

modifier to be reported with every code for

physician and hospital

services furnished in off-

AAAAI Impact on CMS' 2015 MPFS Final Rule

For hospital claims, CMS created a HCPCS modifier that is to be

reported with every code for outpatient hospital services furnished in

an off-campus PBD of a hospital. The code would not be required to be

TOPIC	PROPOSAL	AAAAI COMMENT	OUTCOME		
Lising OPPS and	Using OPPS and ASC Rates in Developing PE RVUs				
General Issues	While CMS did not make any proposal to implement the use of hospital cost reports to revise the Medicare physician fee schedule (MPFS) practice expense (PE) methodology for CY 2015, the agency has asserted that hospital cost report data are more reliable than data provided by non-facility providers.	AAAAI cautioned CMS against implementing any such measure that would use hospital-level data as the basis for physician office PE RVUs.	Given CMS did not make any proposals to use hospital cost reports in this rule, they did not respond to any comments. CMS previously noted it would continue to evaluate this issue, however.		
	CMS desired to better understand the impact of the shift in services from the physician office to the hospital outpatient department, the growing trend in hospital employment of physicians, and the acquisition of physician offices by hospitals and subsequent redesignation of those offices as hospital outpatient departments (HOPDs). CMS proposed to establish a new HCPCS	AAAAI did not agree that a new HCPCS modifier would yield the data and information CMS needs to understand and evaluate the impact of this trend. The existing Medicare claims database contains the information needed to address the agency's questions; it is only a matter of working with CMS' software analytics team and programmers in the writing of a query that would identify and match hospital outpatient and physician claims for the same patient, on the same data of service, for a select set of procedure codes of interest to CMS. AAAAI urged CMS to take this approach rather than requiring hospitals and practices to append a modifier, which is more likely to be misapplied and create unnecessary confusion in the datasets.	While CMS finalized its proposal to collect data on services furnished in off-campus provider-based departments, it did so with modifications consistent with AAAAI's comments. CMS agreed with AAAAI that a HCPCS modifier would not be effective, and instead, for professional claims, CMS deleted current POS code 22 (outpatient hospital department) and established two new POS codes—one to identify outpatient services furnished in on-campus, remote or satellite locations of a hospital, and another to identify services furnished in an off-campus hospital PBD setting that is not a remote location of a hospital, a satellite location of a hospital or a hospital emergency department. CMS will maintain the separate POS code 23 (emergency room-hospital) to identify services furnished in an emergency department of the hospital. The new POS codes would be required to be reported as soon as they become available, however advance notice of the availability of these codes will be shared publicly as soon as practicable.		

TOPIC	PROPOSAL	AAAAI COMMENT	OUTCOME
	campus facilities of a hospital.		reported for remote locations of a hospital defined at §412.65, satellite
Pasaurea Racad Practice Evnance (DE) Polativo Value Unite (PVUs)			

Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

General Issues

CMS proposed reductions in the practice expense relative values for CPT codes 95017 and 95018 of 4.3% and 5.3% respectively. Costs associated with providing these services have not decreased; in fact, costs for some supply items have increased. Should CMS finalize these reductions, the result will be a cumulative cut of 15.3% and 17.1%, respectively, in only two years. These steep reductions in reimbursements force many allergists to discontinue providing these services to Medicare beneficiaries.

CMS did not respond to AAAAI's comments regarding decreased PE values for CPT codes 95017 and 95018.

Potentially Misvalued Codes

General Issues

CMS proposed that CPT codes 94010 (Breathing capacity test), 95004 (Percutaneous allergy skin tests) and 95165 (Antigen therapy services) are potentially misvalued despite increased utilization of these services.

AAAAI disagreed and is working with other organizations within the A/I specialty to respond through appropriate processes.

CMS did not finalize the codes identified through the high expenditure screen, including 94010 (Breathing capacity test), 95004 (Percutaneous allergy skin tests) and 95165 (Antigen therapy services), as potentially misvalued at this time. CMS did not respond to comments in this final rule regarding whether particular codes should or should not be included in the high expenditure code screen and identified as potentially misvalued codes. CMS stated that it would re-run the high expenditure screen at a future date, and propose at that time the specific set of codes to be reviewed that meet the high expenditure criteria.

