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Via Electronic Submission (www.regulations.gov)

September 6, 2016

Mr. Andrew Slavitt
Acting Administrator
Attention: CMS 1654-P
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

Re: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Revisions to the Part B for CY 2017; Proposed Rule,* 81 Fed. Reg. 46162 (July 15, 2016). The AAMC is a not-for-profit association representing all 145 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and, 93 academic and professional societies. Through these institutions and organizations, the AAMC represents 160,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

Academic medical centers (AMCs) are among the largest physician group practices in the country. Faculty physicians at AMCs are typically organized into large multi-specialty group practices that deliver care to the most complex and vulnerable patient populations, many of which require highly specialized care. Often care is multidisciplinary and team-based. Faculty physicians frequently are organized under a single tax identification number (TIN) with many specialties and subspecialties, such as burn surgery, cardiac surgery, and general surgery, to name a few. A large percentage of the services provided at AMCs are tertiary, quaternary, or specialty referral care. A patient may be transferred to or seek care at an AMC because the care needed is not available in a patient's neighborhood/region.

The CY 2017 PFS rule proposes several policy change which impact AMCs**.** Among the areas addressed by this letter are the payment update amount, collection of data on global surgery data, appropriate use criteria for advanced diagnostic imaging services, payment for care coordination and behavioral health care, and changes to the Accountable Care Organization (ACO) program.

The AAMC's key recommendations include the following:

- Provide further research on utilization assumptions for new codes before implementing the budget neutrality adjuster that makes across the board reductions in payments to physicians.

- Modify the proposal regarding global surgical codes to be consistent with the statute and collect claims data only from a "representative sample" of physicians using CPT code 99024 instead of the proposed G codes; capture information on the involvement of residents in pre and post-operative care.
- Finalize the proposal to add payment for codes that could be used in addition to the current evaluation and management (E/M) codes to recognize the different resources specific to primary care and other cognitive specialties in delivering ongoing treatment.
- Finalize the proposal for an automated process for beneficiaries to attest that their "main doctor" is in an ACO so that they can be assigned to that ACO for all ACO tracks.
- Prior to implementation of admissions and readmissions measures that assess an ACO's quality performance, appropriately risk adjust the measures to account for socioeconomic factors, such as homelessness, community resources, available home supports, and other social risk factors.
- Facilitate the process, with regards to the Open Payment system, to verify the accuracy of payments to teaching hospitals by including additional non-public text fields to assist in the review and affirmation or dispute of payment reports as well as develop additional guidance through input from key stakeholders.
- Delay the implementation time frame for appropriate use criteria (AUC) for diagnostic tests requirements to provide sufficient time for providers to comply with requirements for use of clinical decision support mechanisms (CDSMs); allow imaging providers to be paid if they consult AUCs, rather than linking their payment to actions of another provider.
- Expand the Medicare Diabetes Prevention Program (MDPP) and modify the payment structure to better promote prevention practices and promote population health.

2017 CONVERSION FACTOR

More Research Is Needed to Support the Utilization Assumptions for the New Codes Used to Determine the Budget Neutrality Adjuster

In the proposed rule, CMS announces the conversion factor that will be used to determine payment amounts for 2017. The current conversion factor for 2016 is $35.8043 and the 2017 conversion factor would be $35.7751, which is slightly lower despite the 0.5% update that was included in the Medicare Access CHIP Reauthorization Act (MACRA) legislation.

CMS justifies this lower update by proposing to include a budget neutrality adjustment of negative .51% to ensure budget neutrality. The additional payments proposed in the rule for services related to primary care, care coordination, behavioral health care, and extra expenses associated with treating patients with mobility impairments are estimated to increase spending under the physician fee schedule, leading CMS to make an across-the-board reduction to offset the projected increase.

The AAMC recognizes the importance of the proposed add-on payments for primary care and supports them. However, we question whether CMS has accurately projected the utilization for

these new codes in determining the increase in total spending under the fee schedule. In the past, CMS established codes for chronic care management (CCM) (CPT 99490) that were not used as frequently as projected due to burdensome service elements, billing requirements, and low payment relative to the resources involved in furnishing the services. CMS states in the rule (*81 Fed. Reg. 46207*) that "our assessment of claims data for 2015 for CPT code 99490 suggests that the CCM services may be underutilized." In particular, we believe that CMS estimates of the number of beneficiaries for the new mobility impairment code and the inputs need additional research before they can be properly valued. CMS should reconsider its estimates of utilization for these new codes in light of its experience with other similar new codes, such as the CCM code. We recommend CMS consider delaying implementation of the mobility impairment code until the Agency has obtained appropriate information about the costs associated with coverage for this service, including practice expense inputs and utilization.

DATA COLLECTION FOR GLOBAL SURGERY SERVICES

In the rule CMS includes a proposal for collection of data to revalue 10 and 90 day global surgical services in the future. In the MACRA legislation, Congress included a provision that called for CMS to gather information needed to value surgical services from a "representative sample" of physicians starting January 1, 2017. The law also gives CMS the authority to impose a 5% Part B penalty on physicians who do not respond to the request for information until the selected physician reports the requested information. Beginning in 2019, CMS must use the data collected about surgeries to revalue and refine the payment amounts for the surgical services.

