American Academy of
Allergy Asthma & Immunology

June 27, 2016

Andrew M. Slavitt, MBA
Acting Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Via email: CMS Portal

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Acting Administrator Slavitt:

The American Academy of Allergy, Asthma & Immunology (AAAAI) appreciates the opportunity to comment on CMS' proposed rule related to the MIPS, APM incentive, and criteria for Physician-focused Payment Models. The AAAAI represents more than 6,800 medical care professionals focused on advancing the knowledge and practice of allergies, asthma and immunology for optimal patient care.

AAAAI and its members have been active participants of moving towards value-driven care. In fact, the AAAAI QCDR has been an approved QCDR under the PQRS since the introduction of the QCDR reporting option in 2014. Below, we provide our comments on CMS' proposals related to this proposed rule.

In general, we note that the transition from the PQRS, Medicare EHR Incentive Program, and Value-based Payment Modifier to the Quality Payment Program (QPP) (that will include the MIPS and APMs) will be a significant undertaking for our members. We urge CMS to consider the overall scope of changes it is proposing to the nature of a physician's practice as it finalizes requirements for the QPP. Given the substantial changes being made next year related to implementation of the QPP, we urge CMS to delay implementation of any further projects that may add substantial burden to our members, such as the Part B Drug Payment Model.

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Meaningful Use Prevention of Information Blocking and Surveillance Demonstrations for MIPS Eligible Clinicians, EPs, Eligible Hospitals, and CAHs

CMS is proposing to require EPs, eligible hospitals, and CAHs to attest that they have cooperated with the surveillance of certified EHR technology under the ONC Health IT Certification Program, as authorized by 45 CFR part 170, subpart E. Similarly, CMS is proposing to require such an attestation from all eligible clinicians under the advancing care information performance category of MIPS, including eligible clinicians who report on the advancing care information performance category as part of an APM Entity group under the APM Scoring Standard. AAAAI opposes the proposal to require that eligible clinicians attest to three statements regarding information blocking. We specifically oppose the proposal to attest to the second statement, that implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: connected in accordance with applicable law; compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; implemented in a manner that allowed for timely access by patients to their electronic health information; (including the ability to view, download, and transmit this information) and implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers, including unaffiliated providers, and with disparate certified EHR technology and vendors. We believe it may be difficult for eligible clinicians to meet this statement, particularly because EPs have traditionally had issues meeting security risk analysis required under the Protecting Patient Health Information objective.

The Merit-based Incentive Payment System (MIPS)

Identifying MIPS Eligible Clinicians

CMS proposes to use multiple identifiers that allow MIPS eligible clinicians to be measured as an individual or collectively through a group's performance. However, while CMS has multiple identifiers for participation and performance, CMS proposes to use a single identifier, TIN/NPI, for applying the payment adjustment, regardless of how the MIPS eligible clinician is assessed. Specifically, if the MIPS eligible clinician is identified for performance only using the TIN, when applying the payment adjustment, CMS proposes to use the TIN/NPI.

AAAAI supports the use of the Taxpayer Identification Number/National Provider Identifier (TIN/NPI) to apply the MIPS payment adjustment. However, it is unclear how a MIPS eligible clinician being identified for performance only using the TIN will then be scored and have his/her payment adjustment based on the TIN/NPI. Since CMS is proposing not to provide for a registration process for group reporting but instead is choosing an election process, how will the new process differ from previous registration under the PQRS? How will CMS determine whether a MIPS eligible clinician should be assessed for performance as part of a group under the TIN or as an individual? Would MIPS eligible clinicians performing under the same TIN be assigned the same CPS scores for purposes of applying the payment adjustment? How would a MIPS eligible clinician be assessed if the clinician belongs to multiple groups under different TINs?

CMS proposes to define a group as a single Taxpayer Identification Number (TIN) with two or more MIPS eligible clinicians, as identified by their individual National Provider Identifier (NPI), who have

reassigned their Medicare billing rights to the TIN. CMS also proposes to define an APM Entity group identified by a unique APM participant identifier. AAAAI requests clarification as to how the group practice option will function for all performance categories.

Specifically, we would like CMS to specify in the final rule how the group practice option would work for the advancing care information performance category, where the proposed requirements are incorporated from a program that bases performance on an NPI basis. In addition, we would like clarification as to how the group practice option would work for the CPIA activity. Would all clinicians in a group need to perform 60 points worth of activities? Does CMS envision a group practice earning full credit for the CPIA performance category as long as a majority (over 50%) of its eligible clinicians earn the max 60 CPIA points, similar to the 50% rule in the VM?

For the 2019 MIPS payment adjustment, CMS did not provide a proposed option to participate in the MIPS as a virtual group. While we understand the operational limitations for implementing a virtual group option, we encourage CMS to implement a virtual group option in the MIPS as soon as it is feasible. We are willing to provide input on the virtual group option and suggest that CMS hold a listening session to get feedback on how to implement the virtual group option.

Performance Period

CMS proposes that, for 2019 and subsequent years, the performance period under MIPS would be the calendar year (January 1 through December 31) 2 years prior to the year in which the MIPS adjustment is applied. Therefore, the performance period for the first MIPS payment adjustment in 2019 would be January 1, 2017 through December 31, 2017. Particularly for the first year of MIPS, AAAAI opposes the proposed performance period for the MIPS payment adjustments, particularly for the first MIPS adjustment in 2019. If a final rule is issued in November, as anticipated, we do not believe that one month is enough time to adequately educate eligible clinicians prior to the start of the performance period on January 1, 2017. We believe this proposed performance period is particularly troublesome as, for the quality performance category, CMS is proposing to increase the data thresholds from requiring quality measures data on 50% (what has previously been established in PQRS) to 80% of Medicare patients or 90% of all patients, depending on which data submission mechanism is chosen. If these proposed thresholds are finalized, eligible clinicians will have to begin reporting starting in January to be able to meet these thresholds.

As an alternative to the proposed performance period, we recommend that CMS implement a 6-month performance period from July 1, 2017 through December 31, 2017. At the inception of the PQRS (formerly the PQRI), CMS established a shortened 6-month reporting period from July 1, 2007 through December 31, 2007. Therefore, the shortened 6-month performance period has been used in the past when a program is newly introduced.

Alternatively, if CMS prefers collecting data on a full 12 months, AAAAI suggests that CMS delay the start date of the performance period. This would significantly improve our chances of preparing our EPs to participate.

For individual MIPS eligible clinicians and group practices with less than 12 months of performance data to report, such as when a MIPS eligible clinician switches practices during the performance period or when a MIPS eligible clinician may have stopped practicing for some portion of the

performance period, CMS proposes that the individual MIPS eligible clinician or group would be required to report all performance data available from the performance period. Specifically, if a MIPS eligible clinician is reporting as an individual, they would report all partial year performance data. Alternatively, if the MIPS eligible clinician is reporting with a group, then the group would report all performance data available from the performance period, including partial year performance data available for the individual MIPS eligible clinician. We believe it is natural for eligible clinicians to take time off of practice for various reasons, and they should not be held accountable for meeting MIPS requirements while absent. For the quality performance category, one way to alleviate the predicament of counting partial year participation is to provide the option to report on a certain number of consecutive patients, rather than using percentage thresholds. For the CPIA performance category, we believe that CMS' proposal that an eligible clinician perform an activity for any 90 days within the performance period is sufficient.

For the CPIA performance category, we believe that CMS' proposal that an eligible clinician perform an activity for any 90 days within the performance period is sufficient. However, it is unclear how CMS will measure these 90 days, as some of the activities do not have a defined period of performance. For example, CMS proposes the following CPIA: Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations. Clarification as to whether CMS requires that an eligible clinician access feedback reports at least 90 days within the performance period, or if the functionality to access feedback reports has to be available for at least 90 days. Furthermore, we note that some of these activities would not be performed every year, such as activities that are performed towards certification. It would be beneficial to have confirmation that these activities would be available to be used for the CPIA category at the same time as the eligible clinician is in the process of certification, or if there are any limitations on such overlap. Additional information is needed.

For the ACI performance category, we believe that CMS could either finalize a shorter performance period (such as the 90 day reporting period established under the EHR Incentive Program) or allow eligible clinicians to apply for a hardship exemption when they only participate for part of the year.

Exclusions: CMS proposes to define MIPS eligible clinicians or groups who do not exceed the low-volume threshold as an individual MIPS eligible clinician or group who, during the performance period, have Medicare billing charges less than or equal to $10,000 and provides care for 100 or fewer Part B-enrolled Medicare beneficiaries. AAAAI supports establishing a low-volume threshold. However, we believe the proposed $10,000 low-volume threshold is too low. Eligible clinicians performing certain, expensive procedures, or even prescribing and administering certain in-office medications, may very quickly meet this threshold based on just a very few patients. Therefore, we recommend that CMS increase the low-volume threshold as those eligible clinicians who have Medicare billing charges of no less than $50,000, and who provide care for 100 or fewer Part B-enrolled Medicare beneficiaries. Alternatively, CMS might consider the percentage of the patient population of a practice to better determine an appropriate threshold.

