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September 2, 2014

Submitted Electronically: www.regulations.gov

Ms. Marilyn Tavenner
Administrator
Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1590-FC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1612-P; RIN 0938-AS12; Proposed Rule; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015.

Dear Administrator Tavenner,

The American Society of Nuclear Cardiology (ASNC) is pleased to offer comments on the proposed rule for Medicare payments in the Physician Fee Schedule (PFS) for calendar year 2015; published in the Federal Register on July 11, 2014 by the Centers for Medicare and Medicare Services (CMS).

ASNC is a 4,500 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

As the professional society whose members are most involved in the delivery of various cardiac imaging modalities to Medicare beneficiaries, ASNC appreciates that CMS has taken the recommendations of ASNC and other commentators in helping to improve patient care and access.

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Misvalued Codes

CMS proposes a review of high expenditure services across specialties with Medicare allowed charges of $10,000,000 pursuant to authority granted in §220(c) of the Protecting Access to Medicare Act of 2014 (PAMA). There are 65 codes that were identified as potentially misvalued through the high expenditure specialty screen. Codes that were excluded from the high expenditure specialty screen were those that had been reviewed since CY2009, had fewer than $10 million in allowed charges, and those that were anesthesia or E/M services.

ASNC strongly objects to the inclusion of 78452, Myocardial Perfusion Imaging, Tomographic (SPECT), in the list of potentially misvalued codes identified through the high expenditure specialty screen. First, 78452 was last reviewed in February of 2009. The criterion CMS used to develop the list of potentially misvalued codes excluded those that had been reviewed "since" 2009 which suggests that codes included on the list are those that had not been reviewed from Jan. 1, 2009 to the present. Moreover, if "since" is construed as encompassing CY2009 it is still true that 78452 has been recently surveyed and there is little likelihood of a substantive change in physician work and PE RVUs in the intervening period. 78452 has been surveyed several times over the past 10 years, refining its wRVU and PE RVU to a high level. CMS made adjustments to RUC recommendations in 2009 and it is unlikely that any substantive change has occurred.

Second, PAMA directs the Secretary "establish a program to promote the use of appropriate use criteria…for applicable imaging services."[1] Appropriate Use Criteria were developed by medical specialty societies convening experts in the field who determined when and how often a given procedure is warranted using scientific evidence, patient characteristics, and current technological capabilities. The program will identify individual physicians who may have high rates of inappropriate testing without the potential for further cuts to those professionals who are making judicious use of healthcare. There have already been declining volumes in MPI and the new direct use of AUC in the beneficiary population should help further in achieving excellent patient care with good access.

ASNC strongly recommends that the wRVU and PE RVU of 78452 be maintained. It has been rigorously assessed several times in the recent past.

[1] Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, 128 Stat. 1040 (2014).

Collection of Data on Off-Campus Provider Based Departments

Given the growing trend of hospital acquisition of physician offices, CMS proposes collecting data on the extent to which the shift to hospital-based physician practice has occurred. To that end, CMS seeks comment on the development of a HCPCS modifier effective as of January 1, 2015 which would be reported with every code for physician and hospital services provided in an office campus provider-based department of a hospital.

While ASNC does not object to the collection of data for the stated objectives of evaluating the accuracy of practice expense inputs and refining practice expense inputs in different clinical settings, we are concerned about the use of the data to adjust payment rates in future years. The OPPS and PFS use different methodologies to develop their payment rates and a higher rate for one site over the other may be indicative of higher true costs associated with that clinical setting rather than a flaw in reimbursement. Any policy that questions the appropriateness of payment rates in one setting based solely on observations in another clinical setting is logically and methodologically flawed.

In addition, one factor in the increase of hospital acquisition of physician offices is that payment under the Physician Fee Schedule is inadequate. Nuclear cardiology codes 78451-78454 are examples of services where the Medicare payment rate is not sufficient to cover costs for some physician offices. Practices have had to seek alternatives to cover overhead and support ancillary personnel.