Rather than complying with the statute to obtain information from a representative sample, CMS proposes a wide-ranging 3 pronged approach to collect the data. Through this approach, CMS plans to collect data on the frequency of preoperative and post-operative visits related to the surgery and the inputs that are involved for both work and practice expenses, such as equipment and supplies in furnishing these preoperative and post-operative visits.

CMS proposes to collect this information by:

1) Requiring all surgeons to provide information on claim forms regarding the number of pre-operative and post-operative visits and the level of intensity of those visits;
2) Conducting a survey of a representative sample of practitioners about the activities and resources used to furnish these services; and
3) Visiting facilities to directly observing the pre-operative and post-operative care provided to patients.

CMS proposes G codes that physicians would use to report pre-operative and post-operative visits on the claim form. The G codes included in the rule are based on whether the service is provided to the patient during an inpatient visit, an outpatient visit, or via phone or the internet and would distinguish the level of the visit as being typical, complex, or critical. In addition, the codes would be recorded based in 10 minute increments.

As an alternative, CMS requests feedback on the use of CPT code 99024 to report post-operative and pre-operative visits accompanied by a modifier to define levels. The AAMC's comments below were informed by discussions with a number of academic surgeons, each from a different specialty.

CMS Should Collect Data from a "Representative Sample" Using CPT code 99024

The AAMC understands the importance of collecting more recent information regarding the number of visits and types of services provided both before and after a surgery and then ultimately to refine, as needed, the payment amounts for these surgeries based on this new information. To do so it is essential that CMS collect accurate data and that the data collection effort not be overly burdensome to physicians. **The AAMC is pleased that CMS did not propose to implement the 5% withhold for Part B services of practitioners who fail to respond to a CMS request for information. However, we are opposed to the collection of data by reporting codes on the claim form from <u>all</u> practitioners who perform these global services, which is counter to the intent of Congress.** Specifically, section 523 of MACRA calls for CMS to gather information needed to value surgical services from a ***"representative sample"*** of physicians.

We are deeply concerned that the approach proposed by CMS will compromise the accuracy of the data collected and prove burdensome to physicians who will have to make major changes to their workflow while at the same time learning new codes and a new vocabulary. Instead of collecting data from all surgeons, the AAMC recommends that CMS follow Congressional intent and collect data from a "representative sample" that would include various geographic areas, practice types (including academic and nonacademic), practice sizes, and specialties. In addition, we recommend that CMS focus initial efforts on data collection on high volume surgical services, which have a Medicare volume of at least 10,000 claims or $10 million in allowed charges and have at least 100 separate physicians perform them.

As part of this data collection, we oppose use of the proposed G codes for the following reasons:

- **There is insufficient time to educate physicians on these new codes:** The time frame to educate physicians to report these new codes and include supporting documentation is not sufficient. The final rule will be issued around November 1, 2016 with an implementation date of January 1, 2017. Without appropriate education and outreach to physicians, clinical staff, and office staff regarding these new codes, data collected will not be accurate.

- **The 10 minute increments in the G codes is untenable:** With the exception of a few specialties, physicians do not think of providing care in terms of timed increments. Surgeons, in particular, are not accustomed to providing documentation of time for all pre and post-operative visits. To record work in 10 minute intervals will be a huge disruption to workflow. It also seems that CMS is limiting the data collection to face-to-face visits (either in-person or electronically). However, especially for surgeons who work at academic medical centers and often treat patients with many comorbidities, much of the

important patient care is also done when the physician is not in the room with the patient. For example, a surgeon may stop into see a patient for a post-operative visit, then step out to review the patient's pathology report, then review x-rays related to several patients, take a phone call from another physician about a different patient, or consult with other providers about several patients before coming back into the room. This workflow makes it challenging to track in 10 minute time increments and also to attribute a particular task to a particular patient. It also is unclear whether CMS intends to collect data on all of this effort which should be included to provide accurate values for the surgeon's effort. Finally, what is most important is medical decision-making which is not captured by time.

- **Electronic health records need to be changed in a short time frame:** The addition of new G codes would require modifications to electronic health records and billing systems. Problems can arise with respect to claims processing and billing when codes are non-payable. Sufficient time would have to be provided to test modifications to current systems to make sure that these new codes are processed correctly by the billing vendors and CMS which is not feasible by January 1, 2017.

- **The distinction between a typical and complex visit is not clear.** In the rule, CMS includes a table showing which tasks would be considered typical. The assumption is that if these tasks are performed, the visit would be considered "typical." However, this is not always the case. This description of services does not capture the complexity or medical decision-making required to provide a service. For example, changing a dressing for a laparoscopic procedure versus changing a dressing for an open wound is very different. Yet, changing a dressing is included as part of a typical visit without any specificity on the complexity of the patient. As another example, a transplant surgeon's post-operative visits would be considerably more complex with regard to medical decision-making but that complexity is not delineated in the description.

- **The G codes have not yet been tested for validity and reliability.** In the RAND Report, "Developing Codes to Capture Post-Operative Care," RAND recommends that the G codes be pilot tested prior to data collection to "better understand the complexity" of the coding task" and to assess interrater reliability (i.e. whether different physicians/NPPs apply the same code to the same vignette).