For example, if an Allergist/Immunologist in solo practice with only a very few Medicare patients and a total revenue stream from all sources of less than $400,000 has just two Medicare patients receiving Xolair for asthma, that practice will be over the $50,000 threshold just for those treatments. Therefore this very small practice would be required to fulfill all of the same reporting requirements of a significantly larger practice, but at a significantly more burdensome impact on the practice. Small

practices will at that point have no choice but to turn away Medicare patients, causing a program designed to improve patient care to actually reduce patient access. However, if both revenues and a percentage of the relevant patient population can be considered, a determination could quickly be made that the smaller practice fits the intent of the low-volume threshold.

Additionally, we believe CMS should multiply the proposed low-volume threshold by the number of eligible clinicians in a group. Specifically, a group of five eligible clinicians would be excluded from the MIPS if the group has Medicare billing charges less than or equal to $250,000 (5 x $50,000) and provides care for 500 (5 x 100) or fewer Part B-enrolled Medicare beneficiaries.

MIPS: The Quality Performance Category

CMS proposes to establish data submission mechanisms currently available in the PQRS: QCDR, qualified registry, EHR, CMS Web Interface (groups of 25 or more), and CMS-approved survey vendor for CAHPS for MIPS. In addition, CMS proposes to use administrative claims (no submission required) to calculate certain population-based measures. CMS is proposing to only allow use of one submission mechanism per category. AAAAI supports CMS' proposal to retain the data submission mechanisms currently available in the PQRS, particularly the claims, qualified registry, EHR, and QCDR data submission mechanisms, as AAAAI's members have applicable proposed measures in these proposed data submission mechanisms. In general, AAAAI supports offering physicians the widest range of submission mechanisms in order to give eligible clinicians more options in determining how to submit quality measures data.

We oppose CMS' proposal to only allow use of one submission mechanism per category. In order to maximize the submission options for eligible clinicians, we feel they should be able to submit data using multiple submission mechanisms. For example, the proposed Allergy/Immunology/Rheumatology specialty measure set contains measures that may be submitted using claims, EHR, and registry. There are only 2 claims-based measures in this specialty set. If an eligible clinician chooses to report these measures via claims, would the clinician receive a poor score for quality because they only reported on the only 2 currently available measures in the specialty set? This is not the only specialty set for which this scenario may occur, and we believe allowing clinicians to use multiple submission mechanisms within a category, particularly in the quality performance category, could help alleviate these concerns.

CMS proposes the following criteria for individuals and groups: Report at least six measures including one crosscutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures). If less than six measures apply, then report on each measure that is applicable. AAAAI supports CMS' proposal to report six measures, because this is a lower threshold than the PQRS, which currently requires that a MIPS eligible clinician or group generally report on at least nine measures covering three NQS domains. AAAAI also supports CMS' decision to remove the NQS domain requirement and instead use these domains as a guide for selecting measures. We believe the NQS domain requirement adds unnecessary complexity to the reporting requirement.

While the AAAAI supports CMS' effort to better be able to capture meaningful data and encourages the use of outcomes measures, AAAAI opposes the requirement to report on outcomes and high priority

measures. We note that in the proposed Allergy/Immunology/Rheumatology specialty measure set, there are two efficiency measures available, but no outcomes measures. While some of our members will be able to meet the requirement to report on high priority measures, we feel this disadvantages our members who do not have applicable outcomes or high priority measures. At least for the first year of MIPS, we believe CMS must be flexible in its requirements. We believe reporting on outcomes or high priority measures should allow eligible clinicians to earn bonus points rather than making it a requirement to do so.

For the claims submission mechanism, CMS proposes that a MIPS eligible clinician or group would be required to report quality measures data on at least 80% of its Medicare Part B patients. For the qualified registry, EHR, and QCDR submission mechanisms, CMS proposes that a MIPS eligible clinician or group would be required to report quality measures data on at least 90% of <u>ALL</u> its patients. AAAAI opposes the proposed requirement that eligible clinicians report on ALL patients if using the qualified registry, QCDR, or EHR data submission mechanisms. Under the PQRS, qualified registry was not required to report on non-Medicare patients. Therefore, especially given the short timeframe in which the MIPS is being implemented, we feel it would be overly burdensome to request that a vendor make substantial changes to its system to be able to track non-Medicare patients. While EHRs and QCDRs are capable of reporting on non-Medicare patients, we are hesitant to support the functionality to report on all patients because of CMS' proposal to report a higher threshold (90% rather than 50% of patients). We are unsure how much more data this will require qualified registries, EHRs, and QCDRs to collect and are worried that the increased threshold and requirement to report on all patients may overburden third party vendor systems; and without specific feedback on this point from QCDR vendors, we are uncertain if this threshold truly is realistic. AAAAI is concerned that this threshold may cause a larger number of clinicians to fail the reporting requirements under the quality performance category. We also believe that 50% provides a more than adequate sample of quality measures data.

In the past, the PQRS required EPs to report measures data for at least 80% of their applicable Medicare patients using the qualified registry. However, at this time, an EP was only required to report on three measures. When CMS finalized increasing the number of measures that would be reported in PQRS from three to nine, according to the 2014 PFS final rule (78 FR 74459-74461), CMS lowered the reporting threshold to 50% of applicable Medicare patients to compensate for the increase in the number of measures an EP was required to report. While proposing to lower the number of measures required for reporting under MIPS, CMS is also proposing substantial additional requirements, such as requiring reporting of a cross-cutting measure as well as an outcome or high priority measure. Furthermore, the types of measures clinicians will be expected to report are more difficult to perform than many of the measures used in the past in PQRS, as CMS has worked to remove many check box and topped out measures. Given these reasons, it is significantly harder to meet the 80% or 90% threshold for these measures than in the past.

For claims reporting, CMS has never required this high, 80% threshold. CMS has maintained a data completeness threshold of 50%. Claims are arguably the most burdensome submission mechanism to use, because it requires a clinician to attach QDCs for every applicable claim. Requiring reporting on 80% of Medicare patients for at least six measures results in a significant increase in burden for this method. Furthermore, we do not believe CMS has adequately provided reasons as to why it is proposing to increase the data submission threshold for claims. Data inaccuracy should not be a concern; claims data is generally reliably accurate, as the clinicians are the ones proactively reporting. A

third party vendor is not used for claims. We request CMS to establish a threshold of either 50% for claims or a threshold of 20 patients, such as what is currently required under the measure group option for PQRS.

For qualified registry reporting, while CMS has required EPs to report on at least 80% of their patients in the past in PQRS, CMS has never required a qualified registry to report on 90% of its patients. Furthermore, qualified registries were only required to report on Medicare patients. Since qualified registries will now be required to report on all patients, we believe this proposed increase is unreasonable. We believe CMS should establish a threshold of either 50% for claims or a threshold number of patients, such as what is currently required under the measure group option for PQRS.

For QCDRs, CMS has NEVER required this high 90% reporting threshold. The QCDR model is still a relatively new option under the PQRS, and changes have been required by CMS every year to QCDR capabilities since its inception. For example, recently QCDRs have been tasked with providing a group option for its users. In this proposed rule, CMS proposes several extensive new requirements that vendors must provide: additional feedback reports (at least six times a year), the potential to collect data for the CPIA and ACI performance categories, etc. We believe it is an extraordinary and unnecessary burden to require QCDRs to collect this excessive additional level of data in addition to modifying their systems to account for other proposed QCDR changes. We simply fail to see how this extensive of a data threshold increase is warranted, and find it unjustifiable while we continue to meet annual demands for changes to these systems. This is too large of a jump to make, particularly within the proposed timeframe. We believe CMS should establish a lower and more realistic threshold, such as what is currently required under the measure group option for PQRS.

For EHR reporting, in order to maintain consistency with the other submission mechanisms, we request that CMS establish a threshold consistent with the other submission mechanisms. Therefore, we believe CMS should establish a threshold of either 50% for claims or a threshold of 20 patients, such as what is currently required under the measure group option for PQRS.

Based on our comments, we recommend CMS amend the reporting criteria for the quality performance category as follows:

CLAIMS: Report at least six measures including one crosscutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures); if less than six measures apply then report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in or a set of specialty specific measures. **If less than six measures within a submission mechanism apply to the eligible clinician in a specialty specific measure set, the eligible clinician would report on all applicable measures within the specialty measure set and one cross-cutting measure.** Report on **50 percent (or 20 consecutive Medicare Part B patients)** of MIPS eligible clinician's Medicare Part B-only patients.

QUALIFIED REGISTRY and EHR: Report at least six measures including one crosscutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures); if less than six measures apply then report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in or a

set of specialty specific measures. **If less than six measures within a submission mechanism apply to the eligible clinician in a specialty specific measure set, the eligible clinician would report on all applicable measures within the specialty measure set and one cross-cutting measure.** Report on **50 percent (or 20 consecutive Medicare and non-Medicare patients)** of MIPS eligible clinician's or groups Medicare and non-Medicare patients (must contain at least one quality measure for at least one Medicare patient).

QCDR: Report at least six measures including one crosscutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures); if less than six measures apply then report on each measure that is applicable. Report on **50 percent (or 20 consecutive Medicare and non-Medicare patients)** of MIPS eligible clinician's or groups Medicare and non-Medicare patients (must contain at least one quality measure for at least one Medicare patient).