Finally, ASNC believes there is already claims data available to CMS which would allow them to complete this tabulation process without adding further administrative burden to the health care system.

Continuing Education Exclusion

ASNC opposes CMS' proposal to remove the current exclusion [§ 403.904(g)(1)] from the Open Payments system the reporting of payments associated with continuing education (CE). On February 8, 2014 the CMS issued the Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests. The rule requires reporting of "direct and indirect payments or other transfers of value

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provided by an applicable manufacturer to a covered recipient."[2] CMS proposes eliminating § 403.904(g) which excludes transfers of value in compensation for continuing education programs provided those payments meet other requirements. ASNC appreciates CMS' concern that listing certain organizations whose standards must be followed could operate as an endorsement of those organizations. However, we believe removing the exclusion entirely and redesignating CE payments under the exclusion in §403.904(i)(1) leaves CE speakers/faculty vulnerable to reporting by manufacturers or applicable group purchasing organizations (GPOs), which could have a chilling effect on CE in this country.

Under §403.904(i)(1), indirect payments or other transfers of value are excluded from reporting where the applicable manufacturer is "unaware" of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. This means that manufacturers who fund CE must be unaware of a speaker, who is a covered recipient, for essentially up to a year and a half after the indirect payment has been made. We believe this standard of "unaware" is wholly unrealistic because it would not be uncommon for industry to learn the identities of speakers/faculty, and potentially participants, through brochures, programs, and other publications after funds have been transferred.

CMS states in the proposed rule, "When an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under §403.904(i)(1)." We believe this exclusion should be made explicit under §403.904(i)(1). However, we hold the position that any standard based on the time at which a manufacturer or GPO becomes aware of a CE speaker/faculty is unreasonable and will prevent covered recipients from serving as speakers/faculty, and potentially participating, in CE programs. Clarifying that reporting for CE activities would only be triggered where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity is a necessary improvement to CMS' proposal. However, the "before" standard does not account for the common practice of continued solicitation of industry support for a CE program after the program course and faculty have been confirmed and publicized.

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[2] Transparency Reports and Reporting of Physician Ownership or Investment Interest; Final Rule, 42 CFR Parts 402 and 403 §403.904(a) (2013).

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Given the ramifications of deleting § 403.904(g)(1), we ask the section be maintained until CMS can arrive at an alternative solution that will provide the same level of exclusion as currently offered to CE activities under § 403.904(g)(1).

Migration from Film to Digital Practice Expense Inputs

ASNC supports CMS' proposal to accept the RUC recommendation to remove a list of supply and equipment items associated with film technology since these items are not typical resource inputs any longer. However, we disagree with CMS' decision to allocate minutes for a desktop computer (ED021) as a proxy for the PACS workstation as a direct expense. Not only does this determination severely undervalue the cost of PACS but it also takes no account of personnel and training costs required to properly manage a PACS. ***ASNC urges CMS to accept the RUC recommendation that correctly valued Picture Archiving and Communication Systems (PACS) equipment for inclusion in imaging services as they are now a typical resource input for those services that previously relied on film.***

Payment for Secondary Interpretation of Images

In CY 2015, CMS proposes restricting payment for secondary interpretations to high-cost advanced diagnostic imaging services, such as magnetic resonance imaging, computed tomography, and nuclear medicine. Routine payment for secondary interpretation of images for all diagnostic testing should be supported for consistency across modalities and all physicians should receive adequate reimbursement for their time and expertise in interpreting existing images where secondary review is appropriate.

Alternatives to the Current Process for Valuing New, Revised, and Potentially Misvalued Codes

CMS states in the proposed rule that in recent years it has increased its scrutiny of recommendations submitted by the American Medical Association's Relative Update Committee (AMA RUC) and has found cause to modify RUC recommended values in establishing interim final values under the PFS. We therefore appreciate that CMS recognizes that a review of CMS process for valuing codes is needed given the greater scrutiny of RUC recommendations and in response to concerns expressed by stakeholders.