- **Physicians may not understand the importance of the reporting requirements and may not respond to CMS's request for information:** Given the short time frame it is likely that many surgeons may be unaware of the new reporting requirements and therefore may not report. If physicians do not report this information, the results would be inappropriately skewed toward a lower number of visits.

Based on discussions with a number of surgeons, the AAMC supports the use of CPT code 99024, instead of using G codes, to capture the number of pre-operative and post-operative visits. CPT code 99024 already exists and has been included in electronic health record

platforms, such as Epic. However, we believe that attaching a modifier to this code to capture information on the level of the visits would raise the same concerns as the use of the G codes. Therefore, we recommend that CMS have a "representative sample" of physicians report CPT code 99024 and then supplement the information on the frequency of visits with a survey of physicians that would request information on the level of post-operative visits.

If CMS decides to require the use of a modifier to capture level of visits with 99024, the AAMC recommends that the levels be determined based on the existing E/M codes which already are familiar to surgeons and are based on the complexity of the medical decision-making. Levels should **not** be based on 10 minute time increments or typical, complex, and critical descriptions as proposed for the G codes. Physicians are familiar with E/M services and therefore would be able to more accurately report levels if descriptions were consistent with these services. For the post-operative visits, we recommend that the modifier be used by the physician to report the level of the post-operative visit based on the medical decision-making component of the E/M services, which would be described as straightforward, low complexity, moderate complexity, or high complexity. For these post-operative visits, the documentation should support the level of medical decision-making but the physician should not be required to record all of the other components of the E/M, such as the full history.

It is also important for CMS to recognize that the post-operative care includes care coordination services furnished when the surgeon is not with the patient. A patient with multiple comorbidities or new diagnoses, such as cancer, may require coordination and consultation with a number of other providers, which will require significant extra time for the surgeon. As CMS collects data, these services should be accounted for in determining value and ultimately payment amounts for global surgery.

Modifiers Should Be Used to Identify Post-operative Visits Involving Residents

In the proposed rule, CMS is requesting information regarding whether special provisions are needed to capture pre-and post-operative services provided by residents. CMS also questions whether residents are functioning as hospitalists or resident surgeons. When a surgical resident is involved in the post-operative visits, he/she is functioning in the capacity of a surgical resident and is under the supervision of an attending surgeon. For example, post-surgery the resident may see if the patient is eating, drinking, able to go to the bathroom, and whether the wound is healing properly, review laboratory and radiological examinations, and discussing post-operative care with the patient. The attending physician would be overseeing these services that the resident is involved in providing. The patient's may also receive care from a hospitalists who may provide follow-up for a patient's comorbidities, such as managing the care for a diabetic patient post-operative.

Under the teaching physician guidelines for billing when a resident is involved in the patient's care, the teaching physician must be present during all critical or key portions of a visit to bill for the service. The teaching physician uses the GC modifier to code for those services. If the teaching physician is willing under the primary care exception, the GE code is used to indicate

that the teaching physician was supervising up to 4 residents beyond their initial 6 months of residency, and that the resident's services were levels 1, 2, or 3.

The AAMC suggests that CMS ask that teaching surgeons use the GC and GE modifiers in a similar way to identify those services in which surgical residents are involved. This will allow CMS to obtain information on the full scope of preoperative and post-operative services. After this information is analyzed, CMS can further discuss with stakeholders the way in which this information should be included in the valuation of the global services. To obtain accurate data on which services are being provided to the patient post-operative, the AAMC recommends that CMS ensure that CPT code 99024 accompanied by a GC modifier if the attending also is present, or the GE modifier if the resident provides the service without the presence, though still under the supervision, of the attending surgeon.

MEDICARE SHARED SAVINGS PROGRAM

ACO-43 Should Not be Added to the Quality Measure Set

In the proposed rule, CMS proposes several changes with respect to the Medicare shared savings program, including changes to quality measures, alignment with the new Quality Payment Program, and beneficiary attestation for use in attribution.

Specifically, CMS proposes to add three measures to the quality measure set. One of the new measures is ACO-43 Ambulatory Sensitive Condition Acute Composite (AHRQ PQI #91). The AAMC has significant concerns with the use of this measure in the shared savings ACO program. The Prevention Quality Indicators (PQIs) were originally designed by the Agency for Healthcare Research and Quality (AHRQ) to measure ambulatory sensitive conditions at a community level and the rate calculated per 100,000 population. Such a large sample size allows communities to evaluate their primary care system at a macro level. These measures were not tested or endorsed by the National Quality Forum (NQF) for use at the clinician level, where the population is much smaller. We have major concerns with applying measures that are intended to address overall admission rates at a population level to ACOs that have much smaller populations than 100,000.

These measures would penalize ACOs and physicians that treat complex patients with multiple chronic conditions because there is no appropriate clinical risk adjustment. Not accounting for the clinical variation in the underlying population disproportionately affects the ACOs and physicians who care for the most complex patients. As CMS states in the rule, this measure is used currently in the Value-based modifier (VM) program. In the 2015 Value Modifier Experience Report, groups that had patients with higher risk scores performed worse on this measure and were unfairly penalized as a result. As is true for many measures used in CMS quality programs, these measures should be subject to appropriate clinical risk adjustment prior to implementation in any program. In addition, as reasons for admissions and readmissions are often connected to the broader community, CMS should consider adding an adjustment or stratification to account for socio-demographic factors.