CMS is not proposing the use of measures groups for reporting in the quality performance category. We urge CMS to retain the option to report measures groups. We believe all reporting options currently in the PQRS should be maintained by CMS, particularly as eligible clinicians work to transition from existing quality reporting programs, such as the PQRS, to the MIPS. Measures groups have been deliberately constructed to encourage eligible clinicians to report on related measures. We believe the measures group option has been a useful and less intimidating way to report measures via the PQRS, as EPs do not have to sort through the PQRS measures list of 300 measures to determine which measures are relevant to them. We believe the measures group option will be equally beneficial in the MIPS.

In addition, while CMS has proposed measure specialty sets, we do not believe that, at this time, the measure specialty sets are an adequate replacement of measures groups. For example, below, AAAAI raises serious concerns with the Allergy, Immunology, and Rheumatology measure specialty set as it includes rheumatology measures that are not applicable to A/I eligible clinicians. We urge CMS to incorporate the following criteria for measures groups:

- For the performance period for the 2019 MIPS payment adjustment, a MIPS eligible clinician or group would report at least 1 measures group for 20 applicable patients. Measures groups containing a measure with a 0% performance rate will not be counted.

If CMS chooses to use a percentage data threshold and would like to align the measures group threshold with other reporting options, we request that CMS incorporate the following criteria for measures groups:

- For the performance period for the 2019 MIPS payment adjustment, a MIPS eligible clinician or group would report at least 1 measures group for 50% of applicable patients. Measures groups containing a measure with a 0% performance rate will not be counted.

CMS proposes to allow registered groups of two or more MIPS eligible clinicians to voluntarily elect to participate in the CAHPS for MIPS survey. In addition, CMS proposes that the CAHPS for MIPS survey would count as one cross-cutting and/or a patient experience measure, and the group would be required to submit at least five other measures through one other data submission mechanisms. A group may report any five measures within MIPS plus the CAHPS for MIPS survey to achieve the six measures threshold. Furthermore, CMS seeks comment on whether the CAHPS for MIPS survey

should be required for groups of 100 or more MIPS eligible clinicians or whether it should be voluntary. AAAAI supports CMS' proposal to allow registered groups of two or more MIPS eligible clinicians to voluntarily elect to participate in the CAHPS for MIPS survey. We agree that the CAHPS for MIPS survey should be optional for all group practices, even large group practices of 100 or more eligible clinicians. The CAHPS for survey measure should count as 3 measures, including one cross-cutting and a patient experience measure, since that is weight given to the CAHPS for PQRS survey.

Depending on the group size, CMS proposes to assess eligible clinicians on two or three population based measures that currently exist under the VM: All-cause readmissions; AHRQ acute preventive quality indicator composite (bacterial pneumonia, UTI, dehydration); and AHRQ chronic preventive quality indicator composite (COPD, HF, DM). **CMS also proposes to include the all-cause hospital readmissions measure from the VM.** We recognize that there is evidence that community-level interventions improve individual health outcomes and encourage CMS to develop other approaches to support public health interventions. However, AAAAI opposes the use of population-based measures, especially in the quality performance category. While clinicians have a responsibility to work collaboratively with their patients to address population- and community-level issues that impact patient health and well-being, we believe attributing population health measure outcomes to specific clinicians is not appropriate. Particularly within the performance category, we believe using these population-based measures under the quality performance category may dilute the otherwise successful performance an eligible clinician or group would have reporting on measures of their choosing. We believe the eligible clinicians should only be scored on measures they choose in this category. In addition, we believe these measures are problematic and confusing for eligible professionals and do not see the value these population-based measures bring to scoring an eligible clinician.

Scoring the Quality Performance Category

If a MIPS eligible clinician has no measures applicable to him/her under the quality performance category, CMS proposes that it would use their authority under section1848(q)(5)(F) of the Act to assign a weight of zero to the performance category and redistribute the weight for the quality performance category. AAAAI supports CMS' proposal to reweight the quality performance category to zero if an eligible clinician does not have any applicable measures. We request that, at least for the first year of the program, CMS redistributes the weight of the quality performance category to the CPIA performance category, as we believe eligible clinicians would have the most control over their performance in the CPIA performance category relative to the resource use or advancing care information performance category.

CMS proposes that if a MIPS eligible clinician has fewer than three scored quality measures (either submitted measures or measures calculated from administrative claims data) for a performance period, it would consider the MIPS eligible clinician not to have a sufficient number of measures applicable for the 2019 MIPS payment adjustment. CMS proposes to reduce the weight of a performance category if there are only one or two measures applicable by two-fifths and one-fifth respectively. CMS would then redistribute the weight proportionately to the other performance categories for which the MIPS eligible clinician did receive a performance category score. AAAAI supports the proposals to re-weight the quality performance category as proposed for MIPS eligible clinicians who may have less than 3 applicable measures to report in the quality performance category. As we note above, we request that, at least for the first year of the program, CMS redistributes the

weight of the quality performance category to the CPIA performance category, as we believe eligible clinicians would have the most control over their performance in the CPIA performance category relative to the resource use or advancing care information performance category.

In the final rule, we request that CMS explain how eligible clinicians and groups who report on insufficient measures will be scored relative to other MIPS eligible clinicians who can meet the six measure requirement. We urge CMS to hold clinicians with insufficient measures harmless with respect to scoring the quality performance category. AAAAI requests that CMS provide an example of how an eligible clinician or group with insufficient measures would be scored.

CMS intends to develop a validation process to review and validate a MIPS eligible clinician's inability to report on the quality performance requirements. CMS anticipates that this process would function similar to the Measure Applicability Validity (MAV) process that occurred under PQRS, with a few exceptions. First, the MAV process under PQRS was a secondary process after an EP was determined to not be a satisfactory reporter. Under MIPS, CMS intends to build the process into our overall scoring approach to reduce confusion and burden on MIPS eligible clinicians by having a separate process. Second, as the requirements under PQRS are different than those proposed under MIPS, the process must be updated to account for different measures and different quality performance requirements. While we understand the MAV process as it relates to PQRS, we request that the public be provided the opportunity to comment on the process and clusters that would be created for the MAV process for the quality performance category. We believe that this is especially important now, as eligible clinicians will now be assessed based on performance in the MIPS, rather than as pay-for-reporting under the PQRS. We request that CMS hold a listening session to discuss the MAV process and ways to improve the process prior to the start of the performance period for the 2019 MIPS payment adjustment.

CMS proposes to use a lower scoring benchmark for topped out measures. CMS proposes to identify "topped out" measures by using a definition similar to the definition used in the HVBP: Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors; or median value for a process measure that is 95 percent or greater (80 FR 49550). AAAAI seeks clarification as to which measures it is proposing to include in MIPS that are "topped out." Without knowing which measures are topped out, it is difficult to provide support or opposition for this proposal. Regardless, in general, AAAAI opposes CMS' proposal to score topped out measures at a lower benchmark than other quality measures, especially for the first year of MIPS. We strongly believe all measures should be scored equally, as it has been under the PQRS. If measures are deemed topped out and therefore receive reduced points with respect to scoring, we believe this may negatively affect clinicians who have been high performers and enthusiastic participants in PQRS in the past. In addition, physicians who are beginning the quality reporting process should be allowed to use these measures at an equal value as those who have used them previously, and their participation is devalued by comparison if these measures are scored lower. We note that in PQRS, since there has not previously been a consequence for reporting on measures that were topped out, EPs choose which measures are most applicable to their practice. This proposal would be a departure from how clinicians are used to participating, and we feel that there should at least be a grace period before this proposal is implemented, and that it should only be implemented when measures deemed to be "topped out" can be included in the proposed rule for the reporting year in question.

For each set of benchmarks, CMS proposes to calculate the decile breaks based on measure performance during the performance period and assign points for a measure based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. We request that CMS specify the benchmarks that will be used for each measure. Prior to the performance period or immediately after CMS establishes the benchmarks for the measures, whichever comes first, we request that CMS hold a listening session and community outreach to explain these benchmarks and accept any comments the public may have.

CMS proposes to cap the bonus points for the high priority measures (outcome, appropriate use, patient safety, efficiency, patient experience, and care coordination measures) at 5 percent of the denominator of the quality performance category score. AAAAI does not believe there should be a cap on bonus points for the submission of high priority measures. We believe the cap minimizes the incentive to report higher priority measures.

CMS proposes that MIPS eligible clinicians who report measures with a performance rate of 0 percent would not be included in the benchmarks. AAAAI supports this proposal, as we do not believe eligible clinicians should be scored on measures that are not applicable to them.

CMS proposes to create separate benchmarks for submission mechanisms that do not have comparable measure specifications. CMS proposes to develop separate benchmarks for EHR submission options, claims submission options, Qualified Clinical Data Registries (QCDRs) and qualified registries submission options. AAAAI supports CMS' proposal to develop a different set of benchmarks for each submission mechanism, and in the case of QCDRs, doing so in conjunction with the developers of the specialty measures included in the QCDR.

Measures for the Quality Performance Category

In the final rule, we encourage CMS to explain how eligible clinicians and groups who do not report on at least six measures or a specialty set with less than six measures due to lack of applicable measures will be scored relative to other MIPS eligible clinicians who are able to meet the six measure threshold. We urge CMS not to unintentionally harm these eligible clinicians when scoring for the overall CPS is taken into account simply because of a lack of applicable measures.

