance year 2020, CMS is proposing to remove quality measure – ACO-14: Preventive Care and Screening Influenza Immunization, and replace it with quality measure – ACO-47: Adult Immunization Status.

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The AOA believes it is premature for CMS to add measure ACO-47 to the ACO quality measure for performance year 2020, as the measure has not undergone thorough testing to determine whether it is appropriate for use at the ACO or physician level. Therefore, holding ACOs accountable for the measure would be inappropriate. For these reasons, the AOA encourages CMS to not finalize the proposal to add measure ACO-47 to the Shared Savings Program quality measure set for performance year 2020. Instead, we recommend CMS maintain the current vaccination measure ACO-14.

Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm
As part of the participation provisions for the OTP, CMS is proposing to revoke or deny a physician's enrollment if they have been subject to prior action from a state oversight board, federal or state health care program, independent review organization, or other equivalent governmental body as a result of actions by the physician that led to patient harm.

The AOA recognizes the importance of protecting patient safety; however, we have strong concerns with how the provision is written and urge CMS to withdraw the proposal for several reasons. First, CMS does not have the clinical expertise to make judgments regarding the competency of health care professionals to perform medical procedures. Second, having not been involved in licensing board disciplinary process or its deliberations in evaluating the genesis of a complaint, the veracity of allegations or the reasoning behind a decision settlement, CMS is not positioned to make an informed decision. Denial or revocation based on an after-the-fact desk review is wholly inadequate, will punish rehabilitating physicians inappropriately, and lead to further physician shortages.

UPDATES TO THE QUALITY PAYMENT PROGRAM

MIPS Value Pathways (MVP) Request for Information (RFI)
CMS acknowledges that the Merit-based Incentive Payment System (MIPS), while intended to simplify administrative burden and ease reporting, is still burdensome and overly complicated. In order to develop a more meaningful program for all MIPS eligible clinicians, regardless of practice size or specialty, CMS solicits comments through a RFI on a new framework, the MIPS Value Pathways (MVPS).

Request for Feedback on MVP Approach, Definition, Development, Specification, Assignment, and Examples
The AOA believes that eventually MVPs have the potential to improve MIPS participation. However, we also recognize that it is a new model that will take time to implement and refine. To support successful implementation of the MVPs, the AOA recommends CMS use a phased-in approach and pilot test the MVPs, to allow time to develop the necessary number of MVPs prior to requiring mandatory use.

Since the Promoting Interoperability performance category will cut across all MIPS performance categories, we recommend CMS allow a "yes/no" attestation for participation. We also recommend that CMS issue eligible clinicians a high-weight (20 points) for the Improvement Activities performance category for early adopters of MVPs. CMS should also allow attestation to participate in a specialty accreditation program to satisfy the Improvement Activities performance category requirement for the MVP.

Request for Feedback on Selection of Measures and Activities for MVPs
For the start of the MVPs, CMS should limit the number of quality measures to four for all eligible clinicians, regardless of size or specialty, and allow use of multiple collection methods for reporting. To facilitate development of appropriate MVPs, CMS should initiate a "Call for MVP" quality measure similar to the annual Call for Measures and Measure Selection Process.

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Request for Feedback on MVP Assignment
The AOA strongly opposes mandatory assignment of MVPs for eligible clinicians, and recommends CMS allow them to voluntarily choose how they participate in MIPS, with the ability to self-select which MVPs to report on, or to continue to report measures through the traditional MIPS pathway.

Request for Feedback on Transition to MVPs
While we appreciate CMS' efforts to develop a more meaningful framework for MIPS participation, we are concerned that the implementation timeline is too aggressive and would place undue burden on eligible clinicians. CMS must recognize that it will take time to develop a sufficient number of MVPs to allow the majority of physicians the opportunity to participate in the MVP track. Eligible clinicians will also need time to be educated on MVP scoring rules and methodologies and make updates to electronic systems, such as QCDRs and EHRs. Therefore, we recommend CMS delay the January 1, 2021 start date for the MVPs to allow eligible clinicians and group practices adequate time to adjust their practice workflows and systems.

