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September 6, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program [CMS-1693-P]

Dear Administrator Verma:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the CY 2019 Physician Fee Schedule (PFS) and other policies addressed in this proposed rule.

The ACC is the professional home for the entire cardiovascular care team. The mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, offers cardiovascular accreditation to hospitals and institutions, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications.

In this letter the College provides comments on many important proposals but devotes considerable attention to several key areas.

- The ACC appreciates the Agency's focus on reducing clinicians' documentation burden by proposing changes to documentation standards for evaluation and management (E/M) services. The College urges CMS to implement some of those changes in 2019 while not implementing payment policy changes that necessitate further review than allowed

under the proposed timeline. (pages 2-9)

- Comments on updates to Year 3 of the Quality Payment Program (QPP) address scoring and components of the Merit-Based Incentive Payment System (MIPS), Qualified Clinical Data Registries (QCDRs), and Advanced Alternative Payment Models (Advanced APMs). (pages 9-31)
- Feedback is provided as CMS defines the process ordering and furnishing clinicians will use to report Appropriate Use Criteria (AUC) consultation and begins to consider a methodology for the identification of outliers after reporting begins in 2020. (pages 31-36)
- The ACC provides recommendations regarding other payment policy proposals, including updates to direct practice expense inputs and relative value units for specific codes of interest to members that are being updated or newly implemented. (pages 36-47)

Changes to Evaluation and Management (E/M) Visits

Overview of CMS Proposals

The 2019 proposed rule includes an array of changes to documentation standards, payment policies, and payment rates for the office or other outpatient E/M services reported with CPT codes 99202-99205 for new patient visits (Levels 2-5) and 99212-99215 for established patient visits (Levels 2-5). The Agency proposes to allow practitioners to document for these visits using Medical decision-making or time, while still allowing the use of the current 1995 or 1997 E/M guidelines. Time could be the governing factor in selecting visit level, regardless of whether counseling or care coordination are the focus of the visit. Practitioners could focus on history and exam documentation or changes since a prior visit or on pertinent items that have not changed, provided they review and update the previous information. Practitioners could also review and verify certain information entered in the medical record by ancillary staff or the beneficiary rather than re-entering it themselves. Separate from these proposals on Levels 2-5 visits but still related to E/M documentation, CMS proposals to eliminate additional documentation requirements to justify provision of a home visit instead of an office visit and to eliminate the existing prohibition on practitioners in the same group and specialty billing for E/M visits on the same day.

This new documentation flexibility is paired with payment changes that include an E/M multiple procedure payment reduction (MPPR), a single, weighted payment rate for all levels of new patient visits, a single, weighted payment rate for all levels of existing patient visits, new G-code add-ons to recognize the added complexity of primary care and some specialty care, new G-code add-ons for podiatric E/M visits, a new prolonged face-to-face services G-code add-on, and a technical modification to the practice expense (PE) methodology to adjust indirect PE for E/M visit services. To justify payment for E/M visits from levels 2 through 5, a clinician would only have to meet documentation requirements currently associated with a level 2 visit for history, exam, and/or medical decision-making.

Simplifying Documentation

A consistent theme from ACC members reviewing CMS's proposals is gratitude at the recognition that documentation places a significant burden on clinicians that consumes a significant amount of their time that could be better spent taking care of patients. However, those same members do not see the areas that would be mitigated by CMS's proposals—review of systems, family/social history—as being major pain points. Those areas do certainly contribute to "note bloat" with many words and pages devoted to redundant information that makes it difficult to locate relevant information about a patient's present illness. More time is typically spent on documenting the history of present illness and assessment and plan that require time to select ICD-10 codes and place orders. Significant non-face-to-face documentation time also consumes significant time for clinicians, as they often perform numerous tasks that are consistently undervalued, such as prescription refills, telephone consults with patients, pre-operative assessments, patient questions after hours, and disability forms to name a few.

The ACC appreciates the emphasis CMS has placed on removing obstacles to care through its "Patients Over Paperwork" initiative. The initiative aligns with the fourth pillar of the "quadruple aim" to support professional well-being by combatting burnout through a reduction in administrative burden. That same emphasis on clinician well-being is incorporated in the ACC's strategic plan. While aligned strategically the ACC fears the current slate of proposals by CMS would have negative repercussions that worsen clinician well-being. **Therefore, the ACC urges CMS not to finalize this package of proposals in its entirety for implementation on January 1, 2019.** Instead, the College urges CMS to finalize several of its documentation proposals while engaging with the medical community to work through the complicated and granular issues regarding accurate documentation, coding, and payment for different levels of E/M visits.

Specific proposals that could be finalized for 2019 include:

1. Allowing clinicians to document the level of E/M service using medical decision-making or time—eliminating the need to achieve certain points by adding a review of symptoms and complete history and physical exam–in addition to the 1995 or 1997 E/M documentation guidelines;
2. Eliminating the requirement for clinicians to re-document information in the medical record previously entered by ancillary staff or the beneficiary;
3. Accepting documentation of the changes in the interval between visits as an alternative to "history of present illness" or "current symptoms;"
4. Eliminating the prohibition that practitioners of the same group and specialty cannot bill for E/M visits on the same day;
5. Eliminating duplicative requirements for notations in the medical record by teaching physicians for E/M services;
6. Eliminating the requirement for additional justification for provision of a home visit rather than an office visit.

Simplifying Payment Amounts

CMS proposes to implement a single payment amount for new patients at a level that is between the current payments for 99203 and 99204, and a single payment for existing patients that is between the amounts for 99213 and 99214. However, believing that payment amount to be inadequate for certain clinicians who commonly bill higher levels of E/M services due to the complexity of primary or specialty services, CMS proposes additional add-on codes GCG1X for "Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health services" and GCG0X for "Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care." To further allow clinicians to capture the work of complex patients, CMS proposes another add-on code GPRO1 for "Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requirement direct patient contact beyond the usual service; 30 minutes."

The Agency makes clear it believes documentation proposals are intrinsically linked to the payment proposals. It is not clear to the ACC exactly why that must be the case. Whatever the driver, the ACC has significant concerns with implementing such a dramatic change to the structure of E/M coding and payment on this timeline. Because of the unsettled issues described below, **the College urges CMS not to finalize any E/M payment changes in 2019** and instead collaborate with the medical community to work through the complicated and granular issues regarding accurate documentation, coding, and payment for different levels of E/M visits. This collaboration could be done through requests for information, town hall meetings, and direct meetings with stakeholders. **Of particular value to this enterprise will be the American Medical Association's (AMA's) Joint Current Procedural Terminology/Relative Value Scale Update Committee (CPT/RUC) Workgroup formed to further the administrative burden reduction goals of the proposals.** CMS engagement in that process will be important for developing meaningful solutions.

E/M MPPR

As part of a summary of the comments CMS received in response to solicitation in the CY 2018 fee schedule, CMS abruptly transitions to its assertion that duplicative resource costs exist when a separately identifiable visit is furnished in conjunction with a procedure that are not accounted for by current coding and payment. Therefore, CMS proposes "an E/M multiple procedure payment adjustment to account for duplicative resource costs when E/M visits and procedures with global periods are furnished together…" This would reduce the payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on

the claim by appending modifier 25. **The ACC disagrees with this premise and urges CMS not to finalize its E/M MPPR proposal for several reasons.**

E/M visit codes are not billable on the same day by the same clinician as a procedure unless the visit is for a significant, separately identifiable E/M service. A significant, separately identifiable E/M service is defined or substantiated by documentation that satisfies the relevant criteria for the respective E/M service to be reported. The E/M service may be prompted by the symptom or condition for which the procedure and/or service was provided. As such, different diagnoses are not required for reporting of the E/M services on the same date. For example, a patient who visits a cardiologist complaining of occasional chest discomfort during exercise. The patient has a history of hypertension and high cholesterol. After the physician completes an office visit it is determined that the patient needs a cardiovascular stress test that is performed that day by the same physician. Both an E/M visit and the procedure would correctly be billed with modifier 25 attached to the visit. Applying a 50-percent reduction to the stress test significantly underpays for the value of the two services and diminishes the convenience and continuity provided to the patient by performing both services during a single visit.

CMS is well aware that recommendations for procedural RVU values from the RUC specifically exclude the work of a separate preceding E/M service. CMS understands that interval history and physicals before procedures required by the Joint Commission are not included in the pre-work of procedures, representing additional work by physicians that is not reimbursed under the current physician payment system.

No data are described or presented to indicate that 50 percent is a correct reduction Instead, it appears that CMS chose 50 percent because the reduction is equivalent to the 6.7 million RVUs needed to offset other proposed changes for compressing E/M payment into single levels and allowing use of the new add-on codes. Imposing the E/M MPPR as one of several fixes on the flawed foundation of uniform payment is not productive way to set payment policy.

CMS and the RUC are already highly vigilant in considering how likely a given procedure is to be performed on the same day as a visit. In instances where it is known or anticipated multiple services will be provided on the same day, redundant time and resources—often in the preservice and postservice periods—are removed. By assigning multiple procedure status indicator "2" to E/M services, CMS would further reduce payment for nearly 5,000 individual CPT code combinations when they are performed on the same day as an E/M.

In a scenario where multiple procedure codes are billed on the same day as a visit, it is unclear from the language in the rule and the information provided in related addenda materials whether CMS intends the MPPR to apply only to the "least expensive procedure or visit" as it says in the rule or if it would follow the policy for status indicator 2. The payment rules for status indicator 2 require the contractor to rank the services by fee schedule amount from highest to lowest and apply reductions of 50 percent to second and all subsequent services. Is the adjustment made only to the least expensive procedure

or visit as stated in the proposed rule or to all but the highest service as in the CMS manual? It is important for CMS to clarify this discrepancy.

Unintended Consequences and Questions Regarding All E/M Payment Changes

The College is concerned about a lack of clarity and the possibility for unintended consequences should these payment policy and payment amount changes move forward as proposed. Some of these concerns align with specific areas where CMS itself solicits additional comments as it works through some of the anticipated bumps in its proposals. Others center on downstream consequences that may occur. Finally, other concerns are simply questions from a lack of understanding about what the actual, day-to-day impact would be based on the information available in the rule. For instance, CMS indicates the proposal is a "relatively broad outline of changes" and that "many details related to program integrity and ongoing refinement would need to be developed over time through subregulatory guidance." The number and variety of obstacles discussed here suggests that implementation in 2019 would be disruptive to the point of harm and that other options should be considered for 2020 and beyond, including maintenance of existing codes and payments.

Through meetings, the ACC has learned that CMS was guided by four principles when it developed the package of proposals:

1. Decrease administrative burden associated with documentation and coding
2. Mitigate the need for audits
3. Reduce unnecessary documentation that does not enhance patient care (note bloat)
4. Avoid redistribution of payments

Again, the College appreciates the focus and vigor on administrative burden and clinician well-being. Each of these goals is admirable; however, the package of proposals is so disruptive and the timeline so abrupt, the result is the opposite of that intention. Cardiovascular care team members are working to anticipate the impact to their practices and patients, taking time and attention away from their care-related activities to do so.

Beneficiary Impacts

Medicare beneficiaries will be negatively affected by these changes. This payment construct would mean that patients seen for low-level complaints would face the same out-of-pocket expenses as those seen for management of severe and advanced cardiovascular disease. Patients may also be impacted should practices be forced to adapt to lower payments. By reducing the payment amount for level four and five visits, CMS undervalues instances when clinicians spend long amounts of time treating and managing complex patients. This is true even when including the new add-on codes. A response to this change in incentives could be for patients to make additional visits. Similarly, a response to the E/M MPPR could be for patients to return on a different day for even modest tests and procedures that are currently, reasonably performed on the same day as a visit.