Section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act (i.e., the NQF convened Measure Application Partnership (MAP) process) is not required for MIPS quality measures. Nonetheless, CMS proposes to consider the MAP's recommendations as part of its comprehensive assessment of each measure under consideration for MIPS. While we are not opposed to CMS using MAP recommendations to consider whether or not to introduce measures into the MIPS, we do not believe CMS should place equal weight into MAP recommendations as it has under the PQRS. We believe the MAP recommendations should only be one factor for considering whether a measure should be introduced.

CMS will submit new measures for publication in journals before including such measures in the final annual list of quality measures. CMS requests comment on this proposal and on what mechanisms could be used, such as the CMS website, to notify the public that the requirement to submit new measures for publication is met. AAAAI supports the proposal to submit new measures for publication in a journal, as it promotes transparency. However, we hope this does not add another level of

complexity and lengthen the time it takes to introduce a measure into the MIPS program. We believe CMS should work to find a way to shorten the timeline for implementing measures into the MIPS. With respect to notifying the public, we believe posting this information on the CMS website is sufficient. We strongly encourage CMS to work with the relevant specialty societies as it works on new measures.

This year, in addition to the MAP's input, CMS received input from the Core Measure Collaborative on core quality measure sets. The Core Measure Collaborative was organized by CMS in coordination with America's Health Insurance Plans (AHIP) in 2014. It has developed several condition-specific core measure sets to help align reporting requirements for private and public health insurance providers. While we support efforts to collaborate, we caution CMS in using recommendations in the Core Measure Collaborative without consultation with other affective specialties and groups. For example, as discussed later in this section, CMS is proposing to remove PQRS measure #53 (NQF 0047) – Pharmacologic Therapy for Persistent Asthma Ambulatory Care Setting and to replace it with measure NQF 1799 – Medication Management for People with Asthma. This move, which comes as a recommendation from the Core Measure Collaborative, makes the measure inaccessible for many Eligible Providers.

CMS seeks comment on its proposal to allow reporting of specialty-specific measure sets to meet the submission criteria for the quality performance category, including whether it is appropriate to allow reporting of a measure set at the subspecialty level to meet such criteria, since reporting at the subspecialty level would require reporting on fewer measures. AAAAI strongly supports allowing specialty-specific measure sets to meet the submission criteria for the quality performance category, even if it would mean an eligible clinician or group would report on fewer than six measures. This is especially important for our physicians, since so many of our Allergists practice with a narrow specialty focus.

CMS proposes an Allergy/Immunology/Rheumatology specialty measure set. While AAAAI supports the construction of a specialty measure set, we strongly object to the way this specialty measure set is constructed. Simply put, Rheumatology should NOT be incorporated into a specialty measure set with Allergy/Immunology. We note that the American College of Rheumatology agrees.

Therefore, we request that the following measures be removed from this specialty measure set:

- Rheumatoid Arthritis (RA): Tuberculosis Screening
- Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity
- Rheumatoid Arthritis (RA): Functional Status Assessment
- Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis
- Rheumatoid Arthritis (RA): Glucocorticoid Management

Also, while asthma and sinusitis measures are certainly measures that many allergists will report, quality measures related to rheumatoid arthritis, HIV/AIDS (NQF 0405) and Tuberculosis (337) are NOT sufficiently relevant to Allergist/Immunologists to be included. Therefore we strongly recommend removing these rheumatology and other measures, and renaming this specialty measure set as the Allergy/Immunology specialty measure set. Finally, we ask that NQF 53, Pharmacologic Therapy for Persistent Asthma, be added to this reconstituted Allergy/Immunology specialty measures set, and 1799 should be removed for the reasons discussed below.

CMS is not proposing the use of measures groups for reporting in the quality performance category. We urge CMS to retain the option to report measures groups. Specifically, we request that CMS retain the asthma measures group as it is currently established in the PQRS for 2016, for the reporting period for the 2018 PQRS payment adjustment. The asthma measures group as currently composed in the PQRS contains the following measures:

- 53: Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting;
- 110: Preventive Care and Screening: Influenza Immunization;
- 126: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan;
- 130: Documentation of Current Medications in the Medical Record;
- 226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention; and
- 402: Cessation Intervention: Tobacco Use and Help with Quitting Among Adolescents.

We also request that CMS maintain the sinusitis measures group. The sinusitis measures group as currently composed in the PQRS contains the following measures:

- Documentation of Current Medications in the Medical Record;
- Pain Assessment and Follow-Up
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse)
- Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)
- Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)

We note that these measures groups not only encourage A/I eligible clinicians to report on measures that target a specific condition, the measures groups also place an emphasis on reporting cross-cutting measures as several cross-cutting measures are in these measures groups. To the extent that CMS is proposing to remove any of the measures in the aforementioned measures groups, we note that we oppose CMS' proposal to do so as we request that all measures in these existing measures groups be retained in the MIPS. Please note that we also suggest criteria for reporting measures groups for the quality performance category above.

CMS proposes the removal of PQRS measure #53 (NQF 0047) – Pharmacologic Therapy for Persistent Asthma Ambulatory Care Setting and proposes to replace it with measure NQF 1799 – Medication Management for People with Asthma. AAAAI opposes this change and requests that CMS retain PQRS measure #53 (NQF 0047) – Pharmacologic Therapy for Persistent Asthma Ambulatory Care Setting in the MIPS. We thank CMS for listening to our concerns on a recent conference call regarding this extremely important issue for our specialty and for our patients. For many years, AAAAI and others in the specialty advocated removing the upper age limit that had been included in NQF 0047, which was once as low as 40 years old. CMS finally agreed to remove the upper age limit from this measure in final Physician Fee Schedule for 2015, recognizing the importance of measuring quality care in older patients with asthma. Measure NQF 1799, which CMS now suggests using in lieu of NQF 0047, measures only asthma patients from 5-64 years of age, reintroducing this rather arbitrary age limit, and again removing Medicare patients from the measure. We believe this measure unnecessarily restricts the applicable patients for whom both specialty and primary care physicians may report, and thus minimizes the importance of evidence based care for elderly asthma patients.

The prevalence of asthma in adults age 65 and older is estimated at 4 to 8 percent. The prevalence of asthma among all adults in the United States is estimated to be 7.7 percent. (1) **Despite asthma being usually considered a disease of younger people, asthma mortality is currently greatest in the over 55 age-group, and in patients older than 65 years is 14 times higher than patients aged 18-35 years** (2). Symptoms and emergency presentations for health care due to asthma place a great burden on the quality of life of those over age 55 with asthma. Asthma in older people is under-diagnosed due to patient and physiological factors. (3). Therefore, CMS should be working to improve quality care for elderly asthma patients, and this change unfortunately does the opposite.

Further, NQF 1799 requires the ability to track prescription refills for reporting purposes. Currently only those physicians wholly employed by large healthcare systems are able to track this data. This makes most allergy and immunology physicians, as well as many others, completely unable to track this information in their systems, and therefore unable to report on the proposed measure. The Common Core measures set, developed with input from private payers, would certainly prioritize a measure that provides prescription refill data, because we know that ongoing treatment of asthma avoids expensive asthma exacerbations. We believe this is important. But the purpose of the MIPS program is about engaging physicians providing and reporting quality care; and adoption of this measure, which shuts out most of the physicians who would otherwise be reporting on it, defies that purpose. Therefore, given the infeasibility of reporting NQF 1799, we request that CMS retain 0047.

In addition, we request that you add PQRS measure #53 (NQF 0047) – Pharmacologic Therapy for Persistent Asthma Ambulatory Care Setting to the A/I specialty measure set.

CMS proposes to remove NQF 0036: Use of Appropriate Medications for Asthma because it is has a high performance rate, shows little variation in care and is clinically close to another measure that is being proposed, NQF 1799: Medication Management for people with Asthma. The AAAAI accepts the removal of this measure, so long as NQF 1799 is removed and NQF 36 is retained instead. If that change is not made, then 36 is needed for physicians unable to report on the pharmacy refills.

Lastly, we support CMS' proposal to include the following measures in the MIPS:

- Preventive Care and Screening: Influenza Immunization
- Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):
- Closing the Referral Loop: Receipt of Specialist Report
- Immunizations for Adolescents

As we noted in this letter and in conversations with CMS, with respect to CMS' proposal to include the **Measure 398: Optimal Asthma Control** measure, we do not support including an upper age limit, especially an age limit as low as 50 years old. There is simply no basis for not including older patients with asthma in measures. Including the upper age limit prevents our physicians from being able to report this measure on older patients. Finally, we ask that CMS clarify the characterization of this measure in the final rule, as it is listed in one location as a process measure, and in another as an outcomes measure.

QCDR Measures. The Quality Clinical Data Registry model represents an important opportunity for specialists to report evidence based quality care specific to their patients better than can be done

through other mechanisms. The organizations that are providing QCDRs have invested very heavily in resources and stakeholder engagement to develop measures that reflect specialty care and improve patient outcomes. CMS has made significant requirements on the QCDRs for improvements and enhancements in each of the 3 years for which the model has been available for reporting. Measures within a QCDR differ from measures proposed in the MIPS measure set in that they have not undergone notice and comment rulemaking except within their own specialties.