Further, an ACO is already accountable for costs and has an incentive to reduce admissions and readmissions. Therefore, use of an additional measure involving admissions and readmissions in the ACO program would be duplicative and inappropriate. We recommend that the issues related to risk adjustment and sociodemographic factors be addressed and that these measures be endorsed by NQF prior to implementation in the shared savings ACO program.

ACO-8: Risk-Standardized, All Condition Readmission, ACO-36, All-Cause Unplanned Admissions for Patients with Diabetes; ACO-37, All Cause Unplanned Admissions for Patients with Heart Failure; ACO-38, All Cause Unplanned Admissions for Patients with Multiple Chronic Conditions.

The AAMC is concerned with several of the measures included in the ACO quality measure set that are currently undergoing NQF review. Specifically, measures ACO-8, ACO-36, ACO-37, and ACO-38 are not risk adjusted for socioeconomic factors. There is overwhelming evidence that admissions and readmissions are strongly affected by community level factors. Measures that extend beyond the hospital stay or that are outside the control of the physician or ACO entity should be appropriately risk adjusted to account for these socioeconomic factors. Before using these measures in the ACO program and other programs, the developer and NQF should explore ways to assess and make adjustments for factors such as homelessness, community resources, available home supports, and other social risk factors.

CMS Should Finalize Its Proposal to Incorporate Beneficiary Preference into ACO Assignment

CMS proposes to allow Medicare beneficiaries the opportunity to voluntarily "align" with the ACO in which their primary care provider participates. CMS proposes to implement an approach under which it could determine which health care provider a Medicare beneficiary believes is responsible for coordinating his/her overall care (the beneficiary's "main doctor) using information that is collected in an automated and standardized way directly from beneficiaries. This beneficiary attestation approach would be available for ACOs participating in Track 1, 2, or 3 by spring 2017 unless the automated system in not available yet.

The AAMC commends CMS for proposing an automated process for beneficiaries to attest that their "main doctor" is in an ACO so that they can be assigned to that ACO for all ACO tracks. Although CMS would retain its current stepwise attribution process when considering the ACO to which a beneficiary should be attributed, we support having beneficiary attestation take precedence over that process. The beneficiary should remain attributed to that ACO until the beneficiary enrolls in Medicare Advantage, moves out of the ACO's service area, or attests to having switched to a new provider affiliated with another ACO.

Allowing beneficiaries to attest to the provider that they want to manage their care, will increase beneficiary engagement in their care. With a more defined and stable population, the ACO can better target specific interventions and manage and coordinate care for the beneficiaries for whom they are accountable. In addition, knowing the patient population prospectively would allow for more opportunity in the future for specific waivers for certain patients, such as the SNF

waiver of the 3 day hospital stay. In the future, we urge CMS to modify its beneficiary assignment policy to allow all ACOs to select either retrospective or prospective beneficiary assignment and to honor beneficiary choice through attestation.

IMPROVING PAYMENT ACCURACY FOR PRIMARY CARE, CARE MANAGEMENT SERVICES, AND PATIENT CENTERED SERVICES

CMS reiterates its commitment to supporting primary care and patient centered care management and its recognition of the need to improve payment accuracy for these services. The Agency acknowledge that there are limitations of the current code set that describes E/M services as it limits Medicare's ability to appropriately recognize the relative resource costs of primary are management/coordination and cognitive services.

CMS is proposing a number of changes to coding and payment policies, which include the following:

- Improve payment for care management services for beneficiaries with behavioral health conditions.
- Improve payment for cognition and functional assessment, and care planning for beneficiaries with cognitive impairment.
- Adjust payment for care visits furnished to beneficiaries whose care requires additional resources due to their mobility-related disabilities.
- Provide Medicare payments the CPT codes for non-face-to-face prolonged E/M services and increase payment rates for face-to-face prolonged E/M services.

CMS proposes specific codes that could be used in addition to the current E/M codes to recognize the different resources specific to primary care and other cognitive specialties in delivering ongoing treatment.

CMS Should Improve Payments for Primary Care and Cognitive Services by Finalizing Payment for These Services

The AAMC supports CMS' efforts to improve primary care and cognitive services and compensate physicians and other professionals for the work they perform managing care for Medicare beneficiaries with chronic conditions and behavioral health issues. Primary care is essential for moving to a system that coordinates health care delivery. Patients with complex chronic conditions require extensive care coordination that is non face-to-face. Yet the current payment system is not designed to reimburse for these activities that are required to furnish comprehensive coordinated care management for certain beneficiaries. Many patients with mental health issues access the health care system through primary care providers. Thus, it is important for primary care physicians to collaborate with psychiatrists and other mental health professionals on behalf of their patients with mental health issues. Ultimately, the integration of behavioral health services and general medical care through collaborative models can reduce costs and improve outcomes for these patients.

CMS Should More Closely Review Additional Resources Associated with Mobility Related Disabilities

While we are supportive of making adjustments to payment to account for additional resources due to mobility-related disabilities, we recommend that CMS consider delaying implementation of the mobility impairment code to allow more time to obtain information about the practice expense inputs and utilization of this code. Patients with disabilities are treated in a number of different settings in which they receive a variety of services, in addition to E/M services. Prior to implementing this proposal, we recommend that CMS examine more thoroughly the accommodations that physicians make to provide these services to patients in multiple settings and for different services.