ASNC supports CMS' process to include proposed work, malpractice relative value units, and direct practice expense inputs for all new, revised and potentially misvalued codes in the first available PFS proposed rule (rather than the interim final rule). We believe this proposed

process, particularly for those codes under review as potentially misvalued, afford stakeholders adequate opportunity for analysis and comment.

CMS is proposing that its new process would take effect for CY 2016 rulemaking. We recognize there is disagreement among stakeholders about when the new process should take effect due to timing of CPT coding changes and RUC activities**. However, we believe codes identified and reviewed as potentially misvalued should be subject to CMS' new proposed process beginning with CY 2016 rulemaking as proposed.** One code of interest to nuclear cardiology is78452, Myocardial Perfusion Imaging, Tomographic (SPECT). Despite our objections, if this code is finalized as potentially misvalued, we believe it is important it benefit from CMS' proposed transparency process, which is unlikely to occur if CMS' proposal does not take effect until CY 2017 rulemaking.

Physician Payment, Efficiency, and Quality Improvements- Physician Quality Reporting System and the Value Based Modifier

ASNC has made significant effort to educate its members about the importance of quality data reporting and performance improvement. Next year ASNC will launch its ImageGuide registry, with plans to establish it as a PQRS Qualified Clinical Data Registry (QCDR). ASNC appreciates that CMS' proposed modifications to PQRS for the 2015 performance year are aimed at improving beneficiary outcomes and that such improvements rely, in part, on the robustness of reporting requirements and measures. However, it is our assessment that our physician members remain unprepared to meet the rapidly evolving changes in PQRS reporting requirements.

Given the amount of payment at risk for non-successful participation in PQRS during the 2015 performance year (-2 percent for PQRS and -4 for the value-based payment modifier), there is a need for greater program predictability and CMS' proposals should better reflect the state of PQRS participation based on available data.

PQRS Measures

ASNC shares CMS' desire to include measures that address performance gaps and lead to improved outcomes**.** ***We respectfully ask CMS to create greater program predictability. Physician practices benefit from consistency and predictability of program parameters.***

CMS is proposing, effective 2015, to change the National Quality Strategy domain for 24 measures, remove 73 measures, and modify allowable reporting mechanisms for 56 measures.

These significant changes are accompanied by increased reporting requirements to avoid the 2017 PQRS payment penalty.

We are specifically opposed to CMS' proposal to eliminate the following measures:

- NQF #228 – Heart Failure: Left Ventricular Function Testing

  Continuation of the category would generally include the powerful predictive measure of ejection fraction in heart failure but continued use of this measure also allows the evaluation of synchrony of the left ventricular function. For example, Evaluation of left ventricular synchrony of the septum assist in the clinical decision making to proceed with Cardiac Resynchronization Therapy. Function evaluation is also of great clinical value in distinguishing ischemic from nonischemic cardiomyopathy because wall motion abnormalities are generally segmental in the former and diffuse in the latter.

- NQF #198 – Heart Failure: Left Ventricular Ejection Fraction Assessment

  Ejection Fraction (EF) remains the most powerful measure predicting morbidity and mortality in patients with reduced ejection fractions whether they have sysptoms of congestive heart failure or not. ***Clinical decision making for medical and device therapy often hinges upon this critical measure and we urge CMS not to delete this measure from the PQRS program.***

Furthermore, we offer comment on proposed modifications on eligible reporting mechanisms for the following measures:

- NQF #6 – Coronary Artery Disease: Antiplatelet Therapy

  Antiplatelet Therapy is the mainstay of treatment of Coronary Artery Disease. Multiple trials have demonstrated its effectiveness and a consensus exists among the academic and practice communities of cardiology for its use unless a patient has contraindications to its use. We urge CMS to retain the claims reporting option for this measure until other reporting pathways are sufficiently robust.