Financial Impacts

Redistribution of resources will absolutely occur under this proposal. While the proposals may have modest impact to a particular specialty overall, it will also be terribly disruptive to many individual practices. For example, cardiologists with practices focused on managing complex heart failure patients, patients with rhythm disorders at risk for stroke, and geriatric cardiology specialists managing frail cardiovascular patients with multiple comorbid conditions generally bill a disproportionate number of high-level E/M visits in comparison to their peers. Preliminary modeling suggests that many of these individuals and groups will experience more than a 20-percent reduction in their E/M payments, even when incorporating the specialty and prolonged service add-on codes.

Timeline Obstacles

The short timeline for these proposals also creates financial and workflow impacts. Practices are well into budgeting and planning for 2019. Contracts have been negotiated—often for multiple years—built around RVUs for both clinician compensation and insurer payment rates. As CMS acknowledges, clinical workflows, electronic health record (EHR) templates, institutional processes and policies, and other aspects of care impacted by the changes would take much longer than the two months allowed for implementation by January 1, 2019.

Variable Requirements Create New Burdens

Should CMS move forward with proposals to alter both documentation standards and payments, clinicians will be working under different and dual documentation systems for some time. This in and of itself creates a new burden. While CMS may be confident that commercial payers will follow their lead to adapt documentation and payment changes, such an outcome is not guaranteed. Commercial payers would take additional time to make any changes, and those changes may or may not exactly mirror those proposed by CMS.

New Code Use

It is unclear to clinicians how the particular specialty care areas allowed to use specialty-level complexity code GCG0X were identified. CMS notes that based on billing patterns, it believes "these are the specialties that apply predominantly non-procedural approaches to complex conditions that are intrinsically diffuse to multi-organ or neurologic disease." However, other specialties that manage complex conditions are not included.

Because CMS states in the proposed rule that it selected "specialties" that can bill code GCG0X, it appears that it is creating a specialty-specific code. That would be conflict with statute. However, in one informational briefing, it was stated that the code is not meant to be limited to specialties, but to care that is centered on the listed specialty areas. *Would it be correct to infer from that statement that an E/M where hypertension is discussed and managed would fit the definition?* The difference between the code being

limited to "specialties" versus "specialty care areas" is important within cardiology. Many cardiologists are further specialized in areas that have also obtained specialty designation codes—cardiac electrophysiology, interventional cardiology, and heart failure/transplant specialists. *Is it CMS's intent that these specialists within cardiology would be able to bill the specialty add-on code?* In a CMS Listening Session on August 22, officials more clearly stated that the primary care and specialty complexity add-on codes are not meant to be limited to specialty. The working understanding stakeholders have from these informal communications is that any clinician in any specialty can use any of the add-ons codes. It would be helpful to see that detail formally clarified in the final rule should these proposals advance.

It is also unclear what documentation would be required to bill for GCG0X. One way this could be accomplished is through diagnosis coding. Clinicians also document a history of the present illness or changes since a prior visit that could serve this purpose, but it is not evident what information CMS would expect clinicians to provide that validates by requiring billing this code.

New add-on code GPRO1 for prolonged face-to-face time remains poorly understood by the clinician community. It seems CMS believes that, by allowing clinicians to bill for an additional 16-30 minutes of face-to-face time, those providers would overcome some of the reductions they would otherwise face for the most complex patients. Because the code is time-based, and because CMS proposes to implement a single time standard for each of the four levels of E/M, *does that mean GPRO1 could be billed any time 16 minutes of face-to-face time is spent beyond the 38 minutes of total time for a new patient E/M service?* Or, since CMS indicates clinicians would bill the same levels of visits currently provided, *does that mean GPRO1 would apply to time spent beyond the usual level for that service as described by CPT?* (CPT indicates a new patient level five visit typically involves 60 minutes of face-to-face time with the patient and/or family.) The College urges CMS to clarify the requirements for billing this code should the proposal be finalized.

GPRO1 also creates new administrative burden because clinicians would have to document both the amount of time spent on the primary E/M service, as well as the time dedicated to the GPRO1 add-on code. However, CMS provides no direction on this point. While this type of information is often issued in subregulatory guidance, the proposed timeline requires it be done earlier to allow for the necessary education before January 1, 2019.

Resource-based Code Valuation

CMS utilized weighted data, several crosswalks, and a reverse building block methodology to revalue the existing E/M codes and to assign values for the new add-on codes. These tactics are not particularly novel in and of themselves. However, their use to recalibrate payment for the foundation of medicine—conversations between clinicians and patients—that constitutes roughly 40 percent of Medicare payment and a majority of revenue for many practices is notable and troubling.

A resource-based relative value system must account for the different resources consumed by care delivery. For patients with multiple comorbidities and/or complex diseases, the clinician's training, knowledge, and experience is a significant resource. When a clinician uses those skills to execute moderate- or high-complexity medical decision-making to diagnose or treat a patient, clinicians should be appropriately compensated. The ACC does not believe the proposed payment changes adequately distinguish between services in a meaningful way. Additionally, the College believes they are not made in a resource-based manner as required by the statute.

Impact on Other Services

While not discussed anywhere in the proposed rule, clinicians are confused as to whether the payment changes for E/M could impact payments for global surgery services. Since adjustments to values for 10- and 90-day global services are not proposed, it seems CMS does not intend to universally apply these changes to E/M. The College urges CMS to clarify whether this was intentional.

Summary of Recommendations

Because of the complications, anticipated consequences, and unanticipated consequences outlined above, **the ACC reiterates its recommendation that CMS not to finalize this package of proposals in their entirety for implementation on January 1, 2019**. In keeping with the four principles behind the development of these proposals, the ACC believes CMS could move forward with several of its proposals to reduce documentation burden without also making dramatic, comprehensive, and disruptive payment policy changes. Instead, because of CMS's renewed focus to this topic, a preferable outcome would be for the agency to build on this momentum to make changes in concert with stakeholders through town halls, requests for information, and most importantly, the AMA's Joint CPT/RUC Workgroup. The Workgroup and stakeholders are striving to develop innovative solutions. Ideally, these could be deployed as soon as 2020. However, it may be necessary to look beyond that timeline in order to ensure appropriateness and accuracy.

CY 2019 Updates to the Quality Payment Program (QPP)

The ACC appreciates the opportunity to provide comments on Year 3 of the QPP. The College is pleased to see that 91 percent of eligible clinicians successfully participated in Year 1 of the program. By allowing clinicians and groups to "pick their pace," those new to value-based program participation were able to focus on building their reporting infrastructure to report a minimum number of measures, while many others maximized their efforts to reach or exceed the exceptional performance threshold.

The ACC strongly encourages CMS to provide participation data on Year 1 of the Merit-based Incentive Payment System (MIPS) program as soon as possible so it can be used to inform future refinements to the program. In this proposed rule, CMS continues to rely on

data from the legacy programs of the Physician Quality Reporting System (PQRS), EHR Incentive Program, and Value-Based Modifier in calculating its historical assumptions. While the goals of the QPP, particularly the MIPS track, are based off of these legacy programs, actual QPP data is needed to understand how to best improve the program.

In reviewing the comments provided in the following sections, the College requests that CMS:

- Prevent the QPP from being an administrative burden on clinicians, particularly those who are solo practitioners or in small practices;
- Balance the need for flexibility along with the ability to offer true incentives to those who deliver exceptional quality patient care;
- Provide all clinicians with a selection of clinically meaningful measures relevant to their patient populations treated;
- Work with clinicians to determine innovative ways to fulfill QPP requirements in future years. For example, seeking opportunities to provide cross-category points could allow a clinician to focus efforts on a single quality improvement initiative such as consultation with appropriate use criteria for imaging, and meet the requirements of all MIPS categories;
- Continue to expand opportunities for clinicians to participate in Advanced Alternative Payment Models (Advanced APMs), as well as MIPS APMs that can serve as a glidepath into more risk-based Advanced APM participation.

Merit-Based Incentive Payment System (MIPS)

Low-Volume Threshold

The ACC supports continuation of the low-volume threshold exempting clinicians from MIPS participation if they treat a small number of Medicare beneficiaries or provide a small number of covered services under Part B. The College agrees that this will appropriately decrease the reporting burden for clinicians who treat few Medicare beneficiaries, especially small practices and solo practitioners.

CMS proposes to add a third factor to the current threshold of $90,000 or less in Part B allowed charges or fewer than 200 beneficiaries. Under the proposal, a clinician or group may qualify for the low-volume exemption by meeting either of these criteria or by providing 200 or fewer covered professional services to Part B beneficiaries. The ACC encourages CMS to continue reviewing the threshold annually to ensure that the low-volume threshold serves the purpose of exempting those for which the work of MIPS reporting would outweigh the number of Medicare beneficiaries impacted. **As part of this review, CMS should also ensure that the low-volume threshold is not overly broad.**

The ACC supports the proposal to implement an opt-in policy for those clinicians and groups that exceed one, but not all three of the low-volume threshold criteria proposed. Clinicians and groups with an interest in participating in MIPS should be

permitted to do so and be eligible for performance bonuses. CMS should clearly communicate the ability to opt-in to those who may be eligible on both the QPP portal and the QPP look up tool. To encourage clinicians and groups to opt-in, CMS should provide technical support and assistance through its small practice and rural networks to those who meet one of the low-volume threshold criteria and voluntarily elect to participate in MIPS.

Group Reporting

The ACC appreciates that CMS continues to explore MIPS reporting as a sub-group rather than limiting group reporting at the Taxpayer Identification Number (TIN) level only. This option will be particularly beneficial to those clinicians within a large setting or multi-specialty practice who want to be scored on measures specific to their patient population rather than larger population-level measures that are still important, but less meaningful to the specific clinician or specialty group.

It is appropriate for CMS to consider that groups wishing to report as a sub-group register with CMS in a manner similar to those who use the CMS Web Interface. Sub-groups could submit a list of clinicians by TIN/NPI to be registered under the sub-group. Upon confirmation by CMS, these clinicians and the sub-group can be assigned a sub-group identifier. Snapshot dates can be scheduled throughout the year where CMS reminds these sub-groups to update their lists based on clinicians who join or leave the practice. Sub-groups should be instructed to share their sub-group reporting status, any identifier assigned, and the list of TIN/NPIs affiliated with the subgroup with any third-party submitters so vendors are aware that the sub-group is reporting independent of the TIN.

To minimize the over-development of sub-groups, it would also be appropriate for CMS to set a minimum threshold size for sub-group designation. For example, a group of two clinicians wishing to form a subgroup could easily report as individuals; however, it may be more appropriate for a group of 10 or more to form a sub-group.

The ACC welcomes further conversation with CMS on how best to score sub-groups in relation to the larger group at the TIN-level. The ACC recognizes that this option requires more management by the group; however, it will encourage engagement in MIPS by allowing clinicians to be assessed on those measures that are clinically meaningful to the care they provide to patients.

Virtual Groups

The College supports the proposal to provide interested participants with greater access to real-time TIN size information for determining whether their group meets the 10 or fewer eligible clinician threshold for virtual group eligibility. The ACC remains interested in the continued improvement of the virtual group election process and reporting option. We request that CMS provide more information on virtual groups through upcoming MIPS Experience Reports and other communication so the public can better understand the

demographics of these virtual groups and their experiences to support further recommendations and improvements to this option.

