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Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS–1656-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Mr. Slavitt:

Re: CY 2017 Outpatient Prospective Payment System (OPPS) Proposed Rule, File Code CMS–1656–P

The Association of American Medical Colleges (the AAMC or Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or Agency's) proposed rule entitled, "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting; Organ Procurement Organization Reporting and Communication; Transplant Outcome Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program," 81 *Fed. Reg.* 45604 (July 14, 2015).

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, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 160,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The major issues that the AAMC will address in this letter include:

- **The implementation of section 603 of the Bipartisan Budget Act of 2015 (BiPA).** The CMS proposal that during 2017 hospitals will receive no payment for services provided in hospital outpatient departments (HOPDs) that fall under section 603 provisions is untenable and should not be finalized. CMS also should not finalize its restrictive

proposals that will not provide payments under OPPS if remote HOPDs relocate or add services outside those provided as of November 2, 2015. Teaching hospitals treat large numbers of vulnerable Medicare beneficiaries at these remote HOPDs and need flexibility to continue to provide them with the best care and at locations that are most convenient to them.

- **Elimination of the L1 Modifier.** AAMC generally agrees with CMS's proposal to eliminate the L1 modifier. However, we oppose packaging unrelated lab tests that will likely result in inadequate reimbursement for lab services, particularly those that are not associated with a primary service. CMS's proposal to change lab packaging from the same date to the same claim is likely to exacerbate this problem.
- **Expansion of "Q1" and "Q2" packaging.** The AAMC opposes the expansion of the "Q1" and "Q2" packaging policy from the same date of service to the same claim because the proposal will have a greater negative impact on teaching hospitals since they treat a higher share of sicker and more complex patients who require more packaged services. The proposal is especially problematic when the packaged "Q1" and "Q2" services have a geometric mean cost greater than $100, which may cause significant underpayment when high-cost ancillary services are provided on the same claim with lower-cost primary services. To ensure adequate reimbursement, the Association also calls on CMS to explore developing composite APCs that provide a composite or tiered payment when two or more pathology services are billed on a claim without other separately payable services.
- **Changes to hospital quality reporting**. New quality measures proposed for the Outpatient Quality Reporting (OQR) program should first be fully vetted by the National Quality Forum (NQF) and reviewed under the NQF's sociodemographic status (SDS) trial period. The AAMC supports CMS's proposal to decouple performance on the HCAHPS survey's pain management questions from value-based purchasing (VBP) payments. The Association requests that these measures be temporarily removed from the survey and from Hospital Compare until new pain measures are developed.

In addition, the AAMC will comment on the following:

- Changes to the Electronic Health Record (EHR) Incentive program;
- The request for information regarding the removal of total knee replacement from the Inpatient Only list; and,
- Changes in the organ transplant program to make additional organs available.

The following are the AAMC's comments on selected proposals in the rule.

CMS SHOULD NOT IMPLEMENT SECTION 603 OF THE BIPARTISAN BUDGET ACT OF 2015 IN A WAY THAT PENALIZES HOSPITALS THAT NEED TO RELOCATE OR ADD NEW SERVICES FOR BETTER PATIENT CARE, OR THAT WILLNOT PAY FOR SERVICES DURING 2017

HOPDs Are Essential Sites of Health Care and Should Not Face Reimbursement Reductions

The AAMC is extremely concerned about the impact of reductions in HOPD reimbursement as this will lead to a reduction of services that affect vulnerable patient populations—especially those with complex medical problems--that receive care there, and may limit the ability to fully train the next generation of health professionals in these outpatient settings. Currently, Medicare recognizes that physician offices and HOPDs are both essential care settings in the health care landscape and that they differ from each other in key ways that warrant different payment methods and rates. The AAMC believes the payment differential appropriately accounts for the differences in the types of patients treated, services provided, and regulatory burden at HOPDs. Additionally, HOPDs are frequently the sole sources of care for low-income and otherwise underserved populations of Medicare beneficiaries, accepting patients who otherwise face difficulty being seen in physician offices. HOPDs need to meet the myriad regulatory requirements, including compliance with hospital conditions of participation and must provide stand-by care not provided in a physician's office. In short, HOPDs are comprehensive and coordinated care settings for patients with chronic or complex conditions. Many centers of excellence are based in hospital settings and provide outstanding team-based, patient-centered care and HOPDs provide wraparound services, such as translators and other social services.