AAMC Supports the Addition of the Complex Chronic Care Management Code (CPT 99487-99489)

In 2015, CMS implemented a separate payment for chronic care management (CCM) services under CPT code 99490. However, stakeholders have continued to express concerns with the CCM code saying that the service elements and billing requirements are too administratively burdensome and do not pay for the services rendered. Additionally, MACRA requires CMS to assess and report to Congress on access to CCM services by the underserved population which CMS found that CCM services are underutilized and are unable to determine the level of patient's complexity through this code. In recognizing these concerns, CMS proposes to reimburse for additional CPT codes for complex chronic care management.

The AAMC supports the addition of these new codes and appreciates that a variety of providers, in a variety of settings, have the option to bill for the services to address population health. The proposed codes will also give CMS insight on a patient's complexity. However, for the future, the AAMC recommends that CMS continue to evaluate the feasibility, utilization, and impact of the CCM codes.

Additionally, CMS needs to further simplify the CCM requirements to alleviate administrative burden. CMS proposes to retain some of the original service element requirements but also proposes significant revisions to other requirements to alleviate the administrative burden and improve payment accuracy. In the proposed rule, CMS states that a clinician no longer has to establish a face-to-face visit for any Medicare beneficiaries that the practitioner has already seen in order to start billing the CCM code. However, if the clinician has not seen the patient in over a year, a face-to-face visit must be established. Additionally, the practitioner is no longer required to include a structured clinical summary record for the structured recording requirements. Providers are also no longer required to obtain written agreement to have CCM services provided as a part of the beneficiary consent.

While the AAMC appreciates CMS's attempt to alleviate the administrative burden, the Association continues to have concerns with the following issues:

- Providers still have to be able to track all the requirements (patient's qualification for CCM code and 20, 60, or 30 minutes for the various CCM codes).
- Proper documentation of patient's authorization and knowing that the patient isn't seeking CCM services with another provider.
- The cost associated with billing and submitting claims will exceed the reimbursement costs.
- Changes in patient enrollment could negate eligibility.
- Logistics to comply with patient requests to be unenrolled from the program.

Further simplifying the documentation and reporting requirements for these codes would be a significant improvement. The AAMC also recommends convening stakeholders to consider how to reduce the administrative burden while not creating incentives for fraudulent behavior.

The AAMC Appreciates that CMS Proposes Additional Codes for Telehealth Services

CMS proposes additional CPT codes for end-stage renal diseases related services (ESRD) (CPT 90967-90970), advanced care planning (CPT 99497-99498), and telehealth consultations for patients requiring critical care services (CPT 99291-99292) to the list of telehealth services for CY 2017. The AAMC supports the addition of these new telehealth codes and the proposal in the rule to expand coverage of telehealth services. Telehealth innovations directly improve care coordination between providers and patients, and those that enhance access to care for populations that experience barriers to appropriate use of services, should be enabled broadly through the reduction of regulatory barriers and the adoption of appropriate reimbursement incentives. Use of telehealth services that bring providers into more effective collaboration but do not generate a face-to-face billable encounter warrant expanded use. Hence, the AAMC encourages CMS to continue to expand the list of eligible telehealth services in future rulemaking.

EXPANSION OF THE INFORMAL INQUIRY PROCESS TO ALLOW CORRECTIONS TO THE VALUE-BASED MODIFIER PROGRAM

In the proposed rule, CMS stated that re-running quality and resource use reports (QRURs) and recalculating quality and cost composites is not always practical and is operationally complex. Hence, CMS proposes to update the value modifier (VM) informal review process and policies to establish how the quality and cost composites would be affected for the 2017 and 2018 payment adjustment periods when an unanticipated program issue arises.

Furthermore, CMS highlights some of the errors or defects in the value-based modifier program that could result in inaccurate determinations of VM payment adjustments. Due to these errors identified during the information review process, CMS proposes the way in which the quality and cost composites under the VM program would be adjusted. CMS defines Category 1 as those groups that meet the criteria to avoid the CY 2017 PQRS payment adjustment as a group practice participating in the PQRS GPRO web in CY 2015 and groups in which at least 50% of the ECs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals. This category also includes those solo practitioners who avoid the payment adjustment as individuals. Category

2 includes groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1. The four different scenarios apply to groups that may shift from category 2 to category 1, errors found for groups that are non-GPRO web users under category 1, or other issues within Category 1 including claims and quality data issues. The proposed rule goes into further details as to how CMS will re-evaluate cost and quality scores depending on the scenarios that apply to the TIN.