MIPS Performance Period

The ACC supports CMS' proposal to maintain the performance periods for the Promoting Interoperability and Improvement Activities categories at a minimum of a continuous 90-day period within CY 2019. Maintaining the 90-day minimum reporting period maintains stability from previous years. This is especially important for the Promoting Interoperability category as some practices may be adjusting to use of 2015 CEHRT during the calendar year.

Regarding the Quality category, the ACC agrees with CMS that a 12-month reporting period is ideal, as it provides clinicians and groups with statistically larger sample sizes and may be necessary to capture multiple visits required by some outcome measures. However, the ACC remains concerned that the timeline for the approval and communication of updated quality measures does not support the ability for clinicians to report 12 months. CMS did not update the measure list on the QPP website for the 2018 performance year until more than halfway through the calendar year. Clinicians and groups relying on this information for measure selection would have been unable to easily access a measure list until months after the performance period began. In addition, QCDR measures have traditionally not been approved until the end of December preceding the performance year, leaving registries with limited time to update their dashboards in time for the January 1 start of the new performance year. The College is also aware of clinicians who need additional time to work with their EHRs to ensure that they are capturing the elements necessary to report on a measure. If measures are not available in a timely manner, this can lead to lost time during the performance year.

While the College encourages a 12-month reporting period and recommends that all participants to strive to meet a full year of quality measure reporting, CMS must recognize that this threshold may not be attainable for all clinicians. Therefore, the College recommends a 90-day minimum for the Quality category.

Quality Performance Category Measures and Activities

Topped Out Measures

The College continues to oppose the removal of topped out measures from the program. Many topped out measures promote evidence-based best practices in patient care; clinicians and groups should be recognized for maintaining these practices. Furthermore, removal of these measures would be misaligned with CMS' goal of implementing more outcome measures, as it would be impossible to develop robust outcome measures without an understanding of the processes that contribute to the outcome.

CMS' rationale for removing topped out non-high priority measures is to eliminate the data collection burden for measures that do not provide value to MIPS eligible clinicians and groups. The ACC reminds CMS that a positive aspect of the MIPS Quality category is that it allows clinicians and groups the ability to voluntarily select those measures that are most clinically meaningful to their practice. The removal of topped out measures does not relieve data collection burden because clinicians and groups would still have to meet the six-measure requirement. In some cases, the elimination of measures would lead to greater burden if clinicians and groups would have to seek other less clinically relevant measures to report.

Rather than removing topped out measures or measures that cannot be benchmarked, CMS should keep these measures available for MIPS reporting unless removal is determined to be appropriate by the measure steward. A reasonable compromise would be for CMS to cap the possible available points on a topped-out measure if performance improvement cannot be statistically measured as is currently done with measures that have no historical benchmark. The College recognizes that this places a responsibility on the clinician or group to seek additional MIPS points through other quality measures or MIPS categories; however, this is more acceptable than complete elimination of topped out measures.

In addition, the ACC opposes the proposal to exclude QCDR measures from the topped-out measure timeline finalized in the CY 2018 QPP final rule. MIPS measures are required to go through the rulemaking cycle; while this process has its limitations, it at least provides clinicians, groups, and measure stewards with sufficient notice to review topped out measures in question and determine if there is a rationale for keeping the measure or if a replacement measure should be proposed. CMS states "because QCDRs have more flexibility to develop innovative measures, we believe there is limited value in maintaining topped out QCDR measures in MIPS."[1] While the ACC appreciates the flexibility given to QCDR measure development, we remind CMS that QCDR measures are still developed under a thorough evidence review process. Instead of immediate removal or non-approval of a measure once it reaches topped out status, CMS should instead initiate discussions with QCDRs to review the measure in question and agree on a timeline for removing, updating, or replacing the measure that still allows the QCDR to undergo its rigorous review process.

Removal of Process Measures

CMS proposes to implement the incremental removal of process measures from the MIPS program. The ACC recognizes CMS' desire to move toward outcome measures; however, the College reminds CMS that many process measures are still important to maintaining patient care. Data collected on process measures is also necessary to understand what actions contribute to optimal patient outcomes. Because process measures are generally under provider control, while outcome measures often reflect the combination of provider, patient, and contextual factors (such as social determinants of health), these measures also provide critical recognition of the realities of providing high-

[1] 83 Fed. Reg. 35900 (Jul. 27, 2018)

quality care, particularly for clinicians caring for medically or socially complex populations. In addition, some specialties and subspecialties may only have process measures available. Eliminating process measures could leave them with fewer than six clinically relevant measures to report. **CMS should proceed cautiously with the elimination of process measures and consult with measure stewards on the best approach to transitioning to outcome measures.**

Categorizing Measures by Value

The ACC supports the continuation of bonus point opportunities for reporting high-priority measures such as outcome measures. This approach is a fair way to incentivize the use of high-priority and outcome measures without mandating that clinicians report them.

However, the ACC opposes the tiering approach proposed in the rule. Specifically, the College opposes the terminology of "categorizing measures by *value*" and the application of a gold, silver, or bronze designation to each measure. There are still many process measures that contribute to high-quality, high-value patient outcomes; the proposed designation as second- or third-tier silver or bronze measures may imply that they are of lesser value to patients. In addition, there are still many specialties and subspecialties that do not have a robust list of outcome or high-priority measures. The College is concerned that if *Physician Compare* were to show that these clinicians only perform against silver or bronze measures, it may create the perception that they provide a lower level of care. The ACC recommends that rather than define this as "categorizing measures by value" and implementing a tiered standard, CMS continue to classify measures by type and award bonus points for the selection of high-priority and outcome measures.

Qualified Clinical Data Registry (QCDR) Benchmarks/New Benchmarks

Under current policy, new measures that do not have a historical benchmark are assigned a score of three maximum points because CMS does not have data available until the end of the first reporting year to develop a performance range to reach the 10-point maximum. CMS has stated that eligible clinicians have voiced concern on this policy, particularly regarding new QCDR measures. To address these concerns, CMS proposes to allow QCDRs to submit historical benchmark data on MIPS-eligible clinicians to establish a performance range that can provide the decile range in the first year of reporting the measure.

The ACC cautiously supports this approach. When possible, a QCDR should be allowed to submit historical data to CMS to create a MIPS benchmark in the first year of reporting, but this must be voluntary, not mandatory. This should not become a requirement for all QCDR measures. The registry should be allowed to determine whether sufficient data exists to establish a benchmark. If a QCDR does not submit historical benchmark data, then CMS should continue to enforce the policy of a minimum

of three points on the measure and not use this as a reason to disqualify a measure from MIPS reporting.

Measure Updates

The ACC supports CMS replacing Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic (Quality ID: 236/NQF: 0018) with the measure Ischemic Vascular Disease: Use of Aspirin or Anti-Platelet Medication (Quality ID: TBD/ NQF: TBD). **The College encourages CMS to continue alignment of the MIPS measure set with those recommended by the Core Quality Measure Collaborative.**

Cost Performance Category

Cost Category Weight

The ACC recommends keeping the weight of the Cost category at 10 percent for Year 3 of the program. Prior to increasing the category weight to 15 percent, CMS must provide clinicians and groups with education on these measures and the attribution methodology, along with detailed and actionable data on their performance in the Cost category as part of the 2018 MIPS Feedback Report. The 2017 MIPS Feedback Report did not include the detailed clinician and case-specific cost measure data that had been part of the previous Quality and Resource Use Reports (QRURs) and Supplemental QRURs provided by CMS under the Value-Based Modifier program. To identify areas of improvement in cost performance, clinicians and groups need this level of data before CMS begins to increase the category weight..

Starting in 2019, CMS proposes to introduce eight episode-based measures as part of the Cost performance score. CMS should maintain the category weight at 10 percent for an additional year as clinicians determine which episodes will be attributed to them and how the episodes impact their overall Cost performance score. As discussed in further detail in the following section, these episode-based measures are new. Should CMS determine during the performance period or in the calculation of performance year data that there is a measure design or attribution flaw, the Agency should remove that measure from calculation into the MIPS score. This will ensure that clinicians and groups are not unintentionally penalized based on the design of a measure as the Cost category weight increases.

Regarding the category weight in future years, the ACC supports a gradual approach to increase the weight of the Cost performance category each year until CMS reaches the statutorily required 30 percent weight for this category for the 2024 MIPS payment year. The described approach provides clinicians and groups with a predictable and stable path toward the final category weight. Keeping the Cost category at 10 percent for the 2019 performance year may slightly alter the percentage increase needed each year to reach 30 percent by 2024; however, the same approach should be used. There is a need to balance a movement toward the 30 percent Cost weight required by statute, along with the need to

carefully phase in the Cost category given the newness of cost measures to many clinicians and groups.

Episode-Based Measures Proposed for the 2019 and Future Performance Periods

The ACC supports the efforts of the multi-stakeholder clinician workgroups convened by CMS and Acumen to develop episode-based cost measures for the MIPS program. Continued development of evidence-based and reliable episode measures will allow clinicians to be more precisely measured on the care they provide.

The College agrees that the reliability of these measures must be a top priority for CMS, and we are pleased to see CMS address this in the proposed rule. Specifically, the ACC supports the proposal to create an alternative case minimum of 30 for both TIN/NPIs and TINs for the Simple Pneumonia with Hospitalization measure. The College recognizes that doing this would result in 29 percent fewer TINs and 84 percent fewer TIN/NPIs meeting the case minimum to be attributed this measure. This would be preferable to clinicians and groups being measured against an unreliable measure. As CMS and Acumen continue to develop more episode groups, the proportion of specialties do not have an applicable episode group measure should decrease.

The ACC also encourages CMS to further monitor the reliability of the Elective Outpatient PCI and Intracranial Hemorrhage or Cerebral Infarction measures to determine if similar updates to the case minimums may contribute to improving the reliability of these measures. Based on Table 34 in the proposed rule, 100 percent of clinicians at the TIN level meet the reliability standard for these measures; however, only 84.1 percent TIN/NPIs under the Elective Outpatient PCI measure and 74.9 percent of TIN/NPIs under the Intracranial Hemorrhage or Cerebral Infarction measure meet the reliability standard. While the College recognizes that measuring at the TIN level will always create a larger sample size, and thus greater reliability, CMS must strive for the same high reliability at the individual clinician level when possible.

Based on this discussion, CMS should consider whether a standard case minimum for all episode groups should continue to be set, or if case minimums should be set accordingly for each individual measure.

Performance Period

The ACC supports further consideration into whether the Cost category should be measured based on a two-year performance period rather than the current one-year performance period. The College agrees with CMS' observation that some clinicians or groups, particularly smaller groups, may never see enough Medicare fee-for-service patients in a calendar year to meet the reliability case minimum for the Cost measures. However, the ACC is concerned that a lengthened performance period may not provide clinicians and groups with timely and actionable feedback on how to improve their cost of care. One approach may be to set the Cost category performance score at a two-year performance period, while continuing to provide performance feedback on an annual

basis. CMS should continue to engage stakeholders on this topic as MIPS participants learn more about their Cost performance in 2018 to determine what approach may work best in future years.

Social Risk Considerations

Many cost measures systematically under-estimate costs for dually-enrolled, medically complex, and other vulnerable beneficiaries. When used in pay-for-performance programs, these measures may place clinicians that care for these populations at a disadvantage. As part of its ongoing review of cost measures, CMS should be prospectively analyzing the potential impact of these measures and determining whether additional adjustment may be necessary.

Improvement Activities Performance Category

The ACC supports CMS' proposal to assign all Improvement Activities using CEHRT as high-weight Improvement Activities, particularly in light of the proposal to eliminate the Promoting Interoperability bonus awarded for participating in an Improvement Activity using CEHRT. This would ensure that clinicians and groups are incentivized to use CEHRT and recognized for the work that it takes to maintain this technology. CMS should seek further ways to incentivize clinicians for their use of CEHRT.