CMS Should Not Penalize Providers That Relocate or Expand their Remote Outpatient Departments

The AAMC strongly opposes the CMS proposals that if the off-campus provider based department moves or relocates from the physical location that was listed on the provider's hospital enrollment form as of November 1, 2015, then neither the PBD nor the items and services provided there would be excepted; in other words, all payment would be under the alternate payment system rather than under OPPS. The Association also opposes the CMS proposal that payment under OPPS would only be made for the provision of items and services that were furnished and billed prior to November 2, 2015 and that any items and services that are not part of a "clinical family" of services also would not be payable under OPPS.

As justification for the relocation proposal, CMS expresses concern that if it were to allow excepted off-campus PBDs to move to larger facilities, "hospitals would be able to . . . purchase additional physician practices, move these practices into the larger relocated facilities, and receive OPPS payment for services furnished by these physicians, which we believe section 603 of Public Law 114-74 intended to preclude." (81 *Fed. Reg*. 45684). If CMS believes that this is likely, then it should craft a proposal designed to prevent this particular behavior. Instead, the overly broad proposal by the agency will unfairly penalize HOPDs and the patients they serve.

CMS asks for comments on whether the Agency should allow relocation in very limited situations, such as when a natural disaster occurs or a hospital experiences extraordinary circumstances. **There is no indication in the statute that CMS has the authority to apply limitations on relocation or service expansion on facilities that furnished covered OPD services prior to November 2, 2015. Therefore, CMS should not finalize this proposal.** However, should the Agency proceed, then AAMC suggests that CMS apply a different standard. An off-campus PBD

should not lose its excepted status if the relocation results in better, more accessible care to the beneficiaries. Circumstances under which relocation should be allowed and encouraged would include improving facilities and services to better meet the needs of the hospital's changing community, or issues outside of the hospital's control, such as buildings that are in disrepair. Relocation also may occur if rent on the off-campus HOPD is raised to an unreasonable amount. This may be likely to occur when landlords realize that hospitals HOPDs are being "held hostage" by CMS rules on relocation. Off-campus HOPDs tailor the services they provide in response to the needs of their communities and payment cuts to HOPDs will directly impact these communities. In addition, rapid advances in technology and treatments demand that HOPDs change in order to offer state of the art services to patients. These changes necessitate expansion of existing buildings and items or services that were not previously billed for under the OPPS. HOPDs should not lose their ability to bill under the OPPS if they choose to expand services in response to changes in clinical care and the needs of their patients.

The AAMC strongly urges CMS not to finalize its proposals that would not allow payment under OPPS if a PBD is relocated or if new services, or new families of services, are added as doing so is beyond the statutory authority granted by Congress. Nonetheless, if the Agency decides to finalize the proposal, it should recognize that making newer facilities and additional services available to patients can lead to better care that is designed to meet the needs of the hospital's patient population. The payment system should encourage hospitals to move or expand their facilities, and offer new services when doing so is to the benefit of Medicare beneficiaries. The AAMC also is concerned that a consequence of the CMS proposal is that they will affect facilities that were under development on November 2, 2015. The AAMC urges CMS to accommodate these facilities in the final rule.

CMS's Inability to Develop an Alternate Payment System for PBDs by January 1, 2017 Means the Agency Must Delay Implementation of Section 603 Until a System is Proposed and Subject to Notice and Comment Rulemaking

In its effort to implement Section 603 of the Bipartisan Budget Act of 2015, CMS is proposing to only pay physicians and other practitioners using the physician fee schedule for items and services furnished in new off-campus provider-based departments (PBDs). Currently, under OPPS, when a patient receives services in a hospital outpatient department, the HOPD is paid a "technical fee" while physicians are paid under the Medicare physician fee schedule (MPFS) at the facility rate. However, the Agency notes that "at this time, there is no straightforward way to [provide a mechanism for an off-campus PBD to bill and receive payment for furnishing nonexcepted items and services] before January 1, 2017." While CMS works to determine the appropriate "applicable payment policy," as directed by Congress, the Agency is proposing that, beginning January 1, 2017, "payment would be made for applicable nonexcepted items and services to the physician or practitioner under the MPFS at the nonfacility rate because no separate facility payment would be made to the hospital." (p. 45689).