CMS is proposing that a QCDR utilizing non-MIPS measures must go through a rigorous approval process by the Agency. This includes a review and analysis of measure specifications for scientific rigor, technical feasibility, duplication pertaining to current MIPS measures, clinical performance gaps evidenced by background and/or literature review, and relevance to specialty practice quality improvement. While non-MIPS measures used by QCDRs are not required to be NQF-endorsed, CMS encourages QCDRs to select NQF-endorsed measures and measures that have been in use prior to MIPS.

The AAAAI is concerned that this increasingly stringent approach that CMS is proposing to take with QCDR measures, combined with yearly requirements for changes to the systems themselves, may make this important opportunity for improving care and measurement innovation impossible to maintain. While the requirements in the proposed rule pertaining to QCDR measures are consistent with requirements placed on measures in the PQRS measure set, the overall investment by both the organizations sponsoring these systems and the users relying on them to participate is significant. QCDR measures should continue to be developed by a multi-stakeholder processes by the relevant specialty societies and reviewed by CMS in the QCDR approval process; they should not be required to undergo MAP and NQF processes that are too time consuming to allow such developments to keep pace with constantly changing CMS requirements.

MIPS: Resource Use Performance Category

CMS proposes that the resource use performance category would make up 10 percent of the CPS for the first MIPS payment year (CY 2019) and 15 percent of the CPS for the second MIPS payment year (CY 2020). As specified in more detail below, until CMS is able to develop better cost measures, we believe CMS should use its authority to reweight the resource use performance category to zero.

For the CY 2017 MIPS performance period, CMS proposes to utilize the total per capita cost measure from the VM, the Medicare Spending Per Beneficiary (MSPB) measure from the VM, and several episode-based measures for the resource use performance category. CMS proposes to use administrative claims to collect data on these measures. **CMS is proposing to use the same cost measures currently used under the VM**. AAAAI vehemently opposes use of these existing VM measures. We are concerned with the cost measures and methodology that would continue to be used to calculate cost composite scores. We continue to be concerned that the available cost measures are not appropriate for our specialty and rely on questionable attribution and risk adjustments methodologies. CMS should work closely with specialty societies to develop specific and meaningful resource use measures. Until these cost measures are improved, we do not believe CMS should assign scores to MIPS eligible clinicians under the resource use performance category.

CMS proposes to establish a 20 case minimum for each resource use measure, including the Medicare Spending Per Beneficiary (MSPB) measure, which currently has an established case minimum of 125. AAAAI opposes using a 20 case minimum for the MSPB measure. AAAAI requests that CMS continue to use a 125 case minimum for the MSPB measure for the resource use performance category. We note that, for the VM, CMS conducted a study and determined the 125 case minimum more appropriate for the MSPB measure than a 20 case minimum, particularly as smaller groups and solo practitioners were added to the VM. Based on this new analysis, CMS believed that a minimum of 125 episodes was preferable. We believe the rationale used by CMS to increase the case minimum for the MSPB measure from 20 to 125 cases still holds true for the resource use performance category of the MIPS: "However, we continue to believe that it would not be appropriate to include this measure in the cost composite with a 20-episode minimum at a sample size that does not produce reliable results even for those groups that performed well. Rather, we believe that it is more important to ensure that only reliable measures are included in the VM, and we want to avoid a situation in which groups or solo practitioners who may have performed poorly on the measure using a 20-episode minimum may receive a downward adjustment to payments under the VM as a result of a measure that was not reliable" (80 FR 71296).

Moreover, CMS proposes to remove the specialty adjustment from the MSPB measure and modify the cost ratio used within the MSPB equation. AAAAI opposes CMS' proposal to remove the specialty adjustment for the MSPB measure. While we do not yet know the effects of the specialty adjustment, as the specialty adjustment was recently implemented in the MSPB measure, we believe the specialty adjustment should be retained to determine whether the adjustment is effective.

CMS is proposing to calculate several episode-based measures for inclusion in the resource use performance category. While we support the inclusion of episode-based measures in the resource use performance category, we note that there are currently no episode-based measures that relate to Allergy/Immunology. We encourage CMS to continue to develop appropriate measures for specialties, such as Allergy/Immunology for the resource use performance category. In addition, since there are currently no episode-based measures that relate to Allergy/Immunology, we question how this will affect how our members are scored on the resource use performance category. While we understand that CMS proposes to score the resource use performance category based on an average of the applicable measures within the category, we wonder whether not having episode-based measures to be scored on would negatively affect our members compared to specialties for which the episode-based measures exist. Since CMS has never factored the use of episode-based measures into scoring, we request that, at least for the first year of MIPS, CMS not include episode-based measures for scoring under the resource use performance category.

MIPS: Advancing Care Information (ACI) Performance Category

AAAAI opposes CMS' proposals to largely incorporate the requirements for Stage 3 of the Medicare EHR Incentive Program into the ACI performance category. The EHR Incentive Program requirements have historically been too onerous for eligible clinicians to achieve. In addition, we do not believe the objectives and measures meaningfully capture interoperability and demonstration of successful use of CEHRT.

CMS proposes QCDRs as a submission mechanism option for the ACI performance category. AAAAI supports the use of QCDRs as a submission mechanism for the ACI performance category. However, AAAAI requests that CMS provides an option for eligible clinicians to use a QCDR in lieu of CEHRT. **Under MIPS, CMS proposes to align the performance period for the ACI performance category to the proposed MIPS performance period of one full calendar year. Thus, the performance period for the ACI performance category would be the same as the performance periods for the other performance categories. There would not be a separate 90-day performance period for the ACI performance category**. For the reasons stated above related to our opposition to the proposed performance period, AAAAI opposes the proposed performance period for the ACI performance category. In addition, we believe that CMS should establish a 90-day performance period for the ACI performance category, at least for attestation. Specifically, we request that CMS allow eligible clinicians to attest for any continuous 90-day period during the ACI performance period.

CMS proposes to use the objectives and measures that have been largely adopted from the Modified Stage 2 and Stage 3 objectives and measures as finalized in the 2015 EHR Incentive Programs Final Rule (80 FR 62829 – 62871). However, CMS is not proposing to maintain the previously established thresholds for each of these measures under MIPS. We support CMS' decision not to maintain the previously established thresholds for each of these measures. However, AAAAI opposes using the objectives and measures that have been largely adopted from the Modified Stage 2 and Stage 3 objectives and measures as finalized in the 2015 EHR Incentive Programs Final Rule. Clinicians have faced much difficulty in complying with EHR Incentive Program requirements. We note that this is an opportunity for CMS to restructure the requirements for this performance category in a way that is more meaningful and inclusive to eligible clinicians.

In its primary proposal, CMS proposes to eliminate two objectives – Clinical Decision Support and Computerized Provider Order Entry – and would require a MIPS eligible clinician to report the numerator (of at least one) and denominator or yes/no statement (only a yes statement would qualify for credit under the base score) for all objectives and measures adopted for Stage 3 in the 2015 EHR Incentive Programs Final Rule to earn the base score portion of the ACI performance category, which would include reporting a yes/no statement for Clinical Decision Support and a numerator and denominator for Computerized Provider Order Entry objectives. AAAAI supports CMS' PRIMARY proposal to eliminate two objectives – Clinical Decision Support and Computerized Provider Order Entry – adopted for Stage 3.

CMS proposes that a MIPS eligible clinician must meet the Protect Patient Health Information objective and measure in order to earn any score within the ACI performance category. AAAAI opposes requiring this objective and measure in order to earn any score within the ACI performance category. We believe CMS should allow for maximum flexibility in meeting the objectives and measures in the ACI performance category. AAAAI urges CMS to collaborate with its federal agency partners to develop more robust guidance for physician offices on conducting security risk assessments; provide data on common security risk failures in physician practices, large and small; and, provide enhanced technical assistance and support on HIT security.

CMS did not propose to modify the Patient Access measure under the Patient Electronic Access objective. While CMS recently extended the timeframe for making records available to 48 hours, instead

of 24 hours, we continue to believe the timeframe may be too narrow and 4 business days would have been more appropriate. We urge CMS to reconsider the timeframe.

CMS is not proposing to modify measures under the Health Information Exchange objective. While CMS is not proposing to make modifications to measures under the Health Information Exchange objective, we urge CMS to clarify how transitions of care/referrals to specialists are counted, as this remains an area where A/I physicians are confused.

ACI Performance Category Scoring

In the final rule, we request CMS to explain whether, if all other things are equal, eligible clinicians who report Stage 3 objectives and measures will receive additional or the same credit as eligible clinicians who report modified Stage 2 objectives and measures.

In lieu of using a base and performance score to account for the ACI score, we urge CMS to award full credit under the ACI performance category to MIPS eligible clinicians and group who meet the proposed CEHRT requirement under for QPs in Advanced APMs – at least 50 percent of eligible clinicians who are enrolled in Medicare to use the CEHRT functions (as outlined in the proposed CEHRT definition) "to document and communicate clinical care with patients and other health care professionals."