The College appreciates the information provided on this category to provide more transparency into the differences between high-weight and medium-weight activities and encourages the Agency to continue education on this category as new activities are added.

Promoting Interoperability Performance Category

Overview

The ACC has long encouraged CMS to refocus the Meaningful Use program on interoperability, usability, and outcomes, rather than centering the program on the process of capturing and reporting data. The ACC has worked with CMS by submitting comments, asking for reassessed thresholds for more realistic benchmarks and eliminating the pass-fail approach to allow for achievement on a sliding scale. Additionally, the College has urged CMS to remove requirements that hold physicians accountable for actions beyond their control and to address the ever-increasing administrative burden's effect on clinician burnout. Through Patients over Paperwork, CMS has focused on identifying and reducing these burdens, and the ACC appreciates the scrutiny of these issues.

Coupled with Patients over Paperwork, the MyHealthEData Initiative is another step in the appropriate direction, striving to give patients control over their health information and to make continued improvements with respect to interoperability. Blue Button 2.0

and expected efforts to prevent information blocking are two additional encouraging initiatives. The ACC applauds the efforts of all HHS agencies to increase interoperability. Finally, the ACC appreciates CMS' efforts to simplify and streamline the Meaningful Use and Advancing Care Information (ACI) programs through the Promoting Interoperability (PI) program. **By acknowledging the shortcomings of previous efforts to encourage EHR adoption through prescriptive rulemaking, CMS is making significant strides towards achieving true interoperability.**

ACC applauds CMS for its work with the Office of the National Coordinator for Health IT (ONC) aligning reporting requirements across care settings, eliminating redundancies and streamlining objectives and measures regardless of the program in which a clinician participates. By proposing to align the PI performance category with the PI program finalized in the CY 2019 Medicare Hospital Inpatient Prospective Payment Systems (IPPS) final rule, CMS has actively worked to reduce the reporting burden clinicians face and streamline federal reporting requirements.

While heartened by the steps taken in the proposed rule, the ACC encourages CMS to use the PI program to promote the appropriate, purposeful and accurate use of health IT solutions, rather than mandate completion of tasks. There are objectives and measures that aim to appropriately promote interoperability. However, CMS should also use PI objectives and measures to focus on the exchange of health information, increased usability of EHRs, and the appropriate realignment of clinical workflows to leverage health IT most effectively to achieve the intention of the PI program and improve patient care.

Certification Requirements beginning in 2019

Under the proposed rule, CMS would require the use of 2015 Edition Certified Electronic Health Record Technology (CEHRT) for CY 2019 and beyond. Requiring only 2015 edition CEHRT will help to simplify the PI program and eliminate confusion around different objective and measure sets available for reporting. **Most importantly, the required capabilities required in 2015 edition CEHRT, such as application programing interface (API) functionality and US Core Data for Interoperability (USCDI) through common clinical data set (C-CDS), will encourage continued progress on interoperability.** While the ACC encourages continued progress towards the adoption of 2015 edition CEHRT, it is important that CMS continue to retain all current hardship exceptions for practices that are unable to meet PI criteria. The ACC also encourages CMS to continue to educate and provide resources on 2015 CEHRT criteria as clinician's transition from 2014 to 2015 edition CEHRT.

Reporting Period

CMS proposes continuing the minimum continuous 90-day reporting period for CY 2019 and CY 2020. **The ACC thanks CMS for continuing the 90-day reporting period for CY 2019 and CY 2020 and further aligning the promoting interoperability**

programs in the inpatient and outpatient settings by setting identical reporting periods.

Scoring Methodology

Under the PI program, CMS proposes a new performance-based scoring methodology for CY 2019 and beyond. This proposed performance-based methodology would reduce the number of measures required for reporting from the current number of up to 13 measures to six for CY 2019 and eight for CY 2020. Members of the cardiovascular care team often cite burdensome federal reporting requirements as a significant contributor to an increase in administrative burdens imposed upon them. **The ACC appreciates the actions taken by CMS in response to the concerns raised by the College and others in the medical community regarding this issue, including a reduction in the number of required measures.** Furthermore, the ACC thanks CMS for proposing to align the measures in both the inpatient and outpatient settings. **Aligning measures across care settings assists in reducing the reporting burden for members of the cardiovascular team that see patients in multiple care settings.**

However, as previously stated in comments submitted to CMS under the proposed Promoting Interoperability program in the Hospital Inpatient Prospective Payment Systems (IPPS) rulemaking process, it is not only the increase in the number of measures required for reporting that has led to this increased administrative burden. Because of that, simply reducing the number of measures required for reporting will not lead to a substantial decrease in the reporting burden. CMS must also consider the operational burden imposed by the required measures and reporting process on clinicians and staff. Extensive documentation requirements necessitate workflow modifications that divert clinician attention from patient visits, adding to frustration and burn out among clinicians. **As CMS considers the total administrative burden placed on clinicians by all quality reporting programs, the ACC urges CMS to also consider and reduce the operational burden placed by each specific measure on clinicians and medical practice staff.**

One component of operational burden unique to the PI program is the usability of EHR systems. Today, the burden placed on clinicians by EHR is largely defined by the approach taken by EHRs to attain the requisite EHR functionality. These include EHR structure, page designs, button placement and utilization, the number of required clicks, tools available through the EHR, and alerts imbedded in the EHR. While CMS should not mandate interface development for systems, the College urges CMS to use its role to ensure vendors continue to work alongside clinicians to improve EHR systems usability and workflow to more appropriately align with clinical practice patterns.

Objectives and Measures

As previously mentioned, the ACC believes there are PI objectives and measures that aim to promote interoperability; however, the ACC is unsure many of the measures currently included in the PI program will lead towards achievement of that goal. **Instead, CMS**

should focus the PI program on a limited handful of high value initiatives that aim to increase the usability of EHR systems, promote clinical data standards, and reduce the amount of necessary manual tasks such as patient matching or data abstraction.

- E-prescribing

The ACC has long acknowledged the benefits of e-prescribing and encouraged cardiovascular specialists adopting this technology. However, this existing measure does not help promote interoperability. Ideally, data would automatically flow to fields that correspond to the medication in question, reducing the burden for reporting and providing patients and clinicians with useful, automated information. Instead, the College urges the Agency to modify the e-prescribing measure to augment the flow of useful, automated information in an EHR.

- Health Information Exchange

Current workflows required by EHR systems are cumbersome, often hampered with poor system-to-system interoperability capabilities and manual abstraction of important health information. While EHRs currently do an acceptable job of sending summary of care records within a system, it remains difficult to send among different EHR systems. These issues lead to the creation of burdensome workflows to manage inbound documents, ensuring charts contain correct information, are correctly labeled, and are actionable for clinicians. This is a cost prohibitive process that only leads to a decrease in productivity and increase in time. The ACC urges CMS to promote an environment that ensures EHR systems allow for the seamless and effortless exchange of health information.

- Provide Patients Electronic Access to their Health Information

The ACC appreciates CMS' proposal to eliminate measure requirements that a patient must view, download and transmit information to a third-party or access using an API chosen by the patient. The College agrees that CMS should not hold clinicians accountable for actions beyond their control.

Additionally, the ACC supports efforts to utilize APIs to facilitate the transfer of health information through methods and in formats chosen by patients and clinicians. However, it is imperative that CMS and ONC provide clinicians and patients with the necessary education, flexibility and protection to ensure these applications do not expose parties to risk and are compatible with all systems. As previously stated by ONC's Principal Deputy National Coordinator, patients have the right to access their data through whatever application is convenient to them, even if the application is not secure or well-known. The College encourages ONC and CMS to work diligently with vendors to develop APIs and provide access to applications that interface with all EHR systems with ease, allowing patients to access their health information in a secure manner.

Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

The ACC believes safe and effective electronic exchange of information is essential to achieving true interoperability, but it is only one component of it. Today, it is common for clinicians to rely upon multiple systems to access and enter vital patient health information, requiring hundreds of clicks, contributing to the length of each patient encounter, and increasing the time necessary to complete a clinical note and provide proper documentation. Many systems can open and share different documents and files, such as a PDF, with relative ease. However, it is often difficult for clinicians to extract any information from the resulting document. Instead, the burden is placed on clinicians and staff to compile the necessary information through manual transcription or other methods such as third-party software. **Solely having the ability to transfer medically necessary information to another facility does not constitute true interoperability. Instead, interoperability must include the seamless transmission and receipt of data using consensus methods and standards that allow for effortless extraction, interpretation, and manipulation of data.**

As CMS considers using health and safety standards to further advance electronic exchange of information, the Agency must address the underlying issues preventing interoperability. **The ACC urges CMS to promote an environment which ensures clinicians can seamlessly transmit and receive data without having to log into multiple systems and with a minimum number of clicks.** CMS must work to improve EHR workflow by collaborating with clinicians and industry partners to encourage the development of platforms that increase efficiency and productivity while improving in the quality of care. Additionally, the College believes that CMS must work with clinicians, industry, standards organizations and other relevant stakeholders to develop consensus standards and methods of data transmission. The development and acceptance of consensus standards and methods of data transmission will reduce the number of systems clinicians must access while caring for each patient. These consensus standards and methods of data transmission will also allow third parties to develop applications that can reduce the cognitive burden required to operate these systems and deliver useful clinical intelligence.

The ACC believes CMS should explore all means for achieving safe and effective electronic exchange of information. While doing so, CMS must balance the potential impact modifications to existing conditions may have on clinicians and care settings and mitigate unintended negative consequences. It is also essential that any revisions to conditions and requirements for improving interoperability apply equally to all relevant care settings to promote interoperability across the spectrum. **Finally, before modifying any conditions and requirements, CMS must secure the commitment of industry partners to provide clinicians and hospitals with tools and technology capable of meeting the requirements, including assurances to prevent data blocking, provide**

necessary data liquidity and portability, and work towards true semantic interoperability.

MIPS Final Score Methodology

Clinical Guideline Changes

As clinical guidelines are developed and updated, approved quality measures must also be updated to reflect the latest standards for optimal patient care**. The ACC shares CMS' concern that misalignment between the rulemaking cycle and the clinical document processes may result in performance years where an approved quality measure does not reflect a recently released guideline. However, the ACC has concerns with CMS' approach to addressing this scenario.** When this occurs, CMS proposes to suppress a measure without scoring, if during the performance period a measure is significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns.

Proper implementation of this policy requires extensive communication between CMS and measure stewards. The ACC supports CMS' proposal that it would be the responsibility of the measure steward to notify CMS of changes to clinical guidelines that may impact existing measures. As part of this discussion, CMS and measure stewards should discuss an expected timeline for updating impacted measures and whether the measure should be pulled from scoring during a given performance period. CMS should take into account the extensive evidence review and validation processes that stewards must conduct in order to update a measure.

The ACC recommends that only measures posing significant and immediate patient safety concerns be pulled from scoring in the event of a guideline or evidence update. These should be measures where continued performance against the measure for one year would lead to significant patient harm or death. Other measures may be affected by guideline changes during a performance year that either have a minor impact to a measure, or where it is in the best interest of the patient if the clinician continues to perform against the measure until the steward can complete its review and update. These measures should be permitted to maintain in the MIPS program until the measure steward can perform a thorough review and update of the measure. This would minimize the burden on clinicians who would be forced to find a new measure to report in the event that one of their selected measures is pulled from the program during a performance year.