Proposing that hospitals will receive no payment, other than what they might negotiate with physicians, is untenable. Not only does it create the possibility that hospitals will suffer a financial hardship, but also that beneficiaries in some areas may find access to care is decreased because of this policy. Training opportunities for medical students and residents

in these ambulatory sites also may be limited. It was not the intent of Congress that hospitals not be paid for items and services during 2017. Rather, Congress directed that Medicare pay the hospital for services furnished in new "off-campus outpatient department of a provider" (PBDs) that began furnishing services after November 2, 2015 under an existing payment system other than the OPPS. If CMS is not able to pay hospitals for services in new off-campus PBDs by January 1, 2017, then the only approach is to delay the implementation of this provision until the Agency has made the "numerous complex systems changes" that are needed. Should CMS choose to develop a new payment system there also must be an opportunity for it to be subject to notice and comment rulemaking. A delay in implementation of this provision will give CMS time to gather and digest stakeholder feedback; address complex issues that will occur when outpatient items and services are paid for under two payment systems that are built on different principles; ensure that systems are in place to operationalize such a dramatic change in payment policy; and, provide adequate outreach and training to providers about the changes. A delay also will safeguard seamless access for beneficiaries to needed healthcare services not accessible elsewhere.

To Ensure that PBDs that are Not Excepted Will Be Eligible for the 340B Drug Pricing Program, CMS Should Clarify that Hospitals Will Be Able to Report These Off-Campus PBDs on their Cost Reports as Provider-based Departments

Congress created the 340B Drug Pricing Program in 1992 to allow certain safety-net hospitals (known as covered entities) to purchase outpatient drugs at a discount from drug manufacturers, "to stretch scarce Federal resources" and expand health care services to vulnerable populations. In the decades of the program's existence, the savings produced by the 340B program have become essential to hospitals as they struggle to meet the needs of the communities and patients they serve in an era of rapidly escalating drug prices. Hospitals use the savings from the 340B program to provide free or low-cost prescription drugs and to expand services and programs to low-income, uninsured patients.

Consistent with the original and continuing intent of the 340B program, AAMC-member teaching hospitals and their clinical faculty, residents, and students are committed to this safety net mission in expanding access to care for underserved and vulnerable patients. While they represent only five percent of all hospitals, major teaching hospitals account for 25 percent of all Medicaid discharges, 18 percent of all Medicare discharges, and 37 percent of the country's charity care. Compared with physician offices and other hospitals, major teaching hospitals provide care to a higher proportion of low-income, dual-eligible, disabled, and minority patients. As major referral centers with highly specialized expertise, these academic medical centers serve a sicker, more complex, and more vulnerable patient population – patients who often are unable to seek the necessary care elsewhere.

Section 603 made no changes to the 340B program, an acknowledgement by Congress that these off-campus PBDs are provider based. Therefore, the Association asks that CMS also acknowledge that section 603 makes no changes in the status of these off-campus PBDs. Further, since the main providers of these off-campus PBDs will continue to report costs and revenues on the appropriate lines of the Medicare cost report, the change in the payment calculation methodology for facility services will not change the fact that costs and revenues will still be appropriately reported in the

cost reports. **Although there is nothing in either the proposal or the legislation that has an impact on continued 340B eligibility of these facilities, we request that CMS confirm that the new off-campus PBD remains reimbursable on the Medicare cost report and therefore will retain eligibility for the 340B drug discount program. The AAMC also urges CMS to work with the Health Resources and Services Administration (HRSA) to align all proposals that may have an impact the 340B program. Any changes that limit hospitals' ability to purchase drugs under the 340B program would cut services to under-served communities**.