Improving the Valuation and Coding of the Global Package

General Issues

CMS proposed to transition all 10-day and 90-day global surgical codes to 0-day global codes. AAAAI was concerned that CMS had not provided any detail about the mechanism by which CMS would unbundle and revalue each discrete service. AAAAI was also concerned about potential unintended consequences, such as increased financial liability on beneficiaries. AAAAI urged CMS to work with the medical specialty societies to ensure the value of discrete services are fair and appropriate, and preserve access to care for medically necessary services.

CMS finalized its proposal to transition and revalue all 10- and 90-day global surgery services with 0-day global periods, beginning with the 10-day global services in CY 2017 and following with the 90-day global services in CY 2018. CMS noted that as it develops implementation details, including revaluations, it would take into consideration all of the comments received to the global surgery proposal, and will provide additional details during the CY 2016 rulemaking.

CMS stated it will actively seek the analysis and perspective of all affected stakeholders regarding the best means to revalue these services as 0-day global codes, and urged all stakeholders to engage with agency staff regarding potential means of making the transition as seamless as possible, both for patient care and provider impact. CMS stated it would consider a wide range of approaches to all details of implementation from revaluation to communication and transition,

and remain hopeful that sufficient agreement can be reached among stakeholders on important issues such as revaluation of the global services and appropriate coding for post-operative care.

Valuing New, Revised and Potentially Misvalued Codes

General Issues

CMS proposed to increase transparency in the establishment of relative value units (RVUs) through a revised process that would provide for improved notice and comment.

AAAAI urged CMS to simply begin publishing revised RVU for misvalued services in the proposed rule. AAAAI noted that CMS' proposal was overly complex, potentially burdensome, and went well beyond the principal request of the medical specialty societies and Congress; that is, for CMS to publish reimbursement changes for misvalued codes in the proposed rule, as opposed to waiting until the final rule. It was AAAAI's understanding that CMS had enough time to incorporate revised values for misvalued codes into the proposed rule, and employ its ratesetting methodologies, which are mostly automated calculations. AAAAI was also deeply concerned that this proposal could delay bringing new therapies to the Medicare population that could be of significant benefit.

CMS finalized its process for establishing values for new, revised, and potentially misvalued codes each year by proposing values for them in the proposed rule.

In the PFS proposed rule for CY 2016, CMS will propose values for the new, revised and potentially misvalued codes for which it receives the RUC recommendations by February 10th for inclusion in the CY 2016 proposed rule.

For those new, revised, and potentially misvalued codes for which it does not receive RUC recommendations in time for inclusion in the proposed rule, CMS anticipates establishing interim final values for them for CY 2016, consistent with the current process.

Beginning with valuations for CY 2017, the new process will be applicable to all codes. In other words, beginning with rulemaking for CY 2017, CMS will propose values for the vast majority of new, revised, and potentially misvalued codes and consider public comments before establishing final values for the codes; use G-codes as necessary in order to facilitate continued payment for certain services for which it does not receive RUC recommendations in time to propose values; and adopt interim final values in the case of wholly new services for which there are no predecessor codes or values and for which CMS does not receive RUC recommendations in time to propose values.

Chronic Care Management

General Issues

CMS proposed to eliminate certain restrictions on billing the new chronic care management (CCM) services, to avoid adopting broad practice standards for providing CCM services, and for allowing CCM services to be performed "incident to." CMS

AAAAI supported these proposals. AAAAI urged CMS to adopt and implement codes for both CCM and chronic disease management (CDM) services, and provide a fair and appropriate payment amount for the work involved coordinating care for both. AAAAI continued to support development of appropriate risk management strategies that recognize that specialties often treat patients with very complicated comorbidities, and appreciated CMS recognition

CMS finalized that it would adopt CPT code 99490 for Medicare CCM services, effective January 1, 2015 instead of the previously proposed G code. CMS finalized that it would adopt CPT code 99490 for Medicare CCM services, effective January 1, 2015 instead of the previously proposed G code. CMS declined to establish more than one code as AAAAI requested, but did state that it would monitor the utilization of this service to evaluate what types of beneficiaries receive the service described by this CPT code, what types of practitioners are reporting it, and consider any changes in payment that may be warranted in the coming years. As part of its evaluation, CMS will consider whether the