To earn points toward the base score, CMS proposes that a MIPS eligible clinician must report the numerator and denominator of certain measures specified for the ACI performance category, which are based on the measures adopted by the EHR Incentive Programs for Stage 3 in the 2015 EHR Incentive Programs Final Rule, to account for 50 percent (out of a total 100 percent) of the ACI performance category score. For measures that include a percentage based threshold for Stage 3 of the EHR Incentive Program, CMS would not require those thresholds to be met for purposes of the ACI performance category under MIPS, but would instead require MIPS eligible clinicians to report the numerator (of at least one) and denominator (or a yes/no statement for applicable measures, which would be submitted together with data for the other measures) for each measure being reported. For any measure requiring a yes/no statement, only a yes statement would qualify for credit under the base score. While the proposal to only accept numerator/denominator information and yes/no statements for the base score is an improvement to measuring every objective on performance, we believe CMS still misses the mark on providing adequate flexibility to eligible clinicians. Specifically, CMS notes that, for objectives requiring a yes/no statement, only a yes statement would qualify for credit under the base score. This proposal does not solve the underlying issue of having objectives and measures in the ACI performance category that may not fit all eligible clinicians. We urge CMS to consider a way to provide credit in the ACI performance category simply by demonstrating use of CEHRT, as is proposed to be required for QPs in advanced APMs. We also request that this requirement can be met via QCDR reporting, as long as the QCDR is CEHRT.

CMS proposes that a MIPS eligible clinician would earn additional points above the base score for performance in the measures for the following objectives: Patient Electronic Access; Coordination of Care through Patient Engagement; and Health Information Exchange. AAAAI does not support using a performance score to count as part of the ACI performance category score. We believe it is premature to assess a performance score during the initial phase of the MIPS. Alternatively, CMS could simply assign more points to the base score. For example, CMS could attribute 60 points to the base score (or 10 points for each proposed objective in the base score).

CMS proposes hardship exemptions for: Hospital-Based MIPS Eligible Clinicians; Clinicians Previously Not Eligible to Participate in the Medicare/Medicaid EHR Incentive Programs – NPs, PAs, CNSs, and CRNAs; and MIPS Eligible Clinicians Facing a Significant Hardship. CMS proposes the following categories that fall under the significant hardship exemption: a MIPS eligible clinician who is classified as a non-patient facing MIPS eligible clinician (based on the number of patient-facing encounters billed during a performance period); insufficient Internet Connectivity; lack of Control over the Availability of certified EHR technology; and lack of Face-to-Face Patient Interaction. AAAAI supports using CMS' authority to reweight the performance categories to zero for these proposed hardships.

MIPS: Clinical Practice Improvement Activity (CPIA) Performance Category

CMS proposes that the CPIA performance category will account for 15 percent of the CPS. AAAAI requests that the CPIA performance category be weighted higher. We believe that the CPIA performance category should count for at least 25 percent of the CPS. To achieve a 25 percent weight for the CPIA performance category, CMS could either distribute all of the weight from resource use or all/part of the weight from the ACI performance category.

CMS proposes the following data submission mechanisms: Attestation, QCDR, Qualified registry, EHR, CMS Web Interface (groups of 25 or more), and Administrative claims (if technically feasible, no submission required). The administrative claims method, if technically feasible, would only be used to supplement CPIA submissions. For example, if technically feasible, MIPS eligible clinicians or groups, using the telehealth modifier GT, could get automatic credit for this activity. AAAAI supports the proposed submission mechanisms, particularly the attestation option. However, while we support the option for QCDRs to be able to report CPIA information, we do not believe QCDR systems will be ready to accept CPIA data by the time of QCDR self-nomination.
In order to achieve the highest potential score of 100 percent, at three high-weighted CPIAs (20 points each) or six medium-weighted CPIAs (10 points each), or some combination of high and medium-weighted CPIAs, CMS proposes that a MIPS eligible clinician must achieve a total of 60 points for MIPS eligible clinicians participating as individuals or as groups. AAAAI supports CMS' proposal to score activities as either medium or high, as proposed.

CMS proposes that MIPS eligible clinicians or groups must perform CPIAs for at least 90 days during the performance period for CPIA credit. While AAAAI generally supports the proposal that MIPS eligible clinicians or groups must perform CPIAs for at least 90 days during the performance period for CPIA credit, AAAAI seeks clarification on this proposal. For example, for the proposed activity "Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities" under the beneficiary engagement subcategory, clarification is needed as to what CMS defines as performing this activity for 90 days. Is participation in a QCDR that performs this activity for at least 90 days sufficient? Would an eligible clinician who enters into an agreement to participate in a QCDR who performs this activity in December 31, 2017 (1 month prior to the close of the performance period) be able to claim this activity? In addition, how does this proposal apply to a group? Would each eligible clinician in the group be required to perform an activity for at least 90 days during the performance period? Would a majority suffice? We request that CMS provide clarification on this

proposal in the final rule, including providing examples as to how an eligible clinician on group would meet or fail this 90-day proposal.

CMS proposes to categorize the CPIAs under the following subcategories: expanded practice access; population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a QCDR; care coordination; beneficiary engagement; patient safety and practice assessment; participation in an APM; achieving health equity; emergency preparedness and response; and integration of primary care and behavioral health. AAAAI supports the activities CMS is proposing under these subcategories. In addition to the activities listed, we urge CMS recognize the following CPIA activities under the CPIA performance category, some of which are particularly important for small and solo practices that have less access to many of the tools and rubrics above:

- Physician attendance and participation in ACGME-accredited events, such as the AAAAI Annual Meeting
- Physician attendance and participation in other CME and non-CME events
- Fellowship training or other advanced clinical training completed during a performance year
- Physician practice accreditation, such as accreditation achieved by the National Committee on Quality Assurance (NQCA), Accreditation Association for Ambulatory Health Care (AAAHC), The Joint Commission (TJC), or other recognized accreditation organizations
- Participation in the NIH's USIDNET registry, or other federally sponsored quality reporting and improvement programs not already affiliated or considered under the MIPS program

Furthermore, AAAAI specifically supports the following proposed CPIAs:

- Use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.
- Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (e.g., comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).
- Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools and processes for quality improvement (e.g., documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).
- Ensure that there is bilateral exchange of necessary patient information to guide patient care that could include one or more of the following:
    - Participate in a Health Information Exchange if available; and/or
    - Use structured referral notes.
- Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
- Access to an enhanced patient portal that provides up to date information related to relevant chronic disease health or blood pressure control, and includes interactive features allowing patients to enter health information and/or enables bidirectional communication about medication changes and adherence.

- Participation in a QCDR, that promotes use of patient engagement tools.
- Participation in a QCDR, that promotes collaborative learning network opportunities that are interactive.
- Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
- Participation in a QCDR, that promotes implementation of patient self-action plans.
- Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.
- Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.
- Participation in Maintenance of Certification Part IV for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.
- Use of QCDR data, for ongoing practice assessment and improvements in patient safety.
- Participation in the Consumer Assessment of Healthcare Providers and Systems Survey or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).
- Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.
- Participation in a QCDR, demonstrating performance of activities for promoting use of patient-reported outcome (PRO) tools and corresponding collection of PRO data (e.g., use of PQH-2 or PHQ-9 and PROMIS instruments).
- Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status (e.g., use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment).

MIPS: Composite Performance Score (CPS)

In general, we believe the scoring methodology CMS is proposing is too complex. We urge CMS to design a simpler method of calculating the CPS, one that is easily understandable to an eligible clinician. **CMS proposes to reweight the performance categories for MIPS eligible clinicians when there are not sufficient measures and activities applicable and available to them. If the MIPS eligible clinician does not receive a resource use or ACI performance category score, and has at least three scored measures (either submitted measures or those calculated from administrative claims) in the quality performance category, CMS proposes to reassign the weights of the performance categories without a score to the quality performance category. Alternative Proposal: CMS also proposes an alternative that does not reassign all the weight to the quality performance category, but rather reassigns the weight proportionately to each of the other performance categories for which the MIPS eligible clinician has received a performance category score. If the MIPS eligible clinicians have fewer than three scored measures in the quality performance category score, then CMS proposes to reassign the**

weights for the performance categories without scores proportionately to the other performance categories for which the MIPS eligible clinician has received a performance category score. AAAAI believes that the any weight that must be redistributed should be distributed to the CPIA performance category. The quality performance category already counts for 50 percent of the eligible clinician's CPS, so we believe that redistributing the weight to quality would grossly tilt the CPS towards quality.

Beginning July 1, 2017, CMS proposes to include information on the quality and resource use performance categories in the performance feedback. CMS seeks comment on whether we should include first year measures in the performance feedback, meaning new measures that have been in use for less than 1 year, regardless of submission methods. AAAAI encourages CMS to provide information it its feedback reports on first-year MIPS measures, so that eligible clinicians can determine their performance on these measures before they are scored on them. Whether or not feedback on first year QCDR measures should be reported may have to take into consideration such factors as the number of providers reporting on a measure and other concerns, and should be resolved in conjunction with the QCDR sponsor.