Need to Revise 250 Yard Requirement for HOPDs to Have Provider-Based Status

To better serve their communities, and often due to their geographic locations in cities, many academic medical centers have no choice but to locate HOPDs close to the main provider campus, but beyond the 250 yards of the main buildings of the main provider as required in the regulations at 42 CFR §413.65(a)(2). To ensure that academic medical centers and the beneficiaries they serve are not unfairly disadvantaged by this requirement, the AAMC requests that CMS work with stakeholders to better understand their concerns and engage in notice and comment rulemaking to revise the requirement.

MEASURES PROPOSED FOR THE OUTPATIENT QUALITY REPORTING PROGRAM

In the CY 2017 rule, CMS outlines changes to the hospital OQR program which would take effect starting CY 2020. The Agency proposes two new outpatient claims measures, *Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Treatment* (OP-35), *Hospital Visits after Hospital Outpatient Surgery* (OP-36), and five new measures from the Outpatient and Ambulatory Surgery (OAS) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey for inclusion in the OQR program. CMS did not propose to remove any measures from the OQR program in this rule. **A detailed description of these measures and the AAMC's recommendations follow.**

Identifier	Measure	NQF Endorsed?	MAP Approved?
OP-35	Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Treatment	No	Support on the condition that the measure be NQF endorsed and reviewed under the NQF's SDS trial period. These conditions have not been resolved.
OP-36	Hospital Visits after Hospital Outpatient Surgery	Yes	Yes. However, concerns were voiced by some members that the measure should be reviewed under the SDS trial period.
OP-37a – OP-37e	Five Measures from OAS CAHPS Survey	No	The MAP previously reviewed the OAS CAHPS survey in CY 2014 when they were not fully developed. CMS did not

Identifier	Measure	NQF Endorsed?	MAP Approved?
			resubmitted the "fully developed" survey for additional consideration.

CMS Should Justify Deviations from Recommendations made by the Measure Applications Partnership (MAP)

The Measure Applications Partnership (MAP) is a multi-stakeholder group created under the Affordable Care Act (ACA) that provides input to CMS regarding quality measures used in all CMS quality reporting and payment programs. This is the fifth year that the MAP has provided feedback to the Agency. In the CY 2017 rule, CMS proposed measures for the OQR program that were supported by the MAP with conditions, with recommendations, or were undeveloped when they were first reviewed. The AAMC supports CMS obtaining early feedback for measure concepts from the MAP. However, CMS should not propose new measures for any quality program unless the MAP has had a chance to review the fully developed measure specifications. The AAMC urges CMS to address and resolve the conditions set forward by the MAP before they are proposed for a reporting program.

The Outpatient Chemotherapy Treatment Measure (OP-35) should be NQF Endorsed and Reviewed under the NQF SDS Trial Period

CMS proposes to add the *Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Treatment* measure (OP-35) to the OQR program starting CY 2020 payment determination. OP-35 is a claims based measure that separately calculates all inpatient admissions and ED visits for 10 conditions (anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, and sepsis) for 30 days following outpatient chemotherapy. The measure applies to Medicare fee-for-service beneficiaries 18 years and older. As noted above, this measure has not been NQF endorsed, has not been SDS reviewed, and has not met the approval conditions outlined by the MAP.

The AAMC agrees that this is an important measure concept and that there should be a greater focus on reducing preventable return visits for patients receiving chemotherapy treatments. However, CMS needs to ensure that this and other quality metrics are fully vetted by outside experts, especially the NQF, to ensure that they are accurate, valid, and actionable. We have heard concerns from AAMC member institutions that while the measure is adjusted for the type of cancer, it is not adjusted for the stage/severity of cancer. As an example, the care pathways and expected utilization patterns for a breast cancer patient with ductal carcinoma in situ (DCIS) would be very different from those of a breast cancer patient with metastatic cancer. The NQF expert panels are the appropriate venue to address these and other questions. Until such a discussion occurs, relevant stakeholders do not have the necessary information to make a critical assessment as to whether a measure is appropriate for public reporting.

The Hospital Visits after Hospital Outpatient Surgery Measure (OP-36) should be Reviewed Under the NQF SDS Trial Period

CMS proposes to add the *Hospital Visits after Hospital Outpatient Surgery* measure (OP-36) to the OQR program starting CY 2020 payment determination. This is a claims based measure that assesses all ED visits, inpatient admissions, and observation stays that occur up to 7 days following outpatient surgery for Medicare Patients 65 and older. Unlike OP-35, this measure calculates a single rate for all patient return visits. This measure was NQF endorsed, and was recommended by the MAP for inclusion in the OQR program on the condition that the measure be considered in the SDS trial period, which has not yet occurred.