In Light of the Importance of the Accuracy of this Information under MACRA's Quality Payment Programs, the AAMC is Concerned about CMS's Ability to Identify Errors

The AAMC has strong concerns regarding the significant errors identified by CMS as part of the VM informal review process that had an impact on payment adjustments to providers. Given the complexity of the new quality payment programs under MACRA, we question whether CMS has the systems in place to ensure that performance scores and payment adjustments are correct. MACRA's Merit-Based Incentive Payment System (MIPS) is far more complex than the VM program as it involves four performance categories. To make matters more complicated, there will be various TINs that will submit information for multiple clinicians within the TIN because the clinicians may be involved in numerous payment tracks. For example, TIN XYZ will submit GPRO web information for their clinicians reporting under MIPS but will also submit additional quality information for their clinicians participating in an Alternative Payment Model (APM). Therefore, it is imperative that CMS take steps to avoid errors. Feedback reports should provide objective information about performance with the broad aim of facilitating assessments and improving delivery of care. Additionally the accuracy, completeness, and timeliness of the data is particularly critical if physicians are to rely on the presented data as indicators of their need for quality improvement[1] and as determinative of future payment amounts. It is essential that CMS improves efforts in providing timely and accurate information.

Additionally, as a part of the Agency's improvement efforts in publicly reporting some of the QRURs' content, CMS needs to develop a process that effectively and efficiently updates and corrects information concerning the group practice on Physician Compare. The AAMC continues to hear of circumstances in which either the group information is incorrect or the wrong providers are affiliated with the group. Currently, correcting information is a challenging process and it may take CMS weeks before the information is refreshed on the website. The AAMC would be happy to work with CMS to develop a more streamlined process.

REPORTS OF PAYMENTS OR OTHER TRANSFERS OF VALUE TO COVERED RECIPIENTS

The AAMC appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS) request for feedback on the "Open Payments" program and commends CMS' efforts to identify areas in the rule that might benefit from future revision through rulemaking or guidance.

[1] ***http://www.ahrq.gov/sites/default/files/publications/files/privfeedbackgdrpt.pdf***

Nature of payment categories as listed at § 403.904(e)(2)

CMS has inquired as to whether the "nature of payment" categories are inclusive enough to facilitate reporting of all payments or transfers of value to covered recipient physicians and teaching hospitals and whether there should be further categorization of reported research payments. The AAMC has heard from member institutions that the lack of specificity in the nature of payment categories has led to apparent over-reporting or lack of critical contextual information, especially in the "in kind" category. The most common issue we have heard about is when a manufacturer provides the study drug for a large clinical trial and then reports the retail cost of that drug as an in-kind transfer of value attributed to the principal investigator. In the context of large multisite oncology trials, for example, the reported value of the study drug may be substantial, leading to a public report that erroneously suggests significant remuneration for a physician or institution. **The ability to further refine reports of in kind transfers of value would greatly enhance transparency, with additional categories such as "equipment," "study materials" for provided drugs or devices, or "editorial support" for when a company elects to report its own costs in assisting with the publishing process as a transfer of value to the investigator authors.**

Pre-vetting of Payment Information Prior to Reporting in Open Payments

CMS has suggested the addition of a new requirement for applicable manufacturers to "pre-vet" payment information with covered recipients and physicians owners or investors before reporting to the Open Payments system. The AAMC understands that pre-vetting the accuracy of large payments has been a helpful process in some cases and encourages applicable manufacturers to provide information directly to covered recipients in advance of reporting to Open Payments, especially to physicians, a high percentage of whom have not been participating in the review and dispute process. CMS should encourage those entities to contact physicians and teaching hospitals directly to verify the accuracy of payments that will be reported *outside of the Open Payments portal, and close in time to the actual transfer of value.*

However, we do not see the benefit of requiring through regulation a new process in advance of the review and dispute process to pre-vet certain or specific payments. CMS should provide recommendations to applicable manufacturers about the benefits of pre-vetting payments before reporting, including, perhaps, suggested threshold dollar amounts. But to add another compulsory step before the review and dispute period has the potential to increase burden of all parties and further compress the tight timeframes. We note that the review and dispute period must be at least 45 days, but can be extended with no rulemaking change, an alternative that should be considered.

The AAMC is also concerned that a compulsory pre-vetting process could make the resolution of payment disputes during the review and dispute period more difficult. We understand that connecting the appropriate representatives at companies and at teaching hospitals through the Open Payments interface to accurately verify in kind transfers of value connected with research grants, for example, has been a challenge. If a "pre-vetting" process was assumed to have been

completed but had not been verified with the correct individuals or departments, a GPO or applicable manufacturer might reasonably conclude that no resolution discussion or change to a pre-vetted reported transfer of value should be entertained during the review and dispute process.

Instead of a new formal pre-vetting process, **the AAMC strongly suggests that CMS: 1) extend the time period for the review and dispute period to ensure that there is ample opportunity to review and resolve issues before publication; 2) create a mechanism in the Open Payments system to flag certain reported payments during the review and dispute period as over a certain threshold; and 3) provide applicable manufacturers as well as covered recipients recommendations on pre-vetting payments, as well as a mechanism to facilitate this communication.**