Regulatory Impact Analysis (RIAs): Burden Estimates for the MIPS

The AAAAI requests that CMS revise the estimates it provides in its RIA. In the proposed analysis, CMS uses estimates derived from RIAs that were previously established under previously existing programs: The Physician Quality Reporting System (PQRS), EHR Incentive Program, and Value-based Payment Modifier (VM). While these previously established estimates may have been more accurate for these programs, we believe these estimates do not entirely correlate to the burden associated with participating in the MIPS. We note that the MIPS is a new program, so eligible clinicians will spend a significant amount of time, at least at first, to understand the program. In addition, we believe the MIPS, as proposed, is much more complicated than the programs preceding it, particularly because the proposed scoring methodology is very complex. According to the proposed requirements for the quality performance category, unlike the PQRS, eligible clinicians will have to be more strategic in the measures they choose as reporting on topped out measures may negatively affect their scoring. In addition, unlike the PQRS, eligible clinicians will now have to analyze measure benchmarks to see how their scores measure up against other clinicians.

MIPS: Third Party Data Submission

The AAAAI Allergy, Asthma & Immunology Quality Clinical Data Registry, in collaboration with CECity, is intended for physicians specializing in Allergy/Immunology (AAAAI members & non-members) to foster performance improvement and improve outcomes in the care of patients with allergies, asthma, immune deficiencies and other immunologic diseases. The registry provides participating providers with important information resources: timely custom continuous performance monitors; performance gap analysis and patient outlier identification; access to improvement interventions to close performance gaps including patient care management tools; targeted education; resources and other evidence-based interventions; and comparison versus registry benchmarks and peer-to-peer comparison.
The AAAAI QCDR is comprised of 31 quality measures, including measures for allergy immunotherapy developed by the Joint Task Force on Quality Performance Measures (approved by AAAAI and ACAAI); PQRS asthma measures modified to remove the upper age limit; and a modified version of the asthma

outcomes measure, approved for use by Minnesota Community Measurement in the QCDR without an upper age limit. Sixteen of these measures are custom quality measures designed specifically for practitioners providing care for patients with allergies, asthma, immune deficiencies and other immunologic diseases. Data can be uploaded or entered manually. Each measure has predefined data elements and data definitions. The AAAAI QCDR has been a QCDR for purposes of PQRS reporting since 2014. Below, we provide our comments related to CMS' proposals for QCDRs participating in the MIPS:

CMS proposes a self-nomination period from November 15, 2016 until January 15, 2017, including providing descriptions and narrative specifications for each measure activity or objective for which it will submit to CMS by no later than January 15 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data. For future years of the program, starting with the 2018 performance period, CMS proposes to establish the self-nomination period from September 1 of the prior year until November 1 of the prior year. We request that CMS extend the self-nomination deadline to February 28, 2017. We believe it is particularly important to allow QCDRs more time to self-nominate as the MIPS in order for the QCDR to determine whether its systems may be updated to account for new requirements under the MIPS. We note that, unlike the PQRS, CMS is allowing QCDRs the option to submit data for other performance categories (advancing care information and CPIA) on which it has not traditionally submitted data. We urge CMS to allow QCDRs more time to determine its capabilities for the performance period prior to self-nomination. We also note that requiring QCDRs to provide narrative measure specifications by January 15 (and November 1 for future years following the 2019 MIPS payment adjustment) during the applicable performance period is not reasonable, particularly for new measures the QCDR plans to introduce for the applicable performance period. Therefore, AAAAI recommends that CMS finalize a deadline of February 28 of the applicable performance period for a QCDR to submit descriptions and narrative specifications for each measure activity or objective for which it will submit to CMS.

CMS proposes that a QCDR must provide the following information to the agency at the time of self-nomination to ensure that QCDR data is valid:

- **MIPS performance categories (that is, categories for which the entity is self- nominating, for example, quality, advancing care information, and/or CPIA).** We request that CMS continue to make this requirement optional for QCDRs.
- **Describe the method that the entity will use to accurately calculate performance data for CPIA and advancing care information based on the appropriate parameters or activities.** We request that CMS continue to make this requirement optional for QCDRs.
- **Describe the process that the entity will use for completion of a randomized audit of a subset of data prior to the submission to CMS (for all performance categories the QCDR is submitting data on, that is, quality, CPIA, and advancing care information, as applicable). Periodic examinations may be completed to compare patient record data with submitted data and/or ensure MIPS quality measures or other performance category (CPIA, advancing care information) activities were accurately reported and performance calculated based on the appropriate measure specifications (that is, accuracy of numerator, denominator, and exclusion criteria) or performance category requirements**. The AAAAI will comply with all requirements for the QCDR but is extremely concerned about the burden resulting from the

compounding weight of so many changes and requirements at one time, particularly within a short time frame.

CMS proposes to require the QCDR to agree that data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent of the total number of MIPS eligible clinicians submitted by the QCDR may result in notations on CMS's qualified QCDR posting of low data quality and would place the QCDR on probation (if they decide to self-nominate for the next program year). If the QCDR does not reduce their data error rate below 3 percent in the subsequent year, they would continue to be on probation and have their listing on the CMS website continue to note the poor quality of the data they are submitting for MIPS. Data errors affecting in excess of 5 percent of the MIPS eligible clinicians submitted by the QCDR may lead to the disqualification of the QCDR from participation in the following year's program. As CMS gains additional experience with QCDRs, the agency intends to revisit and enhance these thresholds in future years. AAAAI requests that CMS provide a grace period for implementing this proposed requirement, particularly since we are entering into a new program. For the quality performance period, AAAAI requests that CMS provide a one-year grace period from implementation of this proposed requirement, as QCDRs will need to update their systems to account for changes in data submission from the PQRS to the quality performance category of the MIPS. For the ACI and CPIA performance categories, AAAAI requests a two-year grace period for implementing this proposed requirement, as QCDRs will need to gain experience with these new categories. We look forward to working with CMS to provide an effective and user-friendly tool for reporting quality data that reflects specialty care for our patients, but again must express our concern about the constant and constantly increasing demands on these systems.

CMS proposes to require a QCDR to obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the QCDR, has authorized the QCDR to submit quality measure results, CPIA measure and activity results, advancing care information objective results and numerator and denominator data and/or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation. This documentation must be obtained at the time the MIPS eligible clinician or group signs up with the QCDR to submit MIPS data to the QCDR and must meet the requirements of any applicable laws, regulations, and contractual business associate agreements. Groups participating in MIPS via a QCDR may have their group's duly authorized representative grant permission to the QCDR to submit their data to CMS. If submitting as a group, each individual MIPS eligible clinician does not need to grant their individual permission to the QCDR to submit their data to CMS. AAAAI requests that CMS provide a time limit for keeping this documentation. For example, AAAAI requests that CMS only require a QCDR to obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the QCDR, has authorized the QCDR to submit quality measure results, CPIA measure and activity results (if applicable), advancing care information objective results and numerator and denominator data (if applicable) and/or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation for 3 years beyond each reporting year for which a user participates via the QCDR. Furthermore, with respect to the requirements surrounding the ACI and CPIA performance categories, we request that CMS indicate that these requirements would be optional, as QCDRs would have the option to report CPIA and ACI performance category information.

With respect to submitting QCDR measure specifications, CMS proposes to require QCDRs to:

- **Provide descriptions and narrative specifications for each measure activity, or objective for which it will submit to CMS by no later than January 15 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data**. AAAAI opposes CMS' proposal to have measures specifications submitted by January 15, as we do not believe this gives enough time for QCDRs to determine which measures would be appropriate for the MIPS following the issuance of the final rule, which is expected to be released in November 2016. We request that CMS extend the deadline for providing descriptions and narrative specifications, as well as information for the CPIA and ACI performance categories (if applicable), to February 28 of the applicable performance period for the 2019 MIPS payment adjustments and beyond.
- **In future years, starting with the 2018 performance period, those specifications must be provided to CMS by no later than November 1 prior to the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data**. AAAAI opposes CMS' proposal to provide measure specifications to CMS no later than November 1 prior to the applicable performance period for which the QCDR wishes to submit quality measures or other performance category. As noted previously, we request that CMS extend the deadline for providing descriptions and narrative specifications, as well as information for the CPIA and ACI performance categories (if applicable), to February 28 of the applicable performance period for the 2019 MIPS payment adjustments and beyond.

CMS notes that documentation or "check box" measures are discouraged. Measures that have very high performance rates already or address extremely rare gaps in care (thereby allowing for little or no quality distinction between MIPS eligible clinicians) are also unlikely to be approved for inclusion. AAAAI opposes this note. At least in the first year of MIPS, we recommend that CMS provide flexibility in terms of accepting measures for the QCDR option.

CMS proposes that if at any time it determines that a third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) has not met all of the applicable requirements for qualification, CMS may place the third party intermediary on probation for the current performance period and/or the following performance period, as applicable. We do not support this proposal. While we understand that there may be a need to implement a probationary phase for QCDRs lacking certain requirements, we do not believe that a probationary period should be implemented at this time. We believe QCDRs should be given time to become familiar with new requirements under the MIPS prior to implementation of a probationary period.

In addition, CMS proposes to require a corrective action plan from the third party intermediary to address any deficiencies or issues and prevent them from recurring. CMS proposes the corrective action plan must be received and accepted by CMS within 14 days of the CMS notification to the third party intermediary of the deficiencies or probation.