The ACC is especially concerned with the impact of this policy on Qualified Clinical Data Registry (QCDR) measures. CMS states that because QCDR measures are exempt from the rulemaking process, the expectation is that they are more nimble and can update their measures to the current guidelines. While QCDRs do have flexibility, the College reminds CMS that QCDR measure updates also go through extensive clinician-led evidence review, testing, and specification development. In recent years, it has been CMS' expectation that the ACC update its QCDR measure for hypertension within one month of the new hypertension guideline release or the measure would not be available

for MIPS reporting. This would completely disregard the amount of staff time it takes to re-specify a measure and the amount of volunteer clinician time it takes to perform thorough evidence review.

Ensuring that the MIPS Quality category reflects the latest clinical guidelines and evidence is a priority for the College; however, we continue to urge CMS to work with measure developers to explore ways to better reconcile the regulatory and QCDR measure approval cycles and the processes and timelines for updating and developing clinical guidelines and subsequent measures.

Small Practice Scoring

The ACC supports the continuation of small practice bonuses and flexibility for solo practitioners and groups of 15 or fewer eligible clinicians. CMS proposes to move the small practice bonus from five points awarded on the MIPS composite score to three points on the Quality performance category because this would simplify the bonus and not contribute to unintentional score inflation. The ACC believes it would be simpler to apply all bonuses to the MIPS composite score rather than requiring groups to decipher various bonus point opportunities within categories. That said, the ACC accepts the proposed approach as long as CMS continues to determine the best and least complicated way to apply the bonus in future years.

The ACC cautions CMS against the perception stated in the proposed rule that because the Cost category does not require submission of data, there is less concern that small practices are burdened by the requirements of this category. The College would argue that small practices that are attributed Cost measures may be burdened by this category because treating a smaller population may translate into greater difficulty for small practices in moving performance in this category. CMS should continue to monitor the impact of all MIPS categories on small practices and solo practitioners to ensure that all clinicians under MIPS are scored fairly and accurately.

Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories

The ACC appreciates CMS' effort to find the least administratively burdensome approach to participating through facility-based measurement, specifically the use of Hospital-Value Based Purchasing (VBP) measures for the MIPS Cost and Quality scores. While this option will reduce burden for those primarily practicing in the hospital inpatient and outpatient settings, the ACC recommends that CMS monitor implementation of this option to ensure that clinician engagement in meaningful measurement and performance is maintained. CMS must also ensure that the ability to report on facility-based program measures does not place these clinicians at an unfair advantage over those who can only report MIPS measures, and vice versa.

Under the Meaningful Measures initiative, CMS has streamlined and reduced duplication of measures under the Hospital VBP. While the ACC supports this effort to reduce

administrative burden for hospitals, we ask CMS to consider its potential impact on facility-based measures for clinician-level scoring. Meaningful measures under the MIPS program are those measures aligned with processes or outcomes tied to the clinician's or care team's direct care to the patient. As CMS explores movement away from certain condition-specific measures toward less administratively burdensome hospital-wide metrics of cost and outcomes, the ACC is concerned that this could dilute the connection that clinicians have to their facility-based measures used for MIPS. If CMS finalizes facility-based measure scoring, CMS should balance the mission to reduce administrative burden with the need to maintain some measures in the hospital programs that are also relevant to clinician-level performance.

Determination and Election

CMS plans to use "data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period with a 30-day claims run out in determining eligibility for facility-based measurement." While this aligns the MIPS determination period with the Hospital VBP determination period, the ACC reminds CMS that clinicians may change employers/practices within the 2-year determination period, potentially impacting their eligibility for facility-based scoring. CMS should provide ample notice to clinicians should their status change, so clinicians are aware whether they need to implement the infrastructure for reporting at the individual or group level.

Rather than implementing an opt-in or opt-out process for facility-based measurement, CMS proposes to eliminate the election process altogether. Instead, CMS would accept the highest submission received for the clinician or group if a facility-based submission is received along with another MIPS submission. The ACC agrees with the value of this approach. However, CMS should consider whether to include a voluntary opt-out mechanism on the QPP website. There may be some clinicians and groups that qualify for facility-based measurement but do not want to use it toward their MIPS score for a variety of reasons, such as they prefer to submit their self-selected MIPS measures, or they do not want their facility's Hospital VBP score to be used for their *Physician Compare* performance. These clinicians should be provided with a window in which they can voluntarily opt-out and then be responsible for their own MIPS reporting.

Complex Patient Bonus and Considerations for Social Risk

The ACC supports continuation of the complex patient bonus for the 2019 performance year/2021 payment year. Furthermore, the College commends CMS for continuing to work with the Office of the Assistant Secretary for Planning and Evaluation to further examine how to better account for patient social risk factors in the MIPS program and looks forward to the development of future policies to address this area.

Qualified Clinical Data Registries (QCDRs)

Proposed Update to the Definition of a QCDR

The ACC strongly supports CMS' proposal to modify the definition of a QCDR to state that the approved entity must have clinical expertise and quality measure development, with additional recommendations. The College is pleased that CMS continues to recognize the importance of QCDRs in the proposed rule and has noticed that certain entities with limited understanding of quality metrics or measure development have been approved as QCDRs.

The ACC agrees with the direction of the proposed definition but recommends that CMS further tighten the definition to ensure that only the intended entities qualify for QCDR designation. The Agency proposes the following definition in the proposed rule:

> *Qualified Clinical Data Registry (QCDR) means an entity with clinical expertise in medicine and quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.*[2]

The College presents two options for CMS' consideration. The first option would be for CMS to adopt the definition of a "clinician-led clinical data registry" in the 21st Century Cures Act.

> *"DEFINITION. —For purposes of this Act, the term ''clinician-led clinical data registry'' means a clinical data repository—*
> *(1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy;*
> *(2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;*
> *(3) that provides feedback to participants who submit reports to the repository;*
> *(4) that meets standards for data quality including—*

[2] 83 Fed. Reg. 36075 (Jul. 27, 2018).

(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and
(B) being subject to regular data checks or audits to verify completeness and validity; and
(5) that provides ongoing participant training and support."[3]

This definition was developed by the clinician community. Using this definition would not only address CMS' concerns but would also begin alignment of a "clinical data registry" definition across federal programs.

At a minimum, the second option would be for CMS to update the proposed definition to refer to entities "with clinical expertise in medicine, *guideline development*, and quality measurement." Organizations with both guideline and quality measurement experience will be most current on best practice, available evidence, and the aspects of clinical care are appropriate for measurement. These organizations are also most likely to already have systematic approaches for the "evidence review, consensus development, scientific rigor, and clinical assessment" that CMS expects for QCDR measure development.

QCDRS Seeking Permission from Another QCDR to Use an Existing, Approved QCDR Measure

The ACC strongly opposes the proposal to require a QCDR to enter into a license agreement with CMS permitting any QCDR to submit data on the QCDR measure for purposes of MIPS. The College understands that having multiple QCDRs report on the same QCDR measure allows CMS to collect a larger pool of measures, which statistically helps establish more reliable benchmarks and a wider performance range. However, this approach disregards the original intent of QCDRs to submit data on non-MIPS measures focused on disease-, condition-, procedure-, or therapy-specific patient populations.

The ACC and other medical societies devote extensive resources to measure development, data collection, and data validation. The data collected through QCDRs are used not only for MIPS reporting, but also for research and analysis used to support guideline development and quality initiatives. Allowing CMS to permit any QCDR to report another QCDR's measures would place a significant strain on QCDR and medical specialty staff because any data collected from an outside source would have to be subject to the same extensive quality review process prior to use for research.

CMS should not finalize the requirement that QCDRs permit CMS to allow another QCDR to submit data on the first QCDR's measure. Should CMS finalize a revised QCDR definition as discussed above, this should limit the need for one QCDR to license another QCDR's measures because each entity would have its own measure development

[3] 21st Century Cures Act. Pub. L. 114-255. 130 Stat. 1033 (Dec. 13, 2016).

expertise. CMS must keep in mind that the QCDR reporting mechanism allows QCDRs to develop their own quality measures for use in the MIPS program. QCDRs should not be required to license a measure from another QCDR in lieu of developing their own measure.

Remedial Action and Termination of Third Party Intermediaries

The ACC opposes CMS' proposal to allow the Agency to terminate "immediately or with advance notice," the ability of a third-party intermediary to submit MIPS data on behalf of an eligible clinician or group. Such termination should only occur with notice and through a clearly defined process established through rulemaking. This process should reflect current procedure, which includes a probationary period involving discussions between the entity and CMS to ensure understanding of specific deficiencies identified by CMS and development of a corrective action plan by the affected entity. Should the entity fail to comply or meet improved data standards following agreed completion of this process by both CMS and the entity, then the entity's third-party status may be terminated with notice.

Public Reporting on *Physician Compare*

Public reporting performance data through *Physician Compare* can better inform beneficiaries assuming the data is accurate and actionable. The ACC supports proposals not to publicly report first-year data on quality and cost measures to allow clinicians and groups to get feedback on these measures before they are publicly reported. In addition, CMS should continue to provide clinicians and groups with preview periods to review and validate the accuracy and appearance of their data before it is publicly posted.

As CMS collects performance data across additional years of MIPS, the Agency should continue to consider whether a five-star rating on each MIPS measure is the most accurate way to illustrate the difference between a high-performing clinician and a low-performing clinician. CMS encourages clinicians to report on measures where they have the ability to address improvement gaps; however, this may result in a clinician being listed as less than five stars for a particular measure. Conversely, if all clinicians report their highest performing measures to CMS, most clinicians on Physician Compare would be five-star providers, and there would be no way for beneficiaries to make comparisons. CMS could consider a methodology that highlights the top 10 percent of clinicians and groups and the bottom 10 percent of clinicians and groups based on performance. All others would be considered quality clinicians for purposes of public reporting. This would minimize the data overload on beneficiaries while highlighting those clinicians who have meaningful performance differences.

Advanced Alternative Payment Models (Advanced APMs)

The ACC acknowledges CMS' interest in moving toward Advanced APMs that encourage clinicians to coordinate care for a population under a two-sided risk model.

The College is encouraged by the Bundled Payments for Care Improvement Advanced model that will provide opportunities for cardiologists and other specialist clinicians to participate in an Advanced APM.

CMS should continue to develop Advanced APMs that provide opportunities for specialist clinicians to meaningfully participate. The ACC encourages CMS to review ACC's comment letter on the CMS Request for Information: Innovation Center New Direction and the Request for Information: Direct Provider Contracting for additional feedback on developing specialty focused Advanced APMs. **Particularly, ACC reiterates the request that CMS work with Congress to reduce the payment and patient thresholds for Qualified Provider determination per the MACRA statute.** ACC believes that the thresholds will become increasingly difficult for clinicians to achieve as they increase.

Other Payer Advanced APM Option

The ACC strongly supports implementation of the Other Payer option for determining Advanced APM qualifying participant (QP) status for the initial 2019 performance period. This may provide the opportunity for more clinicians to participate in the Advanced APM pathway, particularly specialists who may find it difficult to meet the payment/attributed patient thresholds through Medicare models alone.

The College recommends that CMS take a cautious approach to operationalizing the first performance period where this option is available to clinicians. For example, CMS does not maintain the participation list or affiliated practitioner list for other payer APMs. The ACC continues to have concerns that this will limit the ability to provide clinicians with accurate notice of their QP status unless CMS is able to coordinate this information across payers in a timely manner. CMS should work to address these and other infrastructure limitations during the first performance period.