Definition of a Covered Recipient Teaching Hospital

Like CMS, the AAMC recognizes that since implementation of the Open Payments program the reporting of payments or other transfers of value to a covered recipient teaching hospital (as defined at §403.902) has been challenging. The AAMC has received feedback from its members that the application of the current definition routinely leads to disputes in reported transfers of value when: 1) an academic institution does not own the clinical enterprise but sponsored research funds that go in part or in whole to a teaching hospital flow through the institution that isn't a covered recipient, and do not go directly to the teaching hospital (i.e., research payments are made to the university then dispensed to the teaching hospital); or 2) research payments are made to an institution's affiliated medical school that is a separate legal entity but reported payments are misattributed to the institution's affiliated teaching hospital that does not conduct research. These substantial issues seem to have less to do with the definition of a teaching hospital than with the consistent application of reporting practices when it comes to teaching hospitals. Of particular concern has been the identification of a teaching hospital through tax ID number, which has made it difficult to distinguish between payments that are routed to teaching hospitals from those that go to universities or other non-covered recipients that are affiliated in some way with a teaching hospital. **The AAMC recommends that CMS work with key stakeholders to develop additional guidance for applicable manufacturers related to these situations to ensure consistency in the application of the current definition and accuracy in the payments reported.**

Additionally, for the purposes of communicating with teaching hospitals both by CMS and applicable manufacturers, CMS should include a hospital's Medicare Provider number in addition to the hospital's name and address. This would ensure that the information CMS uses to validate its published list of teaching hospitals is up to date and accurate. It would also help distinguish teaching hospitals that fall under the same corporate umbrella (i.e., that have the same tax ID number).

Verification of Receipts of Payments or Transfers of Value to Teaching Hospitals

The AAMC commends CMS' commitment to "ensure that all published Open Payments data is valid and reliable" and shares the concern that the level of detail provided with a reported

payment or transfer of value to a teaching hospital rarely has sufficient context to allow appropriate individuals at the hospital to understand, verify, or dispute the reports. In the AAMC's June 2, 2014 letter related to the Open Payments review and dispute process, we emphasized the importance not only of providing meaningful context around final reported payment information, but also ensuring that the review and dispute process allows the reported payments or transfers of value be seen by the right individuals at the institution:

"The key to transparency is ensuring that the information in question is accurate and presented in a meaningful and useful context. … Congress, individuals and institutions who will be listed in the database, and the American public need to know that the information ultimately presented has been reviewed by those who are the subjects of the reports and that CMS has taken every opportunity to confirm that the database more faithfully represents transparency into the relationships between manufacturers and health care providers."[2]

The AAMC supports the Agency's suggestion to include additional required non-public text fields to assist in the review and affirmation or dispute of payment reports. These should include at a minimum contact information (name, email, institution, department) for individuals at the teaching hospital that the applicable manufacturer knows were involved in the receipt of the payment or other transfer of value to facilitate the provision of that information to the appropriate internal contact from the authorized representative of the hospital. In addition, the AAMC recommends that reported payments to teaching hospitals also include non-public information about the specific contact person at the manufacturer (e.g., name, email, phone, department name) that has enough context about the initial payment to be able to quickly answer questions or help resolve a dispute. This additional information would facilitate communication between the covered recipient and manufacturer within the 45-day review period, before publication of the data. The need for effective and efficient communication between a covered recipient and applicable manufacturer during this brief period, is critical to ensure that the information published on the Open Payments website is accurate. Further, including additional context around payment information as recommended above would greatly enhance the ability for authorized representatives to verify payments across their institution. These additional facilitation steps would increase the accuracy of information in the Open Payments system, instilling public confidence in the information reported on the Open Payments website as well as the benefit of the review and dispute process.

We further propose that the Agency include a publicly available identifier unique to each physician (e.g., medical license number) to ensure that the information published is consistent and accurate and minimize the potential for mismatched names and payments. This is especially important for medical schools and teaching hospitals who use the Open Payments database as a tool to evaluate the accuracy of their physician's disclosures and reported payments.

[2] AAMC Comment Letter, June 2, 2014 (available at https://www.aamc.org/download/380688/data/ombcmsonsunshinecollection-june22014.pdf).

Improving Oversight, Compliance, and Enforcement

CMS has requested suggestions on how to make the process more efficient and facilitate its role in oversight, compliance, and enforcement. **In addition to our previous recommendations, we suggest that CMS consider the following:**

- **Explore ways to decrease the amount of time it takes physicians and authorized officials to register in the CMS Enterprise Portal and the Open Payments systems and address specific difficulties reported to CMS through the help desk and direct feedback from system users**. Efforts to reduce this timeframe would decrease administrative burdens as well as frustration with the review and dispute process and the Open Payments system, and increase physician participation in the process.

- Add a mechanism into the Open Payments system to allow physicians and teaching hospitals to follow up to get more information about a payment without lodging a dispute. We have heard from many members that since the only option is to dispute a payment or affirm it through silence, both physicians and authorized representatives for teaching hospitals have had to dispute payments simply as a mechanism for getting more information, an inefficient process that makes it impossible for a manufacturer to distinguish between inquiries and disagreements and also gives CMS and the public an incomplete understanding about how many reported payments are actually disputed, as opposed to simply lacking sufficient context to understand why it was included.

The AAMC believes that continuous engagement and input from key stakeholders is essential to uphold the overall goals of transparency and accountability of the Open Payments program. We appreciate CMS' efforts to reassess the concerns related to this rule and look forward to engaging with CMS and AAMC member institutions to support these efforts.