The AAMC supports public reporting of return visits following outpatient surgeries and appreciates that CMS has obtained NQF endorsement before submitting the measure through rulemaking. However, the Association has concerns that performance on this measure may be heavily influenced by factors outside of the hospital's direct control. Patient populations who do not have family or home care aides, or ready access to pharmacies for medications may be more likely to return to the ED compared to patients with these benefits. The AAMC believes that this measure should be reviewed by the NQF's SDS trial to determine whether there is a conceptual and empirical relationship between the measure's outcomes and SDS factors before it is publicly reported.

AAMC Does Not Support Inclusion of the Outpatient CAHPS Survey Questions

CMS proposes to add five measures from the Outpatient and Ambulatory Surgery (OAS) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey to the OQR program starting CY 2020 payment determination. Any patient 18 years and older who undergoes a same day surgery or procedure would be eligible to receive the outpatient survey. Three of the five proposed OAS CAHPS measures, listed below, are composites consisting of at least six separate questions. The other two measures are global measures.

OP-37a: OAS CAHPS – About Facilities and Staff [6 question composite]
OP-37b: OAS CAHPS – Communication about Procedures [5 question composite]
OP-37c: OAS CAHPS – Preparation for Discharge and Recovery [9 question composite]
OP-37d: OAS CAHPS – Overall Rating of Facility [Global rating question]
OP-37e: OAS CAHPS – Recommendation of Facility [global rating question]

CMS did not discuss how the questions would be displayed on the Hospital Compare website and noted that this would be discussed in future making if the measure is finalized. The OAS CAHPS survey measures are not NQF endorsed.

The AAMC supports the use of feedback surveys to assess the overall quality of patient care. However, the Association has serious concerns with the proliferation of these surveys across settings and the potential unintended consequences that may result from an over-surveyed patient population. Currently, there are patient-experience of care surveys for physicians, hospitals, nursing homes, and home health agencies. In addition to the OAS CAHPS, CMS has implemented the HCAHPS for inpatients and is testing an ED survey. Those who receive overlapping care in

these settings could receive multiple surveys, leading to confusion for the patient as to which clinicians or facilities are being assessed. Compounding this problem is the fact that surveys are not distributed until days or even weeks after patients have received care.

In addition, the AAMC is concerned that mail and telephone surveys, the way in which the CAHPS surveys are currently distributed, are both expensive to administer and are no longer the methodology of choice for certain patient populations. The cost associated with a mailed survey prevents hospitals from sampling a larger population of recent patients, thereby having a negative impact on their ability to respond to concerns at the provider and unit level. CMS should consider allowing patients to choose an option to receive these surveys electronically, which would allow hospitals to collect feedback from a larger sample and would give patients the flexibility to choose the methodology that works best for them.

The AAMC does not support the inclusion of another patient experience survey until these issues are resolved. The Association strongly recommends that CMS convene a stakeholder group of providers, consumers, venders, and other relevant parties to discuss the CAHPS survey questions holistically to address how these surveys should be distributed in the future, prioritize the development of these survey tools to a limited subset of provider settings, and determine how to manage the issue of overlapping care. Finally, these survey measures should be NQF-endorsed and approved by the MAP before they are proposed for inclusion in the OQR program.

PROPOSED CHANGES TO THE HOSPITAL VALUE BASED PURCHASING PROGRAM

In the proposed rule, CMS notes its intention to remove the HCAHPS pain management questions from the hospital VBP program for payment purposes starting FY 2018. The AAMC thanks CMS for addressing stakeholder concerns on this critical issue and for separating the questions from performance in the Hospital VBP program. No changes, however, are proposed to the requirements for the HCAHPS measure in the Inpatient Quality Reporting (IQR) program, to the HCAHPS star rating calculation, or regarding public display of HCAHPS performance on the Hospital Compare website. Therefore, we presume it is CMS's intent that the HCAHPS pain management questions will continue to be required under the IQR Program and the results publicly displayed on the Hospital Compare website.