CMS is proposing to streamline the process for multi-year arrangements so that the payer and/or clinician will provide information on the length of the agreement, and if there were no changes to the payment arrangement, the payer and/or eligible clinician would not have to annually attest there were no changes to the payment arrangement. **The ACC supports this added flexibility and believes the ability to submit documentation only once will increase uptake of the Other Payer option.**

CMS is proposing to allow for QP determinations under the All-Payer Option to be requested at the TIN level in addition to the APM Entity and individual eligible clinician levels. **The ACC strongly supports this added flexibility in measuring risk for purposes of QP determination.**

Nominal Risk Standard

CMS proposes to maintain the generally applicable revenue-based nominal amount standard at eight percent of the average estimated total Medicare Parts A and B revenue

of providers and suppliers in participating APM Entities through the 2024 Medicare QP performance periods The College supports this proposal to maintain the current generally applicable revenue-based nominal amount standard rather than increasing the standard for the 2019 and 2020 Medicare QP performance periods. Maintaining the current standard will provide clinicians additional time to adjust to performing within the current standard. The ACC encourages CMS to maintain similar stability as it reconsiders this standard in future years.

MIPS APMs

CMS is proposing to revise the wording of a MIPS APM criterion to state that the APM "bases payment on quality measures and cost/utilization." This is intended to clarify that the cost/utilization part of the MIPS APM criteria is broader than specifically requiring the use of a cost/utilization measure. The ACC appreciates CMS clarifying this and the increased flexibility in MIPS APM arrangements the revised criterion allows.

Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

The ACC is encouraged by CMS announcing the MAQI Demonstration. **The College believes it is important for clinicians in high Medicare Advantage (MA) penetration areas to receive credit for their participation in payment arrangements with similar requirements as Advanced APMs.** The ACC also appreciates CMS' transparency in announcing the details of the demonstration in the CY 2019 Physician Fee Schedule proposed rule and the opportunity to provide constructive feedback and suggestions on the demonstration.

MIPS Exemption Waivers

The ACC strongly supports an exemption from MIPS for clinicians participating in qualifying payment arrangements. This will allow these clinicians to receive credit for their participation in payment arrangements that have similar requirements to Advanced APMs. Clinicians exempted from MIPS reporting requirements can focus on the successful transition to value-based care for MA beneficiaries. The College believes that the exemption will support the demonstration's goals of increasing participation in qualifying MA payment arrangements and encouraging clinical practice transformation.

In the proposed rule CMS requests comment on whether removing these clinicians from the pool of MIPS-eligible clinicians for which the MIPS payment adjustments are calculated will impact the potential for negative or positive payment adjustments. The ACC appreciates CMS being cognizant of this potential impact and seeking public comment on this aspect of the demonstration. **The College believes that the benefit of encouraging value-based care in the MA program and giving credit to those clinicians for their participation in qualifying payment arrangements outweighs the potential for an impact on the level of the MIPS payment adjustment.** As the

demonstration is implemented, CMS should closely monitor any impacts on the MIPS payment adjustment.

Additional Incentives for Participation in Qualifying Payment Arrangements

The ACC strongly encourages CMS to consider the addition of a bonus payment similar to that provided for Advanced APM participation. The criteria for a qualifying MA payment arrangement and the criteria for an other-payer Advanced APM are identical and under the same section in the Code of Federal Regulations. These clinicians must also meet the same patient and/or payment thresholds as those in Advanced APMs, while only receiving the MIPS exemption. Furthermore, clinical practice transformation and the assumption of downside risk involve significant infrastructure investment, which may be impeded without the financial incentive that a bonus payment provides. Therefore, clinicians in the demonstration should have equal access to bonus payments for similar work advancing value-based care.

Eligibility Thresholds

The ACC is concerned that the patient and payment thresholds for MAQI participation may be difficult for clinicians to meet, especially as they increase each year. Even in high MA penetration areas clinicians may have difficulty qualifying for the demonstration. Clinicians in areas with moderately high MA penetration could be uniquely disadvantaged with the potential for them to not meet the demonstration thresholds but also not have sufficient patients or payments to facilitate meaningful MIPS or Advanced APM participation. Additionally, the College is concerned that CMS is holding participants to the Advanced APM patient and payment thresholds without providing them the benefits of the Advanced APM bonus payment.
The College encourages CMS to implement lower patient and payment thresholds for the MAQI and hold them consistent throughout the demonstration.

Application Process

The ACC encourages CMS, where possible, to require MA organizations to submit qualifying payment arrangement documentation rather than the participating clinician. Requiring applicants to provide detailed summaries of payment arrangement contracts may pose a barrier to participation by small and rural practices. **The College also requests that CMS work to ensure that payment arrangement submissions are kept confidential given the proprietary nature of the contracts.**

Under the demonstration, CMS will evaluate whether participants meet the waiver thresholds at the eligible clinician level, not at the APM entity level. Measuring risk at the individual eligible clinician level could be a barrier to entry to the demonstration because this puts the onus on an individual to meet high patient and/or payment thresholds. **The College disagrees with the decision to measure risk at the individual eligible clinician level and encourages CMS to instead measure risk at the level of the APM entity.**

Medicare Shared Savings Program Quality Measures

ACC generally supports CMS' efforts to align the Medicare Shared Savings Program (MSSP)'s quality measure set with the measure set in MIPS. The College is encouraged by CMS's efforts to remove and replace measures in the MSSP set with those in MIPS for the 2019 Performance Year.

CMS is proposing to remove from the MSSP quality measure set two cardiovascular relevant measures:

- ACO–36—All-Cause Unplanned Admissions for Patients with Diabetes
- ACO–37—All-Cause Unplanned Admission for Patients with Heart Failure

ACC cautiously supports using the measure ACO–38 Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions given that the admissions figures captured in these measures are also captured in the numerator of measure. The College recommends that CMS ensure that this measure is adequately risk adjusted.

ACC supports CMS replacing the measure ACO–30 - Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic with the measure Ischemic Vascular Disease: Use of Aspirin or Anti-Platelet Medication. **As previously stated, the College encourages CMS to align its inclusion of this measure with future determinations by the Core Quality Measure Collaborative.**

<u>Appropriate Use Criteria for Advanced Diagnostic Imaging Services</u>

The ACC remains committed to developing, updating, and promoting the use of appropriate use criteria (AUC) in clinical decision-making to improve patient care and health outcomes in a cost-effective manner and to reduce excessively burdensome pre-authorization processes.

The College greatly appreciates the work done by CMS to implement this program to date and commends the Agency for engaging stakeholders throughout the process. The ACC recognizes the substantial effort that CMS and all stakeholders have put into simultaneous implementation of the AUC program and the Quality Payment Program (QPP). Based on our continued evaluation of the AUC program and other value-based initiatives under Medicare, the ACC has determined that accomplishing the goals of the AUC program through existing programs such as the QPP presents a less burdensome approach to both clinicians and the Agency. As designed, the MIPS and Advanced APM pathways of the QPP provide ways to measure clinicians on the quality and cost of care. CMS has already designated AUC consultation through a clinical decision support mechanism as an Improvement Activity under MIPS and there are several quality measures based on AUC available for the Quality category. The ACC believes that there

is an opportunity to further enhance the value of AUC consultation through the existing QPP requirements that are already familiar to clinicians.

The ACC recognizes that fully aligning the AUC program under the QPP still requires action by Congress, as well as refinements to the QPP through the rulemaking process to ensure that the QPP adequately incentivizes clinicians to consult with AUC, report on appropriate use measures, and engage in practices to reduce the cost of care by reducing potentially unnecessary imaging services. As the ACC looks forward to engaging CMS in this discussion, the College recognizes that absent a change to the statutory requirement of the Protecting Access to Medicare Act of 2014, the Agency must continue to work toward implementation of a separate AUC program. As such, the ACC provides the following comments on the program should it begin in 2020.

Expanding Applicable Settings

The ACC supports the addition of "independent diagnostic testing facility" to the definition of an applicable setting to ensure that all outpatient advanced diagnostic imaging services are furnished. Expanding this definition ensures continuity of the program across all outpatient imaging settings.

Consultations by Ordering Professionals

The ACC supports the proposal to allow clinical staff working under the direction of the ordering professional to perform the consultation with AUC through a qualified clinical data support mechanism (CDSM), subject to applicable state licensure and scope of practice law. This approach recognizes the importance of team-based care and will also lessen the burden on ordering professionals. This should not diminish the ordering professional's interest and engagement in AUC since as he/she is responsible for the services ordered under his/her NPI. If a member of the ordering professional's clinical staff were to report a high rate of "does not adhere to criteria" ratings, it would be the ordering professional, not the member of the staff who may be subject to outlier status.

Reporting AUC Consultation Information

In this proposed rule, CMS proposes to use HCPCS G-codes and modifiers to indicate consultation with AUC through a qualified CDSM on the claim form. Last year several stakeholders recommended that CMS use unique consultation identifiers (UCIs) to identify this information. A UCI would be generated each time a clinician consulted with AUC through a CDSM. The UCI offers several advantages in that as new CDSMs enter the program, there would be no need to create a new HCPCS code for reporting. **While the College sees value in data that can be captured via a UCI, there is currently no field on the Medicare claim form for reporting this identifier. Therefore, documenting AUC consultation through the use of HCPCS G-codes and modifiers for documenting AUC consultation on the claim form seems reasonable only as it fits within the current claim form structure; this approach will still require**

extensive staff time to learn how to use the new codes and implement them in their billing systems. CMS must also still note the potential limitations of this approach, such as the ability of a limited set of modifiers to capture the scope of data needed to identify true outliers. As CMS issues further guidance, the Agency should prioritize processes that reduce administrative burden to clinicians and their staff.

As with any new requirement, CMS must educate clinicians and their staff early on how to use these new codes. The ACC recommends that CMS begin education in 2019, so clinicians can take full advantage of the 2020 educational year to begin submitting claims using the new codes. At the end of 2020, CMS should provide clinicians with reports stating whether they have been properly documenting AUC consultation on their claims submissions, as well as preliminary data on their adherence patterns to allow them to prepare for the start of data collection for outlier calculation in 2021.

CMS expects documentation of AUC consultation to be included on all claims submitted by the furnishing professionals and facilities, meaning that the codes and modifiers for AUC consultation must be included on the ordering professional's claim for the professional component and on the provider's or supplier's claim for the facility or technical component of the advanced imaging service if a global service is not reported. The College is concerned that this would require a clinician performing an interpretation only, with no face-to-face interaction with the patient, to also obtain information from the ordering professional. **The ACC recognizes that CMS addresses professionals with no face-to-face encounters under the significant hardship exceptions; however, the ACC recommends that CMS simplify this policy by stating that claims for interpretation-only services do not need to include documentation of AUC consultation by the ordering professional.** If the advanced imaging service was ordered with the needed consultation of an approved AUC, it should logically be concluded that the associated interpretation would also be approved.

Significant Hardship Exception

The College supports the implementation of a significant hardship exemption for those clinicians who may have insufficient internet access, EHR or CDSM vendor issues, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, have been practicing for less than 2 years, and/or lack face-to-face patient interaction.
We appreciate that CMS sought the least burdensome approach for attesting to a significant hardship; however, we request that CMS further clarify and simplify the process outlined in the proposed rule. According to the proposal, ordering professionals attesting to a significant hardship exception and the furnishing professionals would be required to perform the following:

> *"ordering professionals attesting to a significant hardship exception at the time of placing the order would communicate that information, along with the AUC*

> *consultation information, to the furnishing professional with the order and it would be reflected on the furnishing professional's and furnishing facility's claim by appending a HCPCS modifier. The modifier would indicate that the ordering professional has self-attested to experiencing a significant hardship and communicated this to the furnishing professional with the order. Claims for advanced diagnostic imaging services that include a significant hardship exception modifier would not be required to include AUC consultation information."*[4]

It is unclear why the ordering professional would still have to provide AUC consultation information with attestation of a significant hardship if no AUC consultation information is to be provided on the claim. CMS should require that the ordering professional only need to communicate attestation of the exception and reason claimed.