CMS should also consider the costs of implementation and the value of the potential additional payment that is likely to be received in the context of the Return On Investment (ROI) for participating physicians. Given the disappointing ROI physicians have seen in the current MIPS program, unless a favorable ROI is able to be reasonably expected, it is likely that physicians would resist participation.

Request for Feedback on Small and Rural Practices Participation in MVPs
MVPs for small and rural practices should be structured to allow flexibility to ensure successful MVP participation. The AOA recommends that CMS maintain the low volume threshold and allow small and rural practices to report fewer quality measures and activities than large group practices. We also recommend that CMS provide technical assistance for small and rural practices, such as financial incentives to support use of electronic health information technology to mitigate challenges in reporting, and provide meaningful data on quality and use of resource cost to incentivize performance improvement. Limited resources and lack of readiness to take on financial risk are the greatest barriers to physicians effectively transitioning to alternative payment models (APMs), particularly for small and rural practices.

Request for Feedback on Multispecialty Practices Participation in MVPs
The AOA encourages CMS to provide all practices with access to meaningful data on quality and use of resource cost under the MVP to facilitate transition into APMs. This type of information would inform groups if, and to what extent, they are ready to take on financial risk. MVP criteria for multi-specialty groups should be defined by specialty designation, services based on Part B claims and place of service. Multi-specialty groups should not be limited to the number of MVPs that could be reported on. We believe physicians are in the best position to determine which clinical areas are most meaningful to their practice.

Request for Feedback on Population Health Quality Measure Set
The AOA opposes required use of population-based measures included in MVPs. The proposed population health administrative claims measures were developed for use at the county or health-plan level and CMS cannot automatically assume the measures will appropriately distinguish quality among individual physicians and group practices. The measures also move the program away from incorporating the patient's voice, measuring clinical conditions and outcomes, and generating real-time feedback. Measure developers moved away from administrative claims measures due to concerns over attribution, retrospective analysis, inability to measure individual physicians, and outcomes. We also believe that implementation of population health measures will further diminish the viability of small practices.

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Performance Threshold
For CY 2020, CMS is proposing to increase the performance threshold from 30 points to 45 points and up to 60 points for the 2021 performance year. We are concerned that the proposed incremental increases to the performance threshold are too significant and may prohibit satisfactory participation in the MIPS program, and disproportionately harm small and rural practices. We recommend that CMS reduce the increment for the performance threshold to 35 points to ensure continued high participation in the program, to support small practices, and to be consistent with the size of the proposed increase in the exceptional performance threshold increase.

Quality Performance Category
The AOA recommends that CMS maintain the current percentage weight for the Quality performance category for CY 2020. We are extremely concerned about the trajectory of the MIPS program due to the number of proposed changes for CY 2020. Substantial program changes from year-to-year increase administrative burden, increase complexity and cost of the program, and run counter to the Patients Over Paperwork initiative. As part of the Meaningful Measures Initiative, CMS proposes to remove 55 quality measures in 2020, which results in a 21 percent decrease in the total number of available MIPS quality measures. Over the last two years, CMS has removed approximately 32 percent of MIPS quality measures and the program is only in its fourth year.

We fear that there will not be a sufficient number of meaningful and actionable measures for eligible clinicians to report in order to satisfy the Quality performance category. The proposal to remove a large number of measures also do not take into account whether the measures contribute to patient safety or improved patient care. With implementation of MVPs, we are concerned that lack of sufficient measures will force participants to report for the sake of reporting.

Cost Performance Category
The AOA recommends CMS maintain the current percentage weight for the Cost performance category for CY 2020 while CMS addresses concerns with the existing Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures. Keeping the current weight will allow clinicians time to adapt to the 10 new episode-based measures. Altering the percentage weight before the TPCC and MSPB measures have been sufficiently refined may destabilize the program. The episode-based measures are new and many have questionable reliability. We believe more time is needed to test and evaluate the episode-based cost measures prior to implementing them and increasing the percentage weight. As an alternative, CMS should consider increasing the percentage weight of the Improvement Activities performance category to reflect physicians' quality improvement efforts, and adopt a more phased-in approach for the episode-based cost measures. Eligible clinicians need more time to review their cost data and the opportunity to make improvements in practice patterns.

Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) Measures
The AOA echoes the recommendation of the physician medical community for CMS to remove the TPCC and MSPB measures from MIPS. Measures should only cover costs that physicians can reasonably be considered to control. TPCC or the MSPB measures do not meet that criterion because the measures hold physicians accountable for patients' health care that are managed by other providers, and for costs they cannot influence like drug prices. If CMS does not remove the TPCC and MSPB measures, CMS must adequately address concerns with attribution, exclusions, double counting, and validity to sustain the program.

Improvement Activities Performance Category
The AOA supports CMS' proposal to maintain a continuous 90-day performance period for the Improvement Activities performance category. However, we oppose the proposal to increase the participating clinician

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threshold from one clinician to 50 percent of a TIN to receive credit in the Improvement Activities performance category. The MACRA statute does not specify a certain number of clinicians in a TIN to perform the activity. Furthermore, the 50 percent threshold would be a significant increase, and would create complexity for groups to earn credit.

Promoting Interoperability Performance Category Performance Period
The AOA recommends that CMS adopt its proposal for a 90-day continuous reporting period in CY 2020. Since the inception of the MIPS program, CMS has used the rulemaking process to limit the EHR reporting period to 90-days. Instead of issuing a temporary stipulation from year-to-year, we recommend the agency seek a permanent provision for the EHR reporting period. We also urge CMS to deviate from prescriptive Promoting Interoperability measures directly tied to use of certified EHR technology (CEHRT), and instead score measures based on a "yes/no" attestation.

Query of Prescription Drug Monitoring Program (PDMP) Measure
The AOA commends CMS for its decision to rescind the PDMP policy and allow for continued optional reporting of the Query of PDMP measure for CY 2020. We also support the proposal to require a "yes/no" response for the measure, instead of a numerator and denominator. The AOA recommends that CMS finalize both proposals.

Verify Opioid Treatment Agreement Measure
The AOA appreciates CMS' acknowledgement that the Verify Opioid Treatment Agreement measure presents significant implementation challenges and should be removed from the Medicare and Medicaid Promoting Interoperability Program. In our comments on the CY 2019 IPPS proposed rule, we cautioned CMS that the measure, if finalized for mandatory reporting, would increase administrative burden for physicians and hospitals alike, and would fail to promote interoperability. We support CMS' decision to remove the measure, and urge the agency to work with stakeholders to develop more meaningful measures to combat the opioid epidemic.

Future Direction of the PI Performance Category Request for Information
CMS has included several RFIs related to opioid measures, ways to improve efficiency, patient exchange information, patient-generated data in EHRs and engaging in activities that promote safety.

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs
Again, we recommend that CMS move away from prescriptive measures tied directly to CEHRT use. All new measures should be based on a "yes/no" attestation. Removing the burden of compliance and reporting will also help alleviate physician burnout related to EHR use. Continuing to require prescriptive measurement will detract from clinical relevance, increase administrative burden, and focus participation on documentation, reporting and compliance rather than improved patient outcomes.

Request for Information (RFI) on the Provider to Patient Exchange Objective
The AOA appreciates CMS' emphasis on patient access and interoperability measures in the current Promoting Interoperability programs. However, CMS should coordinate with ONC to advance more standardized data elements for patient matching by leveraging the U.S. Core Data for Interoperability (USCDI). Additionally, CMS and ONC should work together to establish guidance surrounding common issues that could be resolved by standardization.

Patient Matching
The AOA believes that accurately identifying patients and matching them to their data is essential to coordination of care and is a requirement for health system transformation and the continuation of our

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substantial progress towards nationwide interoperability. In general, the AOA supports policies that will achieve standardization of identifying data in patient records. As patient electronic health information can be more easily shared between physicians, health information exchanges and payers, patient matching remains a persistent problem in ensuring that EHR data is complete and accurate. Therefore, we urge CMS to coordinate with ONC to advance more standardized data elements for patient matching by leveraging the USCDI. Additionally, CMS and ONC should work together to establish guidance surrounding common issues that could be resolved by standardization.