CMS proposes if the third party intermediary does not reduce their data error rate below 3 percent for the subsequent performance period, the third party intermediary would continue to be on probation and have their listing on the CMS website continue to note the poor quality of the data they are

submitting for MIPS for one additional performance year. We oppose this proposal. CMS notes that many of these inaccuracies stem from TIN/NPI mismatches. Please note that the TIN/NPI information we receive is based on what eligible clinicians provide to QCDRs. Therefore, we do not believe QCDRs should be held accountable for inaccurate information provided by eligible clinicians.

CMS proposes if the third party intermediary does not submit an acceptable corrective action plan within 14 days of notification of the deficiencies and correct the deficiencies within 30 days or before the submission deadline—whichever is sooner, CMS may disqualify the third party intermediary from participating in MIPS for the current performance period and/or the following performance period, as applicable. The AAAAI opposes this proposal, but expresses concern that if this is finalized, it is important to include how participants already using the QCDR for that reporting period can still have their reporting completed.

Physician Compare

In general, AAAAI requests that CMS exercise caution with its proposals to display data on the MIPS. Until we can determine that the data used to calculate the CPS are accurate, and the methodology used to calculate the CPS is fair and takes into account the nature of each eligible clinician's practice, we believe it is premature to finalize any requirements to include MIPS data on Physician Compare.

CMS proposes that these data – the composite score for each MIPS eligible clinician, performance of each MIPS eligible clinician for each performance category, and periodically post aggregate information on the MIPS – to the extent that they meet the previously established public reporting standards, will be added to Physician Compare for each MIPS eligible clinician or group, either on the profile pages or in the downloadable database, as technically feasible. AAAAI opposes this proposal. Until we can determine the accuracy of the CPS scores, including the accuracy of the data used to determine the CPS scores, and preferably whether this collection of data actually is improving patient care, we believe CMS should delay finalizing making additional individual level information publicly available on Physician Compare.

CMS proposes that all measures in the quality performance category that meet the public reporting standards would be included in the downloadable database, as technically feasible. CMS also proposes that a subset of these measures would be publicly reported on the website's profile pages, as technically feasible. In addition, CMS proposes to include a sub-set of resource use measures, that meet the aforementioned public reporting standards, on Physician Compare, either on profile pages or in the downloadable database, if technically feasible. AAAAI requests clarification on how CMS will display QCDR and non-MIPS measures. AAAAI requests that CMS continue to allow QCDRs the option of determining where to post their measures data.

CMS proposes to make all measures under the MIPS resource use performance category available for public reporting on Physician Compare. For the same reasons we request that the resource use performance category be reweighted to zero, AAAAI opposes CMS' proposal to display results on performance on the resource use performance category.

Other Considerations for the MIPS

Meaningful Use Prevention of Information Blocking and Surveillance Demonstration for MIPS Eligible Clinicians, EPs, Eligible Hospitals, and CAHs: CMS proposes to require EPs, eligible hospitals, and CAHs to attest (as part of their demonstration of meaningful use under the Medicare and Medicaid EHR Incentive Programs) that they have cooperated with the surveillance of certified EHR technology under the ONC Health IT Certification Program. Similarly, CMS proposes to require such an attestation from all eligible clinicians under the ACI performance category of MIPS, including eligible clinicians who report on the ACI performance category as part of an APM Entity group under the APM Scoring Standard, as discussed later in this proposed rule summary. AAAAI opposes the proposed requirement for EPs, eligible hospitals, and CAHs to attest that they have cooperated with the surveillance of certified EHR technology under the ONC Health IT Certification Program, as we do not believe physician practices have purposefully blocked the sharing of information among systems. Therefore, we feel this requirement adds unnecessary burden to eligible clinicians.

CMS notes that The U.S. Department of Health & Human Services' (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting studies and making recommendations on the issue of risk adjustment for socioeconomic status on quality measures and resource use as required by section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) and expects to issue a report to Congress by October 2016. AAAAI encourages CMS to incorporate socio-economic status (SES) and other demographic factors that have a clear relationship to quality of care and patient outcomes into resource use (and quality) measurement.

Alternative Payment Models (APMs)

In order to be an APM as a "demonstration required by Federal law," CMS proposes that the demonstration must meet the following 3 criteria: (1) the demonstration must be compulsory under the statute, not just a provision of statute that gives the agency authority, but one that requires the agency to undertake a demonstration; (2) there must be some "demonstration" thesis that is being evaluated; and (3) the demonstration must require that there are entities participating in the demonstration under an agreement with CMS or under a statute or regulation. Within an APM, CMS proposes to define an APM Entity as the participating entity in an APM that is primarily responsible for the cost and quality of care provided to beneficiaries under the terms of a direct agreement with CMS. According to this definition, CMS is proposing to recognize the following models as advanced APMs: (1) Comprehensive ESRD Care (CEC) (LDO arrangement); (2) Comprehensive ESRD Care (CEC) (non- LDO arrangement); (3) Comprehensive Primary Care Plus (CPC +); (4) Medicare Shared Savings Program - Track 1 (MSSP); (5) MSSP- Track 2; (6) MSSP- Track 3; (7) Oncology Care Model (OCM) one-sided risk arrangement; and (8) Oncology Care Model (OCM) two-sided risk arrangement. We believe that CMS should increase its focus on condition-specific APMs for specialty care provider engagement. The AAAAI looks forward to additional information to be provided by CMS on standards for development of APMs and how the vetting and approval process can move forward in such a way as to facilitate numerous proposals in time for reporting for 2018 and beyond.

To be considered an Advanced APM, CMS proposes that an APM must meet all three of the following criteria: (1) The APM must require participants to use certified EHR technology; (2) The APM must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS; (3) The APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model expanded under section 1115A(c) of the Act. For a discussion of our proposals for Medical Home Models under this criterion, see section II.F.4.b.(6) of this preamble. AAAAI agrees with the proposed definition of an advanced APM. However, we are disappointed that only six models are being proposed as advanced APMs: Comprehensive ESRD Care (CEC) (LDO arrangement); Comprehensive Primary Care Plus (CPC +); Medicare Shared Savings Program - Track 2; Medicare Shared Savings Program - Track 3; Next Generation ACO Model; and Oncology Care Model (OCM) Two-Sided Risk Arrangement.

CMS proposes that the group of eligible clinicians would consist of all the eligible clinicians identified as participants in an Advanced APM Entity during the QP Performance Period on a Participation List provided to CMS, with one exception for Advanced APMs whose participants are not eligible clinicians. AAAAI believes determining whether an eligible clinician is a QP should not be limited to a participant list. We encourage CMS to look for additional ways to identify QPs.

Physician-Focused Payment Model (PFPM)

CMS proposes that a PFPM must focus on physician services and contain either individual physicians or PGPs as APM Entities, although it may also include facilities or other practitioner types. CMS proposes to require that PFPMs be designed to be tested as APMs with Medicare as a payer. Other Payer APMs would therefore not be PFPMs. AAAAI supports this broad definition of PPFM, as we believe this definition allows for CMS to consider APMs focused on allergy and immunology.

CMS proposes that PFPM criteria be organized into three categories that are consistent with the Administration's strategic goals for achieving better care, smarter spending and healthier people: payment incentives; care delivery; and information availability. First, CMS proposes a category of criteria that promote payment incentives for higher-value care, including paying for value over volume and providing resources and flexibility necessary for practitioners to deliver high-quality health care. CMS proposes a criterion that PFPMs should provide incentives to practitioners to deliver high-quality health care. CMS proposes a criterion that the PFPM proposal must pay APM Entities under a payment methodology that furthers the PFPM criteria. AAAAI supports the proposed PFPM criteria, as we believe the language is sufficiently broad to implement a PFPM based on allergy and immunology. For example, the AMA and Center for Healthcare Quality and Payment Reform published a Guide to Physician-Focused Payment Models, which describes seven ways of structuring APMs that can be used to address the most common opportunities and barriers that physicians face. Please note that the AMA is supporting the Bundled Payment for Collaborative Treatment of Allergic Asthma. As stated on the AMA website, under this APM, primary care practices and allergy specialists would work together to develop and implement a treatment plan for patients with allergic asthma. The primary care and allergy practices would bill payers for a payment for each patient with diagnosed allergic asthma. The payment would support the development of appropriate immunotherapy treatment by the allergy

practice and administration of the treatments by the primary care practice with telephone support from the allergy practice. The rate at which asthma control medications are used and the frequency of exacerbations would be measured to assess whether patient outcomes had improved and total costs had been reduced.

While we support a model related to the treatment of asthma, we believe it is CRITICALLY important to include patients with non-allergic asthma. Allergy/Immunology physicians commonly manage patients with asthma – "allergic" as well as "non-allergic". We are concerned that based on prevalent misunderstandings regarding our role, we may be identified as specialists who manage "allergic" asthma requiring allergen immunotherapy. Asthma is the #1 diagnosis typically seen by many of our physicians, including many patients not receiving allergen immunotherapy. Access to specialty care for all asthma patients, particularly those with persistent and severe asthma, must be enabled by payment models, and never restricted by them.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members and patients. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

Thomas B. Casale, MD FAAAAI
Executive Vice President

Citations:

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