In addition, CMS should ensure that the process for attesting to a significant hardship exception is not burdensome. CMS proposes that ordering professionals would self-attest to a significant hardship at the time of placing an advanced diagnostic imaging order and that such attestation be supported with documentation of significant hardship to the furnishing provider. The College is concerned that having to attest to a significant hardship with every order will impose additional work on clinicians who are intended to be relieved of program requirements. CMS should consider approaches where ordering professionals could attest once to a furnishing professional and that the single attestation would remain valid for all advanced imaging ordered within a defined timeframe. At the conclusion of that timeframe, the ordering professional could be required to attest again in order to continue the exception.

Regardless of the final process, the College encourages CMS to seek what is least administratively burdensome to both the ordering and furnishing professionals.

Identification of Outliers

Developing a valid and fair methodology requires a thorough consideration of how AUC are designed, the patient factors that may impact a clinician's ordering patterns, and an understanding of other variables that may impact CMS' ability to identify true outliers. CMS must also ensure that the methodology does not unintentionally result in the harmful underutilization of advanced imaging services to Medicare beneficiaries.

The College offers the following questions and initial thoughts around the methodology, while urging CMS to continue discussions with stakeholders, particularly the clinician community, to further develop, refine, and test the methodology using actual data submitted under this program before policies identifying potential outliers are fully implemented. As stated earlier, the College also encourages CMS to consider how the identification of outliers may be addressed through the performance-based QPP.

[4] 83 Fed. Reg. 35870 (Jul. 27, 2018).

- Under the Protecting Access to Medicare Act of 2014 (PAMA), "the Secretary shall determine no more than five percent of the total number of ordering professionals who are outlier ordering professionals." As part of its annual review, CMS should determine an appropriate threshold for outlier identification. If there is no statistically significant difference among ordering patterns in a given year, then CMS should lower the number of outlier professionals identified or even determine that no outliers can be identified.

- CMS should ensure that the methodology is fair, regardless of what provider-led entity (PLE) developed the AUC a clinician chooses to use. Unlike clinical guidelines, not all AUC have been developed on robust evidence; some AUC are specifically intended to address clinical areas where there are gaps in evidence. PLEs utilize thorough, systematic review processes when developing AUC ratings; however, CMS must remember that the rating outcome may vary depending on a panel's assessment of available evidence. Therefore, CMS should consider how this potential variability among AUC for a given condition or modality may impact the outlier methodology.

- CMS should set minimum thresholds where "one-off" tests ordered are excluded from the outlier calculation. For example, a cardiologist will typically order tests addressing the priority clinical area of coronary artery disease (suspected or diagnosed). However, there may be certain instances where that cardiologist may run a test for a different priority clinical area outside of his/her typical patient population. Under this scenario it is likely that the clinician is not as familiar with the AUC for this one-off condition and to receive a "do not adhere" rating. CMS should explore what minimum sample sizes are needed to support a statically valid outlier calculation and whether there is a need to develop case minimums by priority clinical areas or other factors.

- CMS should explore whether additional factors not readily available through claims data have an impact on the outlier methodology. Should CMS be examining differences in ordering patterns by geographic regions, ethnic groupings, or practice settings? Will clinicians who treat a higher proportion of complex patients be more likely to receive "not adhere" ratings because they are treating patients where evidence is still developing? How should this impact their outlier calculation?

- CMS must remember that AUC documents do not cover all possible clinical scenarios. While patients falling outside of the clinical scenarios covered by AUC will be rare, these patients should be excluded from the outlier calculation based on the reasonable medical judgment of the ordering professional.

- CMS should develop the outlier methodology with an awareness of the current CDSM capabilities. Some CDSMs are programmed so that it is nearly impossible to complete an order for a test that results in a "rarely appropriate" or "not

adherent" rating. If most CDSMs operate in this fashion, it will be difficult for CMS to calculate valid outliers as few clinicians should be reporting non-adherence to AUC on the final claim.

The ACC appreciates the opportunity to open this discussion with CMS and encourages the Agency to engage in further conversations with clinicians to develop a fair and valid methodology should the AUC program be fully implemented.

Recognizing Communication Technology-Based Services

In the proposed rule, CMS acknowledges advances in communication technology have changed patient and clinician expectations regarding the quantity and quality of information conveyed via communication technology. These advances include the ability for patients to communicate with clinicians in real-time to determine whether an office visit is necessary. Innovative communication techniques may mitigate the need for potentially unnecessary office visits and help clinicians meet patient's evolving expectations for instantaneous consultations. Rapidly evolving and ubiquitous communication techniques that utilize audio and video as well as real-time data transfer will augment patient expectations for communication methods with clinicians, changing the health care landscape. The College appreciates CMS' clear recognition that reimbursement structures must account for and encourage innovative communication techniques and urges continuous evaluation to ensure these structures allow for innovation and sufficient payment for services and technology.

Potentially Misvalued Services

A public commenter nominated several high-volume codes for review under the potentially misvalued code initiative, citing potential overvaluation of work RVUs based on "a number of Government Accountability Office (GAO) and the [the] Medicare Payment Advisory Commission (MedPAC) reports, media reports regarding time inflation of specific services, and the January 19, 2017 Urban Institute Report for CMS." CMS summarized that the nomination focused on overestimates of services times and that previous reviews by the RUC did not result in reductions that adequately reflected reductions in time. CMS did not propose any of these services for further review. The ACC supports taking no action on these codes, but also provides some feedback here as two of the services nominated—93000 for electrocardiogram and 93306 for transthoracic echocardiography—are commonly provided by cardiologists. Both services were recently reviewed by the RUC and CMS.

The referenced Urban Institute report concludes that the intraservice time to interpret an electrocardiogram is six seconds. Members who provide that service see no way it is possible to completely interpret a study so quickly. The ACC remains concerned by the large emphasis placed on service time by CMS and some stakeholders when it comes to valuation. Time varies by patient, disease, provider, site of service, equipment, clinical staff, workflow, and other considerations. Frequent reviews of long established and mature services like electrocardiography and echocardiography will only produce two

outcomes—the inputs will remain the same or circumstances at some point will align such that it appears they take less time, which open a window for payers to try to reduce payment for services that have not actually changed in years or decades. Eventually these reductive re-valuations produce underpayment.

Market-Based Supply and Equipment Pricing Update

CMS summarizes it's use of a market research contract with a consulting firm to update the direct PE pricing inputs for supplies and equipment for CY 2019. Based on the report from StrategyGen, CMS proposes updated pricing recommendations for 2,017 supply and equipment items currently used as direct PE inputs. The firm utilized market analysis, market scans, vendor information, aggregate databases, field surveys, physician input, and statistical analysis to develop its recommendations. CMS proposes to update these PE pricing inputs during a 4-year phase-in period.

The ACC supports CMS implementing the direct PE pricing transition over a four-year phase-in period as proposed, but recommends CMS begin the transition starting in CY 2020. This delay will allow stakeholders to evaluate the systematic approach used by StrategyGen and/or provide additional information or invoices to correct shortcomings in the systematic approach. The ACC is concerned that the data and resulting methodology are not readily available for independent review.

Supplies and equipment have not undergone a comprehensive review of this nature since 2005. In the interim, many items have been updated through the RUC process. The ACC strongly encourages CMS to carefully consider all pricing data it currently has, including invoices and other supporting evidence submitted during prior RUC reviews, as well as any additional information provided during this comment period as it prepares for future implementation. During the four-year transition, CMS should override PE inputs found to be in error through additional documentation and fully implement those updates to specific inputs for which valid documentation demonstrates the systematic approach used by StrategyGen was incorrect. This should be done through the quarterly update process.

Valuation of Specific Services

Pulmonary Wireless Pressure Sensor Services

The CPT Editorial Panel created new codes to implant a wireless sensor and then to download, analyze, and create a report of that transmitted data. Code 332X0 (Transcatheter implantation of wireless pulmonary artery pressure sensor for long term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed) allows discrete reporting of this service that had previously been billed with an unlisted code. CMS proposes to implement the RUC-recommended work RVU of 6.00 with related practice expense (PE) inputs. CMS also proposes the RUC-recommended work RVU of 0.70 with PE inputs for code 93XX1 (Remote monitoring of a wireless pulmonary artery pressure

sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional). As a participant in the RUC process that led to these recommendations, the ACC supports these values and recommends CMS finalize its proposal for these two codes.

Cardiac Event Recorder Procedures

CMS proposes to implement the RUC-recommended work RVUs and PE inputs for two new codes that describe placement and removal of loop recorders that have shrunk in size such that the placement technique is now more of an insertion than an implantation as described by existing codes. The ACC supports this proposal to implement a work RVU of 1.53 with submitted direct practice expense inputs for CPT code 332X5 (Insertion, subcutaneous cardiac rhythm monitor, including programming) and a work RVU of 1.50 with submitted direct practice expense inputs for code 332X6 (Removal, subcutaneous cardiac rhythm monitor).

Leadless Pacemaker Procedures

New Category I CPT codes 33X05 (Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed) and 33X06 (Transcatheter removal of permanent leadless pacemaker, right ventricular) will be implemented in 2019 after these services were described for several years using Category III CPT codes. CMS proposes to implement the submitted direct PE inputs, but to lower the work RVUs from those submitted by the RUC. **The ACC disagrees with this proposal and recommends CMS implement the RUC work RVU recommendations.**

CMS proposes to crosswalk 33X05 to code 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular) with a work RVU of 7.80 rather than use the RUC survey 25th-percentile recommendation of 8.77. 33X05 has a 61-minute shorter total time with a half-day discharge and no inpatient visits, while 33207includes a full-day discharge and one inpatient visit. This was a point of discussion at the RUC because survey respondents indicated in one place that a visit in the hospital was typical but failed to do so in another location. Ultimately, societies adapted recommendations to remove the visit and recommend the lower survey 25th-percentile value instead of the median. However, differences remain between leadless pacemaker implantation and transvenous pacemaker implantation. Patients receiving leadless pacemakers are already sicker than transvenous patients. They were selected for this therapy because of other comorbid conditions or contraindications. Thresholds tend to change more than with transvenous devices. The risk of embolization is higher. Groin complications are higher than wound complications from transvenous implants. Tamponade is more commonly present. They are more likely to have chronic atrial fibrillation and poor venous access. While it is encouraging to see CMS acknowledge that 33X05 is more intense, the reduction resulting from the proposed crosswalk diminishes

the increment between the codes that was identified by a large pool of survey respondents at the 25th-percentile. Finally, the intensity of leadless pacemaker implantation at the RUC-recommended value is comparable to diagnostic cardiac catheterization procedures. While performed by a different subspecialty of cardiology, the societies feel that further validates the work RVU of 8.77.

For related code 33X06 (Transcatheter removal of permanent leadless pacemaker, right ventricular), CMS proposes to reduce the survey-based recommendation by 0.79 work RVUs. This is the same increment that existed between the values recommended by the RUC for these two codes. Instead of values at 8.77 and 9.56, respectively, CMS proposes values of 7.80 (from crosswalk) and 8.59. While these procedures will be rare, these patients will still have the elevated risk factors mentioned in discussion of 33X05 and warrant the additional work indicated by survey respondents at the 25th-percentile of the survey.