	proposed a reimbursement for CCM services. CMS also proposed to require practices to be meaningful users of EHRs in order to be reimbursed for care coordination services.	that many efforts designed to encourage coordination are not equally adaptable among specialties. Many Allergy/Immunology practices have experienced significant challenges meeting meaningful use while many systems still do not facilitate the specialty well, even if they have adopted or connected to a system dictated by a hospital or clinical affiliation. Until such issues are resolved, AAAAI did not believe CMS should require practices to be meaningful users of ERHs in order to be reimbursed for care coordination services.	new service meets the care coordination needs of Medicare beneficiaries and, if not, how best to address the unmet needs. Against AAAAI's urging, and that of many other stakeholders, CMS finalized its proposal for the CCM scope of service element for EHR technology as proposed, with the following modification. CMS included as an element of the separately billable CCM service the use of, at a minimum, technology certified to the edition(s) of certification criteria that is acceptable for the EHR Incentive Programs as of December 31st of the calendar year prior to the PFS payment year (CCM certified technology), to meet the final core EHR capabilities (structured recording of demographics, problems, medications, medication allergies and the creation of a structured clinical summary record) and to fulfill all activities within the final scope of service elements that reference a health or medical record. For CCM payment in CY 2015, this policy would allow practitioners to use EHR technology certified to either the 2011 or 2014 edition(s) of certification criteria.
Physician Qualit	ry Reporting System (PQR	S)	
General	Under statute, the PQRS incentive payment goes away in 2015 and CMS must apply a 2% penalty to all physicians in 2017 that do not satisfy 2015 PQRS reporting requirements. At the same time, CMS proposed to remove over 70 measures for 2015, many of which are claims based.	AAAAI voiced concern about the ongoing reduction of available measures for claims-based reporting, especially in light of increasing penalties. AAAAI asked CMS to consider the needs of the smallest practices, who cannot necessarily invest in registries or EHRs, by maintaining the claims-based reporting option as widely available as other reporting options.	As a result of concerns, CMS ultimately only removed 50 measures and 6 measures groups from the PQRS (and added 20 new individual measures and two measures groups to fill existing measure gaps) for a total of 255 individual measures. Despite CMS' desire to phase out claims-based reporting, it will preserve this mechanism for the 2015 reporting year, recognizing that this is the only option for some physicians. It also remains the most popular reporting option, even though other reporting mechanisms have seen greater reporting success. CMS encourages eligible professionals to use alternative reporting methods to become familiar with reporting mechanisms other than the claims-based reporting mechanism.
COPD Measures	CMS proposes to remove the COPD measures from PQRS reporting due to a potential lack of a measure	AAAAI is tremendously concerned with this proposal, and asks for an opportunity to work with CMS to engage in the process of seeking a measures steward for these measures.	Given a new steward was identified for the COPD measures, CMS did NOT finalize its proposal to remove these measures for 2015 reporting.

AAAAI does not believe the measures are

AAAAI COMMENT

CMS proposed to remove

steward.

Asthma

TOPIC

PROPOSAL

OUTCOME

Although CMS acknowledged AAAAI's concerns about this proposal, it

TOPIC	PROPOSAL	AAAAI COMMENT	OUTCOME
Measures	PQRS #064 Assessment of Asthma Control – Ambulatory Care Setting from the PQRS for 2015. CMS proposed to replace #064 with PQRS #398 Optimal Asthma Control, with an upper age limit of 50 years of age.	sufficiently similar for the Asthma Assessment measure to be wholly replaced by the Optimal Asthma Care measure. AAAAI strong encourages CMS to drop the upper age limit for asthma measures, maintain the Asthma Assessment measure, and see what difference that presents in the reporting before any further consideration is given for dropping this measures. AAAAI is supportive of the concept of the Optimal Asthma Care measure, but believes that it should not be included in CMS quality programs until significant modifications are given careful consideration. Incorporating this measure as presented with an unsupported, unjustifiable and arbitrary age limit will result in CMS failing to capture an important population and the very group of patients that the PQRS was initially authorized to target. AAAAI believes that there may be several ways to improve the Optimal Asthma Care measure with the inclusion of risk adjustment factors, such as medication use or responsiveness to treatment. AAAAI also believes the measure could be improved by being amended to include a substantial improvement in asthma control during the measurement period as being numerator compliant (defined based on percent improvement (e.g. 20 %) or based on the minimal important difference (MID) of the instrument (3 for ACT and 0.5 for ACQ)).	finalized its decision remove PQRS #064 Assessment of Asthma Control – Ambulatory Care Setting, and replace it with PQRS #398 Optimal Asthma Control. In regards to measure #064, CMS stated its belief that the measure represents a basic clinical concept that does not add clinical value to PQRS because in order to provide effective treatment for asthma, assessment of asthma control is essential. CMS understands the limitations of #398 as it relates to the upper age limit, risk adjustment and the calculation of improvement over time, but feels it represents a more robust clinical outcome for asthma care. CMS also re-evaluated the categorization of measure #398 and determined it was more appropriate to place it under the Effective Clinical Care domain rather than the Person and Caregiver Experience and Outcomes domain. Measure #398 is reportable via registry only in 2015.
		AAAAI proposes that a measure be added for spirometry for management of asthma, parallel to the equivalent measure for COPD. AAAAI encourages CMS to reconsider moving forward with a spirometry measure for patients with persistent asthma.	CMS did not specifically respond to the request for a spirometry measure for asthma.
Asthma	CMS proposed to increase	AAAAI noted that the current Asthma measures	As noted above, CMS did not approve inclusion of the Asthma
Measures Group	the minimum size of a measures group from four	group is insufficiently related to quality care for patients with asthma and that it features only one	Assessment measure for the 2015 PQRS.
3.0up	to six measures for 2015.	measure, Pharmacologic Therapy for Persistent	CMS finalized the Asthma Measures Group as proposed. For 2015, it
		Asthma, that is uniquely related to asthma.	will include the following measures:

TOPIC	PROPOSAL	AAAAI COMMENT	OUTCOME
		Encouraged the reinstatement of the Asthma Assessment measure, with the upper age limit removed, to be included in the 2015 Asthma Measures Group.	-Pharmacologic therapy -Influenza immunization -BMI screening/follow up -Documentation of current medications -Tobacco screening/cessation intervention Tobacco Help with Quitting Among Adolescents
Sinusitis	Droposed to add a pour	AAAAI also suggested CMS reconsider its proposal to increase the size of measures groups. If CMS does increase the size, AAAAI stated that it is very important that the Asthma Assessment measure be retained. AAAAI supported retaining this measure for the Asthma measures group, but also for all reporting methods that were available in 2014. Further, it was noted the meaningfulness of Asthma Measures Group in particular would be significantly enhanced with the addition of a spirometry measure.	CMS did not asknowledge this concern and finalized the Sinusitis
measures	Proposed to add a new Sinusitis measures group for 2015	Recommended that CMS note in the sinusitis measures group that the recommendation regarding amoxicillin is out of date per Infectious Disease guidelines.	CMS did not acknowledge this concern and finalized the Sinusitis Measures Group with the sinusitis measure: -Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Patients with Acute Bacterial Sinusitis: Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis.
QCDRs	CMS proposed to require that QCDRs report on 9 measures across 3 domains for 50% of ALL applicable patients (Medicare and non-Medicare), including 3 outcomes measures (or 2 outcomes and 1 of the following: resource use, patient experience or efficiency/appropriate use measure).	AAAAI supported CMS' proposal to not raise the reporting requirement above 9 measures, but voiced concern about rushed implementation of requirements and asked CMS to specifically reconsider the requirement to report on at least 3 outcomes measures for 2015.	CMS finalized the reporting of 9 measures across 3 domains for 50% of all applicable patients (both Medicare and non-Medicare). However, due to concerns about the reporting burden, CMS decided to only require the reporting of 2 outcomes measures or if 2 are not available, then 1 outcome measure and 1 of the following types of measures: resource use, patient experience of care, efficiency/appropriate use or patient safety (note: "patient safety" is a new category that was not included in the proposed rule, but added to provide additional flexibility).
	Proposed to increase the number of non-PQRS measures that QCDRs can include from 20 to 30.	AAAAI appreciated the opportunity to add additional non-PQRS measures.	CMS also finalized its decision to increase the number of non-PQRS measures that QCDRs can include from 20 to 30.