The AAMC believes that pain management experience measures are an important aspect of patient care, and appreciate that CMS is in the process of developing alternative pain management questions for the HCAHPS survey. CMS has stated that these questions will be proposed for stakeholder review in future rulemaking. That being said, the Association remains very concerned that the continued requirement that hospitals report the current HCAHPS pain management questions under the IQR program may still lead to potential over prescribing of opioids to at-risk patient populations, regardless of whether the responses are tied to payment under the Hospital VBP program. As a necessary precaution – and on a temporary basis until the alternative pain management questions are developed – the AAMC requests that CMS suspend the requirement that hospitals report the HCAHPS pain management questions and that they be excluded from display on the Hospital Compare website and from calculation of the HCAHPS star ratings.

LAB PACKAGING POLICIES

The AAMC Supports Discontinuing the Use of the L1 Modifier; But Generally Does not Support the Packing of Unrelated Lab Tests

Under current policy, CMS packages laboratory tests with certain exceptions. One of these exceptions is for unrelated laboratory tests defined as "tests on the same claim as other hospital outpatient services, but are ordered for a different diagnosis than the other hospital outpatient services and are ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services." Hospitals bill and receive separate payment for unrelated laboratory tests using ''L1'' modifier on the claim. CMS proposes to discontinue the unrelated laboratory test exception (and the ''L1'' modifier) for two reasons: (1) hospitals have found it difficult to determine when a laboratory test has been ordered by a different physician and for a different diagnosis than the other services reported on the same claim and (2) a different diagnosis and different ordering physicians do not necessarily correlate with the relatedness of a laboratory test to the other HOPD services that a patient receives during the same outpatient visit.

The purpose of packaging is to make a single payment for all services and supplies that are "integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services." When a service is unrelated to another service, it does not meet the packaging criteria and should always be separately paid. Even when services meet the criteria for packaging, the AAMC generally believes that packaging can only be justified in those circumstances where the packaged item is low cost and/or commonly furnished with the principal procedure such that its costs will be reflected in the data that CMS uses for rate setting. In circumstances where a service will be higher cost and not commonly furnished with the principal service that the beneficiary is receiving, the claims data will not reflect the cost of the ancillary procedure. Therefore, the ancillary service should continue to be paid separately to avoid the potential for a high cost service being packaged with a principal service that may be of comparable or even less cost than the ancillary service. **The AAMC does not support packaging services unrelated to another outpatient hospital service being billed on the same claim.**

The AAMC also believes the proposed rule underestimates the cost of separate billing of laboratory services using the L1 modifier and that the proposed policy will result in packaging between $39 and $43 million requiring an adjustment of between 0.06 and 0.09 percent to OPPS rates to ensure budget neutrality. Our data consultant, Watson Policy Analysis, arrived at this estimate using the following methodology:

1. Using the OPPS rate-setting data for CY 2017 (2015 claims data), we selected OPPS claims (billtype 13X).
2. With the claims from the previous step, we identified all laboratory procedures (Q4 status indicator) with an L1 modifier indicating that it is an unrelated laboratory test.
3. Using the claims from the previous step, we identified if there was a separately payable procedure on the claim. We identified separately payable OPPS procedures having a status indicator: S, T, V, J1, J2, Q1, Q2, or Q3 consistent with the CY 2016 Final Rule Claims Accounting in the description of how to handle laboratory tests with a Q4 status indicator.
4. We computed the total cost for the lines which met all of the following criteria:

a. On Billtype 13X
b. Have an L1 modifier
c. On a claim with a payable OPPS code

Using this methodology resulted in the calculation of an estimated total cost of approximately $39 million. However, this analysis was conducted on data that is used for the proposed rule which contains only claims processed through December 31, 2015. Due to the time required for claims submission and processing, this estimate is incomplete. For CY 2016, CMS applied a 10 percent adjustment to account for incomplete claims for the prior calendar year when estimating the -2.0 percent adjustment for 2016 needed to budget neutralize the laboratory packaging policy adopted in a prior year. Using the same logic, the AAMC believes the $39 million estimate determined above can be increased by 10 percent to approximately $43 million. Applying this $43 million estimate to an OPPS base of $50 billion (using the OPPS impact file released with the rule) or the $63 billion total OPPS payments stated in the CY 2017 OPPS proposed rule would require an adjustment of between 0.06 to 0.09 percent to achieve budget neutrality.