We share CMS' desire to gradually move away from claims reporting as the predominant reporting mechanism and toward greater use of registry and EHR reporting, especially given the continued high error rate for claims reporting. However, **to improve program predictability, we suggest that CMS institute a policy that allows a phase-out period when measures are to be eliminated or their reporting mechanisms significantly altered (e.g., a reporting mechanism eliminated)**, with an exception for measures that, if retained, could have a

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detrimental effect on patient health and outcomes**.** A transition period provides adequate time for practices to make necessary adjustments in their reporting practices, which is especially important given that physicians will increasingly rely on PQRS measure performance data in their Quality and Resource Use Reports (QRURs) to make practice improvements and adjustments in the context of the VBP modifier. As more eligible professionals choose Qualified Clinical Data Registries (QCDRs) as their mode of PQRS reporting, fewer eligible professionals will be negatively affected by changes in PQRS measures. However, in the interim, physicians are acutely impacted by sudden changes in PQRS measures and reporting requirements.

Finally, we appreciate that CMS has instituted, a continuous "Call for Measures" with the recognition that measure development is a costly and timely endeavor. We appreciate that CMS' aim is to provide timely feedback to measure submitters, including on whether a proposed measure meets the needs of PQRS.

<u>Proposed PQRS Reporting Requirements</u>

Eligible professionals, medical societies and other organizations that maintain clinical registries would greatly benefit from a period of PQRS program stability during which no significant changes to the program are made. In addition, we ask CMS to publish each year, as part of the proposed rule, a multi-year timeline of anticipated PQRS changes. Such a timeline would be a tremendous benefit to organizations, such as ASNC, that are preparing to launch clinical registries. A timeline would also allow eligible professionals to engage in more predictable planning.

Proposed Requirements for Satisfactory Claims Reporting by Individual Eligible Professionals

Eligible professionals participating as individuals and reporting on individual measures must report on at least nine measures covering at least three of the quality domains to avoid a 2017 payment adjustment. These two requirements are uniform across all reporting mechanisms (claims, traditional registry, EHR, or QCDR).

We appreciate that CMS is proposing to increase the number of measures reported by eligible professionals to better capture the picture of beneficiary care, particularly for the purpose of evaluating physician performance under the VBP modifier. However, we are concerned the increase from three to nine measures may result in a greater number of unsuccessful PQRS participants. These increased reporting requirements are proposed at the same time CMS is proposing to set the VBP modifier at -4 percent for unsuccessful PQRS participation. According to the 2012 Experience Report, 83 percent of individual eligible professionals reported using claims. Of those using claims to report individual measures, 72 percent received an incentive payment. Because the reporting threshold in 2012 was only three measures and was accompanied by a significant number of unsuccessful participants, we are concerned that a

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requirement of nine measures will result in an even higher PQRS failure rate, especially if the majority of PQRS participants continue to use claims reporting.

We ask CMS to hold PQRS requirements steady from at least the 2014 to 2015 performance years, which would include not increasing the measure reporting threshold from three to nine.

Alternatively, CMS should explore ways to reduce the risk of payment penalties in 2017 for eligible professionals. For example, CMS could deem an eligible professional a successful PQRS participant if he/she fulfills reporting requirements for three PQRS measures but *demonstrates* an attempt to report on nine PQRS measures. Such an alternative would be particularly valuable for individual eligible professional program participations. The Measures Application Validation (MAV) process would apply. CMS would need to establish what would constitute a reporting "attempt," (e.g., a quality data code that does not match the diagnosis code on the claim form would be considered an "attempt.")

Proposed Requirements for Satisfactory QCDR Reporting by Individual Eligible Professionals

ASNC shares CMS' commitment to greater transparency. However, it is vital that the focus of these initiatives remains to promote quality rather than becoming a punitive measure where the public may be unable to appreciate the context and complexity of the information reported. Thus, any public reporting process should include an opportunity for stakeholders to evaluate the impact of the program on the quality of patient care and should include ongoing monitoring for unintended consequences. A program that requires a QCDR to report on the title and description of the measures they report on for purposes of PQRS would be welcome but if CMS finalizes a program which requires reporting of physician results it is imperative that physician input is solicited as the intricacies of the reporting program are developed.