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Under the law, as a condition of payment to a provider who furnishes imaging services, the health care provider ordering advanced diagnostic imaging services must consult AUC. This would involve entering patient clinical data into an electronic decision tool, referred to as a CDSM, to obtain information on the appropriateness of the services. The AUC must be developed or endorsed by national medical professional societies or other provider-led entities. The results of the AUC consultation must be documented on the claim submitted by providers furnishing imaging services in order to be paid by Medicare.

This rule proposes the requirements and process for specifications of qualified CDSMs under the Medicare AUC program; the initial list of clinical priority areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. CMS proposes to announce the first list of qualified CDSMs no

later than June 30, 2017 and anticipates that furnishing providers could begin reporting AUC information starting January 1, 2018. CMS proposes a delay in the timeframe for providing this information to January 1, 2018 at the earliest because the Agency is still developing CDSM criteria.

The AAMC supports the use of clinician developed, evidence-based AUC to improve the quality of care. We commend CMS for recognizing the complexity of this program and delaying the date for the required consultation with CDSMs. The AAMC urges CMS to provide sufficient time after the CDSMs are announced for providers to comply with this program. There is a need to engage providers and their staffs about the guidelines, introduce them to the CDSM software, modify their work flow patterns, update their EHRs, and pilot test the systems to gradually build up the program. There is a need to engage the providers who furnish advanced imaging services and their staff to ensure that the AUC was consulted before scheduling a diagnostic test. Given these challenges, the AAMC recommends that CMS delay the implementation time frame until the middle of 2018 at the earliest.

As CMS further develops this policy, we request that the following concerns also be addressed.

- The impact this policy will have on providers who furnish imaging services. The imaging providers will have limited control over whether the ordering professional consulted a CDSM as required. Yet, if the ordering professionals does not consult the AUC, the imaging professional would not get paid for the services. We urge CMS to consider allowing the imaging provider to use the AUC themselves, if appropriate, as a way to demonstrate that the test was warranted. This will also allow CMS a way to pay those providers for the service and will avoid linking payment to the actions of another provider over whom they have no control.
- CDSMs need to be designed so that they are easy to use. Providers would prefer CDSMs that can be used quickly and efficiently and that are integrated with their electronic health record system. It is frustrating to providers if they are required to click out of their electronic health record system and go through an entirely new platform to order imaging services. We commend CMS for allowing flexibility in the proposed rule regarding requirements associated with integration of CDSMs in EHRs.

MEDICARE DIABETES PREVENTION PROGRAM

The Medicare Diabetes Prevention Program (MDPP) is a structured health behavior change program delivered in community and healthcare settings by trained community health workers or health professionals. The program targets individuals with prediabetes and consists of 16 intensive “core” sessions of a CDC approved curriculum in a group based setting that provides practical training for overcoming challenges to sustaining weight loss and a healthy lifestyle. The primary goal of the intervention is to have at a least 5% average weight loss among participants.

The AAMC commends CMS’s efforts in expanding models to promote prevention practices and promote population health. Furthermore, CMS has determined that the MDPP model improves

quality of patient care without limiting coverage or benefits which is also notable. However, the AAMC encourages CMS to establish more flexible requirements for the first year in order to allow adequate time to implement and encourage participation. Taking steps such as easing the application and reporting requirements will alleviate the administrative burden. Additionally, CMS should continue to assess both the cost effectiveness and success of the programs at a national level.

The AAMC Recommends that CMS Establish a More Flexible Payment Structure

CMS proposes payment for MDPP services to be tied to the number of services attended by beneficiaries and the achievement of a minimum weight loss of 5% of each beneficiary's baseline weight. The MDPP suppliers would be required to attest to beneficiary session attendance and weight loss at the time claims are submitted. CMS proposes that claims for payment would be submitted following the achievement of core session attendance, minimum weight loss, maintenance session attendance, and maintenance of minimum weight loss. Hence, suppliers would not be able to submit another claim after session 1 until the beneficiary has completed four sessions.

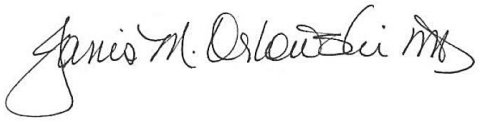
The AAMC is concerned that the payment structure is too stringent and will disincentivize organizations from participating. The Association recommends that CMS initially determine an organization's payment amount by the number of classes beneficiaries attend and continues to attend followed by other achievements. This step will allow for a sufficient transition time to implement necessary infrastructure and operational changes in order to have a meaningful impact on a pre-diabetic patient. Additionally, weight loss is dependent on many factors and occurs at different weights for each individual, many of which will not be under the control of the supplier. Weight loss also not the only marker of success in terms of improving a pre-diabetic patient's health. Factors such as tracking eating habits and exercise activities are also primary contributors to successfully tackling pre-diabetic complications.[3] Hence, CMS should seek feedback from stakeholders such as the American Heart and Stroke Association and American Diabetes Association to establish appropriate measures of success.

[3] http://www.heart.org/HEARTORG/Conditions/Diabetes/AboutDiabetes/Prevention-and-Treatment-for-Pre-diabetes_UCM_461557_Article.jsp#.V7tdR_krLRZ

Conclusion

The AAMC appreciates your consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org or Tanvi Mehta at tmehta@aamc.org. For questions related to Open Payments Program please contact Heather Pierce at hpierce@aamc.org

Sincerely,



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