TOPIC	PROPOSAL	AAAAI COMMENT	OUTCOME		
Physician Value	Physician Value-Based Payment Modifier				
General Issues	As required under statute, CMS must apply the VM to ALL physicians by 2017. CMS proposed to base this on 2015 reporting and to double the VM penalty to 4%.	AAAAI asked that, at the very least, those smaller practices with just one or two practitioners be subject to some lower level of penalty or be held harmless from all downward adjustments during their initial year of participation as the VM implementation expands to include them.	Agreeing in part with AAAAI's concerns, CMS decided to apply a lower penalty of -2% in 2017 to smaller group practices (2-9 EPs) and solo practitioners for failure to satisfy PQRS in 2015. Groups with 10 or more EPs would be subject to a -4% penalty. ALL physicians are subject to quality tiering in 2017. However, CMS decided to hold harmless from downward performance-based payment adjustments in 2017 those groups with 2-9 EPs and solo practitioners. These EPs may only receive a neutral or upward performance-based payment adjustment (up to +2x).		
Cost Measures		AAAAI expressed its great concern about the lack of a connection between the cost and quality measures used to calculate the VBM. AAAAI expressed concern about the interplay between cost mechanisms and the lack of risk adjustment in quality measures as well as in cost measures, and sincerely hopes to see episode-based cost measures take this important issue into account. AAAAI opposed CMS' decision to not apply socioeconomic status adjustments to cost measures under the VM. AAAAI noted that failing to adjust measures for these factors could lead to substantial unintended consequences, including harm to patients and increased healthcare disparities, by diverting resources away from providers treating large proportions of disadvantaged patients.	Despite ongoing concerns raised, CMS will continue to rely on the Total Per Capita Cost measures and the MSPB measure since more specific episode-based cost measures are not yet available. The VM calculation will continue to rely on quality measures that are unrelated to the cost measures. These include: • PQRS measures reported through any mechanism (except new measures, which do not yet have benchmarks); - Additional, previously finalized, claims-based outcomes measures that CMS will automatically calculate: - A composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; - A composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; and - Rates of an all-cause hospital readmissions measure • Groups with 2 or more EPs also will be able to elect to have patient experience of care measures collected through the 2015 CAHPS for PQRS survey included in their quality of care composite. CMS acknowledged support for SES adjustments, but wishes to defer on the issue until after the NQF has finalized its guidance on this topic. CMS feels it's important to proceed cautiously on this topic and will continue to monitor NQF activities.		
Incorporation of QCDR data	CMS noted that it does not yet have the technical capacity to use QCDR data for VM quality calculations so instead would automatically deem	AAAAI voiced concerns about this proposal in light of public reporting (see Physician Compare section below).	Despite AAAAI's concerns, CMS maintained its proposal that, beginning with the 2014 performance period, measures reported through a QCDR that are new to PQRS (first-year measures) will not be included in the quality composite for the VM until such time as CMS has historical data to calculate benchmarks for them. Once CMS has historical data from measures submitted via QCDRs, the benchmark will be the national		

physicians who satisfactorily report to a QCDR as "average" quality for purposes of the VM calculation.

mean for the measure's performance rate during the year prior to the performance period.

For the 2017 VM, in cases where groups are assessed under the "50% option" (i.e., when CMS looks to see if at least 50% of individual physicians in a group practice participated in PQRS in cases where the group as a whole doesn't elect participate in GPRO) and all EPs report via QCDR in 2015, but CMS is unable to receive quality performance data, then it will classify the group's quality composite score as "average" under the quality-tiering methodology.

For groups assessed under the "50% option" where some EPs in the group report data using a QCDR and CMS is unable to obtain the data, but others in the group report using another PQRS reporting mechanism, CMS will calculate the group's score based on the reported performance data it obtains through those other mechanisms.

Physician Compare

OCDR

Proposed to require the reporting of individual EP-level 2015 QCDR measures starting in 2016. Data would have to be reported by April 30 following the reporting year. QCDRs could report the data in the format of their choosing and select whether to report data on Physician Compare or via a link to their own website.

CMS also solicited comments on including specialty society measures on Physician Compare or linking Physician Compare to specialty society Websites that publish non-PQRS measures.

Expressed concern that CMS is moving too quickly toward reporting QCDR measures data, which will impede use of QCDRs among smaller practices. Supported posting QCDR measures data no sooner than 2017, and to have the data posted on the separate website that hosts the QCDR.

Also supported linking from Physician Compare to the website where the QCDR is hosted, but did not support posting of individual quality measures data on the specialty society's website.

Given CMS's proposal to characterize QCDR reporters as "average quality" for purposes of the VM, AAAAI requested that these EPs, who have made a substantial commitment to more meaningful reporting, at least be listed on Physician Compare to show that they did fully report according to the requirements of PQRS via QCDR, but that CMS determined after the released that these measures would not be able to qualify them for the highest ranking. Instead of showing these early adopters as "average" AAAAI thinks they should be given some recognition that

Despite claiming to understand timeline and other concerns regarding the effect this would have on the start up of new registries and registry participation, CMS finalized its proposal to publicly report individual physician-level 2015 QCDR measures data in 2016. CMS feels it gave QCDRs ample notice that this requirement was coming. The final policy includes some modifications, noted below:

- Recognizing that physicians should be afforded the
 opportunity to simply learn from first year data and not have
 this information shared publicly until the measure can be
 vetted for accuracy, CMS will NOT require the public reporting
 of first year QCDR measures. This policy also applies to
 traditional PQRS measures and is consistent with the Value
 Modifier policy. If a QCDR first reports on a non-PQRS
 measure that is already being reported by another QCDR, CMS
 would consider the measure in its first year of reporting for
 that respective QCDR.
- As originally proposed, in order to recognize the burden/time/resources that public reporting measures data could pose to QCDRs, CMS will defer to the entity in terms of the format it will use to publicly report the quality measures data it collects for the PQRS (e.g., individual vs. aggregate level). QCDRs may also choose where to report their performance rates (e.g., through a board or specialty website,

ТОРІС	PROPOSAL	AAAAI COMMENT	OUTCOME	
		reflects that they were willing to be early adopters in a new system designed to better identify quality care for their specialty.	listserv dashboards or other announcement). However, to address concerns regarding the lack of time for QCDRs to establish user-friendly websites for sharing data as well as concerns about data consistency, CMS will NOT REQUIRE reporting on a QCDR website. However, all QCDR data will be available via Physician Compare (i.e., QCDRs are free to provide this information elsewhere, but Physician Compare website will serve as a point where all information will be accessible). • QCDR data will only be publicly reported on Physician Compare at the individual-EP level. • CMS will review all QCDR data prior to public reporting to ensure that the measures included meet the same standards as the PQRS measures being publicly reported (e.g., 20 patient sample size, valid, reliable, etc.). • Due to public concerns about accuracy and reliability, CMS decided to extend the deadline by which QCDRs must publicly report quality measures data outside of Physician Compare (if they so choose) to the deadline by which Physician Compare posts QCDR quality measures data. Note: Other commenters requested NQF endorsement for all QCDR measures, and one commenter suggested that CMS develop rules and guidelines for measure stewards who develop non-PQRS measures housed in QCDRs. CMS did not finalize any provisions related to these suggestions. CMS also appreciated feedback on linking specialty society websites that publish non-PQRS measures to Physician Compare and will consider this in future rulemaking.	
Reports of Payments or Other Transfers of Value to Covered Recipients				
General Issues	CMS proposes to eliminate the CME exception.	AAAAI urged CMS to consider a modification put forward by the American Medical Association (AMA) that calls on the agency to add language that the exemption applies under section 403.904(i)(1) when an applicable manufacturer provides funding to a CE provider, but does not	CMS finalized its proposal to remove the language in §403.904(g), Special rules for payments or other transfers of value related to continuing education programs, in its entirety. CMS believes this approach is more desirable than the alternatives it considered. CMS clarified that if an applicable manufacturer providing an indirect	
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select or pay the covered recipient speaker/faculty directly, or provide the CE provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CE program.

AAAAI also urged the agency to review ongoing issues reported by physicians attempting to register for the Open Payments system and to expand the registration timeframe accordingly to ensure covered recipients have ample opportunity to registry, review, and dispute data on the Open Payments System before publication.

AAAAI also requested that CMS provide clarifying guidance that manufacturers and group purchasing organizations (GPOs) are not authorized to unilaterally dismiss disputes by physicians or teaching hospitals. Information should be flagged as disputed in the public database until resolution is reached between the parties.

payment through a continuing education organization and learning the identity of the physician covered recipient in the allotted timeframe (that is, during the reporting year or by the end of the second quarter of the following reporting year) the indirect payment would not meet the criteria of the indirect payment exclusion and would need to be reported. However, payments or other transfers of value, including payments made to physician covered recipients for purposes of attending or speaking at continuing education events, which do not meet the definition of an indirect payment (see §403.902), are not reportable. For example, if an applicable manufacturer provides funding to support a continuing education event but does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment or other transfer or value in whole or in part to a covered recipient, the applicable manufacturer or applicable GPO is not required to report the payment or other transfer of value. The payment is not reportable regardless if the applicable manufacturer or applicable GPO learns the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year because the payment or other transfer of value did not meet the definition of an indirect payment.

CMS also noted that it intends for physician speaker compensation and physician attendees fees which have been subsidized through the continuing medical education organization by an applicable manufacturer to be reported unless the payment meets the indirect payment exclusion at §403.904(i)(1). CMS will provide sub-regulatory guidance specifying tuition fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers are not expected to be reported.

CMS refrained from addressing the remaining concerns raised by AAAAI given comments were not solicited on these issues in the proposed rule.