Advanced APMs
CMS is proposing technical changes for Advanced APMs (AAPM) for CY 2020. Specifically, an eligible clinician would not be a qualified participant (QP) or Partial QP for the year, if the APM Entity voluntarily or involuntarily terminates their AAPM contract before the end of the QP performance period, or the APM Entity voluntarily or involuntarily terminates their AAPM contract when the APM Entity would not bear the financial risk.

While CMS notes there is an increasing number of clinicians participating in AAPMs, the number of AAPMs available for participation remains limited. The AOA is concerned that models are being submitted to the PTAC without input of those specialties impacted by the model. Model submitters should be required to provide evidence of consultation and concurrence from relevant medical specialties expected to participate in the models prior to PTAC submission to ensure they are physician-focused. We would encourage CMS to move forward with PTAC-approved APMs that have the benefit of robust input from relevant specialties.

Partial QP Status
The AOA opposes the CMS proposal regarding partial QP status because it adds a new layer of complexity to what is already a complicated program and set of decisions for physicians to navigate. A better course would be to give individual physicians the option to choose whichever designation is more favorable to them. CMS is considering a change in the way it applies Partial QP status because it believes some Partial QPs would like to be able to earn positive MIPS incentive payments. Under the current system, decisions about Partial QPs being excluded from MIPS are likely made at an APM Entity level and the physician may not have an opportunity to influence the Entity's decision. The change CMS is proposing would only apply the Partial QP status to the TIN/NPI combination through which Partial QP status is attained, so that physicians can report through the MIPS program through other TINs in which they are involved.

APM Entity Termination
CMS proposes that if an APM Entity terminates from an Advanced APM at a date on which it would not bear financial risk for the QP performance period, then eligible clinicians could not achieve QP or Partial QP status for that year unless they can do so through participation in other APM Entities. The AOA opposes this change and believes it could have an adverse effect on APM participation. AAPMs are payment innovations and physicians who choose to participate in them simply cannot be assured that the APM Entities will be able to share in savings. Physicians participating in APMs that fail midway through the 12-mothh quality reporting period may have little recourse to avoid a MIPS penalty if they cannot be QPs or even Partial QPs. Many physicians who participate in APMs invest significant financial resources in the development and operation of the APM, which will likely be lost if the APM fails, whether or not it is required to make payments to CMS. The AOA urges CMS to withdraw this proposal.

Comment Solicitation on Opportunities for Bundled Payments under the PFS
While the AOA has concerns with operations of the Center for Medicare and Medicaid Innovation (CMMI) and the PTAC; we do not believe either process should be bypassed for development of APMs. Furthermore, CMS is required by statute to establish payment for physicians' services based on the relative resources involved in

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furnishing the service. While this may allow for the bundling of multiple services into a single CPT code, this does not apply for the kind of payment bundling CMS describes in the proposed rule. We urge CMS to work with the CPT Editorial Panel and follow the process currently established for implementing bundled payments.

Advisory Opinions on the Application of the Physician Self-Referral Law

In the proposed rule, CMS notes that the agency reviewed its physician self-referral advisory opinion regulations "in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process." The AOA applauds CMS for taking seriously the recommendations provided in response to previous solicitations for comment regarding the physician self-referral law. Making the process more user-friendly, including with a shortened deadline and expedited review option, will help ensure CMS' goal for a more "accessible process that produces meaningful opinions on the applicability" of the self-referral law is accomplished.

Conclusion

Once again, the AOA is pleased to have the opportunity to comment on the proposed policy changes for the PFS and Quality Payment Program for CY 2020 and beyond. We commend CMS for incorporating feedback from the physician community as it works to reduce administrative burden for physicians and improve other aspects of the Medicare Part B program. The AOA looks forward to continuing to work with CMS on developing final regulations. Should you have any questions regarding our comments or recommendations, please contact Lisa Miller, Senior Director, Regulatory Affairs and Policy Engagement at lmiller@osteopathic.org or (202) 349-8477.

Sincerely,

Ronald R. Burns, DO, FACOFP
President, AOA