As the only information that we have upon which to recommend a point estimate to adjust OPPS rates is the 2015 OPPS data released with the rule, we recommend that CMS apply an adjustment of 0.078 percent for elimination of the L1 modifier. This figure is equal to the quotient of our $39 million estimate of separate billing associated with the L1 modifier and aggregate 2015 OPPS payments from the claims data released with the rule. **The AAMC calls on CMS to provide greater detail regarding the methodology that was used to arrive at the savings estimates for lab packaging.**

"Q1" AND "Q2" CONDITIONAL PACKAGING POLICIES

Currently, in order to identify packaged payments versus separate payments of items and services under the OPPS, status indicators are applied to CPT and HCPCS codes. Depending on the circumstances, some items and services are packaged while at other times they are paid separately. Two of the status indicators that reflect packaging of services furnished on the same day are "Q1" and "Q2". For 2017, CMS proposes to change the logic for status indicators "Q1" and "Q2".

CMS seeks to align the packaging logic for all of the conditional packaging status indicators and change the logic for status indicators "Q1" and "Q2" so that packaging would occur at the claim level (instead of based on the date of service) to promote consistency and ensure that items and services that are provided during a hospital stay that may span more than one day are appropriately packaged according to OPPS packaging policies. CMS acknowledges that this change would increase conditional packaging of items and services.

The AAMC is generally supportive of CMS's attempt to improve payment accuracy through increased bundling of services. While this proposal may be reasonable for some "Q1" and "Q2" status indicator services, the Association is concerned that packaging all "Q1" and "Q2" services will result in significant underpayment for services rendered. Of particular concern are the instances when high-cost ancillary services with a geometric mean cost greater than $100 may be packaged into low-cost primary services. The AAMC also calls on

CMS to explore developing composite APCs, for example for some pathology services, that provide a composite or tiered payment when two or more pathology services are billed on a claim without other separately payable services to ensure adequate reimbursement.

ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAM

The AAMC continues to support efforts to increase and improve the use of electronic health records, as EHRs have the potential to improve patient care and are a key tool for managing population health. CMS has made several proposals that will simplify the program and make it more consistent with the program for eligible professionals. The Agency proposes to lower the reporting thresholds for eligible hospitals for the remaining Modified Stage 2 measures for 2017 and Stage 3 measures for 2017 and 2018 for eligible hospitals and critical access hospitals attesting under the Medicare EHR Incentive Program. Many of the threshold requirements presented challenges for hospitals. For example, interoperability depends on vendors and measures that require actions by patients are beyond the control of a provider.

In response to stakeholder feedback that more time was needed to accommodate updates in the 2015 EHR Incentive Program final rule, CMS is proposing to change the EHR reporting period in 2016 to any continuous 90-day period for returning eligible physicians and hospitals that have demonstrated meaningful use in a prior year. Additionally, all newly eligible physicians and eligible hospitals will avoid the 2018 payment adjustment by attesting to the Modified Stage 2 objectives and measures.

Lastly, CMS proposes to allow certain eligible physicians to apply for a significant hardship exemption from the 2018 payment adjustment. This proposal will relieve the burden on new participants finding it difficult to manage separate requirements under the new Merit-Based Incentive Payment System (MIPS) program performance period and previously adopted reporting for meaningful use.

The AAMC appreciates CMS's consideration of stakeholder concerns and encourages CMS to finalize these proposals. Furthermore, the AAMC suggests CMS align EHR incentive programs in both Medicare and Medicaid to mitigate confusion in the different reporting standards.