ASNC supports allowing an entity that has broken off from a larger organization to be considered "in existence" for purposes of QCDR qualification at the earliest date the large organization begins continual existence. The 1 year "in existence" requirement for purposes of the QCDR is rooted in a desire to ensure that robust data registries qualify as QCDRs. [3] Given the spirit of this requirement, we respectfully ask CMS to allow medical specialty societies who are working with vendors that have other QCDRs who have successfully self-nominated to use the earliest date that they were in continual existence for purposes of the self- nomination process. This would ensure that the infrastructure and information in a prospective registry are developed using rigorous, established methods.

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[3] Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY2014; Final Rule, 42 CFR Parts 405, 410, 411, et al.

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<u>Cross-Cutting Measures in Table 21</u>

For claims and traditional registry reporting, we do not object to CMS' proposed requirement that of the nine measures to be reported, two should be among the broadly applicable cross-cutting measures found on Table 21 of the proposed rule. In fact, according to the 2012 Experience Report, among the top five measures reported by cardiologists, two are among those proposed on Table 21: #130 – Documentation of Current Medications in the Medical Record and #226 – Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.

We believe clarification is needed in the proposed rule on what would happen if an eligible professional cannot identify applicable measures on Table 21 for reporting and such lack of measures is confirmed through the MAV process. Our assumption is that the eligible professional would still need to report on nine measures. We believe this scenario is not adequately addressed in the proposed rule.

<u>Value Modifier</u>

ASNC fervently objects to the increase of payment at risk from 2% in CY2016 to 4% in CY2017. CMS explains that the motivation for putting a larger payment portion at risk is to incentivize widespread participation in PQRS. However, it is possible that lower than desired participation in PQRS stems from a lack of education on PQRS and the ramifications of non-compliance with the program. It is too soon to attribute a lack of participation to insufficient payment risk. ***ASNC urges CMS to keep payment risk at 2% and allow specialty societies and other stakeholders to continue their educational initiatives to encourage PQRS participation.***

<u>Proposed Expansion of the VBP Modifier</u>

Consistent with CMS' mandate, the proposed rule expands the application of the VBP modifier to group practices with two or more eligible professionals and to solo practitioners in CY 2017, which will be tied to CY 2015 physician performance. Using its administrative authority, CMS further proposes to expand the VBP modifier in CY 2017 to non-physician eligible professionals. Expanding the application of the VBP modifier to all eligible professionals necessitates the continued classification of groups into Category 1 as both those self-nominating to participate in the Group Practice Reporting Option (GPRO) or if 50 percent of eligible professionals in a practice meet PQRS criteria as individual reporters. The 50 percent threshold option is important because non-physician eligible professionals may not report the same measures or use the same reporting mechanisms as physician members of a practice. Consequently, if all eligible professionals in a practice do not use the same reporting mechanism, participating as a GPRO is not an option because all eligible professionals under a GPRO must use the same reporting mechanism.

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VBP Categorization of Group Practices and Solo Practitioners Based on PQRS Participation

We generally support CMS' proposed continuance of its policy to place groups of physicians, and now also non-physician eligible professionals, into one of two categories: Category 1 – Group reporters, individual reporters within a group, and solo practitioners who meet the criteria to avoid the 2017 payment adjustment; and Category 2 – Groups of eligible professionals that do not fall within Category 1.

As stated above, we support the continued policy of including in Category 1 those practices that do not self-nominate to participate in the PQRS GPRO but have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory PQRS reporting. This policy allows eligible professionals to use the full range of reporting mechanisms available.