REMOVAL OF TKA FROM INPATIENT ONLY LIST

CMS is again soliciting comments on the possible removal of the Total Knee Arthroplasty (TKA) procedure is from the inpatient only (IPO) list. With the advancement of medical innovation, more surgical procedures are being performed on an outpatient basis. However, only a small percentage of TKAs are performed on an outpatient basis. The AAMC supports CMS's goal of appropriate care for Medicare beneficiaries. **We urge CMS to clarify that the decision whether to perform a TKA as an inpatient or an outpatient should be dependent upon the clinical evaluation of the treating physician. Documentation of the need for inpatient surgery should be enough so as not to trigger added scrutiny by the Recovery Audit Contractors or the Quality**

Improvement Organizations. The AAMC also calls on CMS to clarify that the physician who makes the judgment on where the patient is best treated be based on the clinical conditions of the patient consistent with CY 2016 change to the 2 midnight rule.

Can the simplest procedure described by CPT code 27447 be performed in most outpatient departments?

TKAs remain a complicated, invasive surgical procedure. While TKAs may be successfully performed on an outpatient basis for non-Medicare individuals, it may only be appropriate for a small number of select Medicare beneficiaries who are younger and healthier. Close to half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently which can make even a simple procedure more complicated. Particular challenges to moving this procedure to an outpatient setting relate to anesthesia and pain management post-surgery. Spinal anesthesia is often used for TKAs. Waiting for full sensation to return can take hours and may necessitate an inpatient stay. Pain management, particularly in the immediate postoperative period, remains a challenge. For many patients, management of postoperative pain is best controlled in the inpatient setting.

The AAMC is concerned that if TKA is removed from the inpatient only list hospitals will face auditors who reject inpatient claims even when they are backed by physician documentation in the medical record that demonstrates a patient's need to have the procedure done on an inpatient basis. Therefore, the AAMC asks that CMS continue to study this issue.

CMS also asks for feedback about the impact of moving TKA off the IPO list on the episode-based payment models – Comprehensive Care for Joint Replacement (CJR) and Bundled Payment for Care Improvements (BPCI). The AAMC agrees with CMS that this could result in unfair and inaccurate target pricing. Target prices are based on historical hospital-specific and/or regional averages. As more TKAs are performed on an outpatient basis, historical spending will not accurately reflect the total number or complexity of procedures performed. The TKAs performed on an outpatient basis will likely be less complex than those performed in an inpatient setting and spending on each episode will be less which will directly impact Medicare's target price. As a result, it would be much harder to generate savings under the bundled payment model if the historical period had a larger portion of less resource-intensive cases.. The AAMC agrees that CMS would need to identify a methodology that appropriately adjusts target prices for inpatient procedures to reflect shift of less complex procedures to the outpatient setting.

TRANSPLANT OUTCOMES AND ORGAN PROCUREMENT

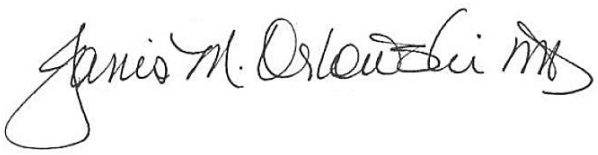
As part of the Medicare Conditions of Participation for solid organ transplant programs, hospitals are required to meet certain thresholds in order for a program to be in compliance. CMS states that the outcomes requirement is based on a transplant program's outcomes in relation to the risk-adjusted national average. As national outcomes have improved, CMS acknowledges that it has become more difficult for an individual transplant program to meet the CMS outcomes standard.

CMS is proposing to change the observed-to-expect (O/E) ratio as it relates to patient deaths and graft failures programs from 1.5 to 1.85. CMS is also proposing to use the same 1.85 threshold for all organ types for both graft and patient survival in an effort to promote consistency and avoid unneeded complexity. **The AAMC supports CMS's efforts to make solid organs available to patients who so desperately need them by not penalizing hospitals that perform higher-risk transplant procedures.**

CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Ivy Baer, J.D., M.P.H., at 202.828.0499 or ibaer@aamc.org regarding Section 603 implementation, Mary Mullaney, M.P.H., at 202.909.2084 or mmullaney@aamc.org regarding transplant, and TKA issues, Ayeisha Cox, J.D., at 202.862.0482 or aycox@aamc.org regarding EHR, Susan Xu, M.P.A, M.S., at 202.862.6012 or sxu@aamc.org regarding payment issues, and Scott Wetzel at 202.862.0495 or swetzel@aamc.org regarding quality issues.

Sincerely,



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