Proposed Changes to the Quality Tiering Methodology

For the 2016 payment adjustment, group practices had the option to elect quality tiering. CMS is proposing for the 2017 payment adjustment that all groups and solo practitioners in Category 1 would be subject to quality tiering. **ASNC supports CMS' proposal to subject groups with 2-9 eligible professionals and solo practitioners to only upward or neutral adjustments derived under quality tiering.**

Even though groups of 2-9 eligible professionals and solo practitioners are not subject to downward adjustments under quality tiering, they are still at risk of a proposed -4 percent adjustment if they fail to successfully participate in PQRS. **We believe an extra step is needed to help physician groups with 2-9 eligible professionals and solo practitioners avoid a negative VBP modifier in 2017. For example, CMS could reinstitute the administrative claims default for calculating a quality score in instances when a group practice or solo practitioner attempts to participate in PQRS but fails to successfully meet reporting requirements and avoid the payment adjustment.**

Proposed Changes to Payment Adjustment Amounts

CMS is proposing to modify VBP modifier adjustments for the 2017 payment year. First, CMS is increasing the payment adjustment from -2 percent to -4 percent for Category 2. Second, for

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Category 1, CMS is increasing the payment adjustment amounts under quality tiering in the following categories: medium quality/high cost (-2%), low quality/average cost (-2%), and low quality/high cost (-4%). ASNC appreciates CMS' challenges in a budget neutral scheme. However, **we object to CMS doubling the Category 2 VBP modifier adjustment during the same year in which the modifier will be applied to all eligible professionals and at the same time CMS is proposing to make the PQRS reporting requirements more stringent.** Alternatively, or in combination, CMS should reduce the potential of a group practice or solo practitioner from being placed in Category 2 and receiving a downward adjustment by maintaining current PQRS requirements and/or by giving credit for attempts at successful PQRS participation.

For eligible professionals and group practices placed in Category 1, we do not understand why CMS continues to propose putting physicians and other eligible professionals who did and did not fulfill PQRS requirements at the same level of downward payment risk.

Given that CMS continues to make methodological refinements to the VBP modifier program and because eligible professionals in Category 1 have demonstrated a desire to improve health quality and outcomes through their successful participation in PQRS, we ask CMS to maintain the current Category 1 maximum downward adjustment at -2 percent in CY 2017.

VBP Modifier Quality Measures

ASNC supports the continued alignment between PQRS and the VBP modifier. In particular, we support CMS' proposal to continue to include all of the PQRS GPRO reporting mechanisms available for the CY 2015 PQRS reporting period and all of the PQRS reporting mechanisms available to individual eligible professionals. We also support CMS' proposal to use all of the quality measures that are available to be reported under these various reporting mechanisms to calculate a group or solo practitioner's VBP modifier in 2017.

Beneficiary Attribution Methodology for Cost and Outcomes Measures

CMS is proposing to refine its two-step methodology for assigning beneficiaries to a group for the purposes of calculating the five total per capita cost measures, as well as the claims based quality measures in the VBP modifier. Under Step 1, beneficiaries would be assigned to a group that had a plurality of primary care services rendered by primary care physicians, NPs, PAs, or

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CNSs during the performance year. If a beneficiary is non-assigned under this step, then, under Step 2, a beneficiary would be assigned to the group practice whose affiliated non-primary care physicians provided the plurality of primary care services. Under the current attribution methodology, NPs, PAs and CNSs are only in Step 2 of the attribution process, not Step 1. Additionally, to help streamline the attribution process, CMS is going to eliminate the pre-step for attribution, which was to identify a pool of assignable beneficiaries that have had at least one primary care service furnished by a physician in the group. CMS notes in the proposed rule that these modifications would only apply for groups and solo practitioners who are not participating in the Shared Savings Program, which we believe is an important exception.

This approach disregards the large percentage of NPs, PAs, and CNSs who are not actually providing primary care, but instead work in various specialty practices and areas. Consequently, under this attribution approach, specialty practices that include non-physician practitioners would be expected to show lower costs than those that did not include the non-physicians, potentially discouraging team-based practices that include both specialists and non-physician practitioners. We request that CMS withdraw this proposal until the agency has studied its impact on group benchmarks and other unintended consequences.

Thank you for your time and consideration of these comments. Should you have any questions or require additional information, please contact Georgia Hearn at ghearn@asnc.org.

Sincerely,

E. Gordon Depuey, MD

President, American Society of Nuclear Cardiology

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