The ACC supports CMS's proposal to implement the submitted direct PE inputs for the family.

Cardiac Output Measurement

After these services with negative IWPUT were reviewed, CMS proposes to value 93561 (Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement) and 93562 (Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output) below the RUC recommendations by crosswalking them to another ZZZ code with similar time for 93561 and then a time ratio RVU value for the 93562 because the times for these two codes decrease while the values increase.

The College acknowledges that is the RUC recommendations are unusual but believes these codes should be treated unusually for several reasons. First, the current times and values are meaningless for these codes. They were derived from original Harvard study times and values, except some time and value has since been removed for changes in moderate sedation. Second, they were surveyed with the intention to change them from 000 global to ZZZ global. Intensity will necessarily increase when preservice and postservice time are no longer part of the codes. In fact, that is exactly the reason these values should increase—the current values create a negative intensity factor, which is the same as saying that doctors are paying CMS to do this work. Finally, these codes were written for use in the adult population, but because of bundling efforts in recent years, their only use at this point is in the congenital heart disease patient population, typically pediatric patients. Given these reasons, the increases in value are appropriate.

The ACC urges CMS to finalize the values recommended by the RUC for these two codes, 0.95 for 93561 and 0.77 for 93562. CPT code 93567 (Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography) was the survey key reference service and is a more

appropriate code for comparison or crosswalk to 93561. It has an identical 15 minutes intraservice time and is also clinically similar as another coronary catheterization add-on service. CMS's proposed crosswalk to 77003 (Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) is only the fluoroscopic guidance for an injection.

Coronary Flow Reserve Measurement

The RUC flagged CPT code 93571 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel) as a service with Medicare utilization higher than 10,000 that increased at least 100 percent from 2009 through 2014. Societies surveyed 93571 along with family code 93572 for coronary flow reserve measurement of additional vessels. CMS proposes to reduce the value for 93571 to 1.38 from the RUC recommendation of 1.50. **The ACC disagrees with this proposal and urges CMS to finalize the RUC-recommended value of 1.50.**

Despite the reduction in time from 20 minutes to 15 minutes, surveys supported maintenance of the current value of 1.80 for 93571. Societies informed the RUC that the work to perform the measurement of 93571 has not changed. Rather, the equipment to perform the service and the staff workflow that occurs to perform the measurement once the decision has been made to measure flow reserve has been streamlined. This is a reduction in low-intensity waiting time, not the time to actually introduce the catheter wire into the vessels and perform the measurement. The RUC determined the time reduction still warranted an RVU reduction and recommend a crosswalk to code 15136 (Dermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof) with an identical time of 15 minutes and a work RVU of 1.50. CMS questions the accuracy of this value because the reduction from 1.80 to 1.50 is not directly proportionate to the reduction in time from 20 minutes to 15 minutes. Instead, the proposed value of 1.38 is a direct crosswalk to code 61517 (Implantation of brain intracavitary chemotherapy agent) that approximates a building block calculation to a value of 1.35. This flawed proposal ignores the previously indicated fact that low-intensity time for setup accounts for the total time reduction, making an RVU reduction proportionate to the time reduction too large. Were CMS to apply the established intensity of 0.0224 for "scrub, dress, and wait" time to the five-minute reduction based on the current value of 1.80, the value would be 1.69. While the ACC did not make a reverse-building block argument for valuation, this comparison demonstrates the decision to recommend a value of 1.50 based on crosswalk to a code with identical time is sound. This value and recommendation are also supported from a relativity perspective by comparison to code 58611 (Ligation or transection of fallopian tube(s) when done at the time of cesarean delivery or intra-abdominal surgery (not a separate procedure)) that has a value of 1.45 and service time of 13.5 minutes.

The ACC supports CMS's proposal to implement the RUC's recommended value of 1.00 for code 93572 when cardiac flow reserve is measured in additional vessels.

However, the ACC notes that CMS does not seem to object in this instance to a value that *overcompensates* for the reduction in time. A building block methodology would produce a value of 1.06 for this code, and yet CMS does not propose to increase this value. This makes 93571 another of many examples through the years where CMS' goal appears to be to implement the lowest possible value that can plausibly be justified rather than the value that appropriately considers the skill, knowledge, experience, and risk of a service relative to other services.

Peripheral Artery Disease Rehabilitation

Since implementation of a national coverage determination (NCD) for Medicare coverage of supervised exercise therapy (SET) to treat peripheral artery disease (PAD), the inputs for existing code 93668 (Peripheral arterial disease (PAD) rehabilitation, per session) have been reviewed by the RUC. The code only contains PE because a physician is not typically involved in an individual SET session. The ACC supports the proposed inputs insofar as they accurately capture the staffing and equipment for an individual session. At the same time, the updated inputs are a reduction to the already modest payment CMS makes for SET. The ACC is concerned that even with a full complement of four patients being monitored continuously by a medical technologist or trainer, it will be financially challenging for this service to be provided in the office setting. This may ultimately limit patients' access to this therapy, accelerating their progression to more invasive and expensive interventions. It would behoove CMS—and the medical community—to continue thinking of ways to offer such proactive therapies in a viable manner. Successfully rehabilitating these patients with conservative therapy before they become sick enough to require more costly interventions provides value to the fee schedule, the healthcare system, and society.

Additionally, while an individual SET session typically has no physician work, such clinics are managed by a medical director. Future coding solutions may be necessary to incorporate that work when it extends beyond E/M services.

Chronic Care Remote Physiologic Monitoring

With the creation of three new codes to describe remote physiology monitoring and management by the CPT Editorial Panel, CMS has an opportunity to support clinicians using technology to monitor and manage patients with chronic diseases. The ACC is pleased to see CMS propose the RUC-recommended work RVU of 0.61 for code 994X9 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month) and direct PE inputs for 994X9 and 990X0 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).

CMS proposes to remove the recommended direct PE input for "Monthly cellular and licensing service fee" for 990X1 (Remote monitoring of physiologic parameter(s) (eg,

weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days). CMS indicates it does not believe these licensing fees are allocated to an individual patient at the individual service level but should instead be considered an indirect cost similar to rent or administrative staff. **The ACC disagrees with this conclusion and urges CMS to reconsider this input removal.** As indicated on the invoices submitted, individual line items are dedicated to these components on a per-device, per-user basis. It is difficult to understand how such costs should be considered indirect when they are directly attributable to a patient's monthly monitoring. If the monitoring does not occur, the cost is not incurred.

More generally, the ACC appreciates CMS' embrace of these and other services for remote pre-recorded services and virtual check-ins. Services like these will become increasingly important in the future as new and exciting ways become available to monitor and manage patients without necessarily requiring an office visit. However, these solutions will only be viable if CMS continues to look for ways to pay appropriately for new technologies. As the fidelity of data collected by products patients may purchase as add-ons to their phones or even standalone physiologic devices improves, clinicians will increasingly be asked to incorporate this data into their care management. In some instances, companies are making significant investments to develop complex algorithms, deploy machine learning, and in the future, utilize artificial intelligence to translate this data into patient management tools. That enterprise is expensive, and, these improvements to patient care could be stifled in the cradle if companies are not able to recoup their investments because CMS believes software licensing/use fees are an indirect practice expense.

External Counterpulsation

The RUC reviewed G0166 (External counterpulsation, per treatment session) through a screen of CMS/Other services with utilization greater than 100,000 annually. The ACC agrees with the proposal that an individual treatment session would have no physician work and supports the proposed direct PE inputs. However, as mentioned previously for PAD SET, future coding solutions may be necessary to recognize management of these services by a medical director that extends beyond E/M services.

Remote pre-recorded services

As discussed earlier in these comments, the ACC is pleased to see CMS advancing clinicians' ability to utilize modern communication technology to care for patients. The proposal to define GRAS1 as "Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment" does an adequate job of defining this type of interaction while providing some parameters that recognize the goal of such services is to more efficiently manage patients remotely where possible. Other

services for chronic care remote physiologic monitoring incorporate the collection, interpretation, and management of patients with submitted data. However, the portion of the description "or soonest available appointment" may be difficult for clinicians to confidently assess, possibly diminishing their ability to utilize the code effectively to report this type of remote management of patients. Similarly, the proposal to value this new service through crosswalk to 93793 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed) seems a reasonable starting point. As is often with case with compelling G-codes proposed by CMS, the CPT Editorial Panel may also consider this issue to present Category I CPT codes with RUC-derived RVU recommendations in the future.

Virtual Check-ins

The proposal to create new G-code GVCI1 (Brief communication technology based service, e.g., virtual check-in, by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion) is another positive development for modernizing Medicare physician payment to recognize communication technology-based services. However, it is essential that CMS broadly define the types of communication technology utilized by clinicians in furnishing these services and not limit these to audio only. Advances in technology through increased availability of mobile platforms and Health Insurance Portability and Accountability Act (HIPAA) compliant applications will allow for new and innovative communication methods using audio, video and other kinds of data transmissions. CMS should not stifle innovation by limiting virtual check-in communication methods to audio-only telephone interactions. The ACC recommends CMS indicate in the code descriptor that "technology based service" includes audio, video, and other types of data transmissions that entail 5-10 minutes of clinician time to execute. CMS' proposal to crosswalk the work and practice expense of code 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion) is an appropriate starting point for this type of service. The ACC does note that 99441 is a code that has existed for over a decade for which CMS has declined to pay, assigning status indicator "N" in CY 2008 rulemaking, making this a non-covered service. As with GRAS1, the ACC expects the CPT Editorial Panel and RUC to engage on this service.

Payment rates for services provided by Off-Campus Provider-Based Departments

The ACC supports maintaining the PFS Relativity Adjuster at 40 percent for CY 2019 and future years unless new data or other considerations warrant an update

through future rulemaking, as this will provide stability for clinicians practicing in these settings and not disrupt patient access to care. The College is pleased to see that in its analysis, CMS considered the policy nuances between the PFS and Hospital Outpatient Prospective Payment System (OPPS), particularly the packaging of payments for certain items and services under the OPPS.

The College acknowledges CMS' interest in eliminating incentives to provide care in a higher-cost setting as this will lead to improved affordability for beneficiaries. CMS must continue to be cautious in its approach to implement site neutrality between nonexcepted off-campus provider-based departments (off-campus PBDs) and physician offices to support practice stability. In addition, CMS should continue to consider when it may be appropriate to provide care in a higher-cost setting for reasons such as patient safety and quality of care. To guide CMS with future implementation of payment policy changes, the ACC provides the following principles for site neutral payment that have been used by the College to evaluate payment proposals since 2016:

- Changes to Medicare payment should not harm access to care and quality of care, especially for vulnerable patient populations.
- Medicare payments should reflect the resources required to provide patient care in each setting—physician office, hospital outpatient, hospital inpatient. The "correct" payment may be different in different settings.
- Any payment differences across sites should be related to documented differences in the resources needed to ensure patient access and high-quality care. Some limits on payment differentials for the same service provided in different settings may be reasonable.
- Medicare payments for all sites of care should account for costs related to emergency capacity, compliance with regulatory requirements, geographic differences, quality improvement activities and higher need populations.
- Proposals to make significant changes to Medicare's payment systems (e.g., site neutral payment proposals) should be carefully aligned with other rapid changes in healthcare, including the movement to value-based purchasing and alternative payment systems.
- Major changes should be implemented gradually to minimize any negative impacts on patient access and quality.

Global Surgery Data Collection

An update is provided in the proposed rule on the global surgery data collection required by Section 523 of MACRA. CMS seeks comments on several aspects of this project—how to encourage reporting, whether to consider an enforcement mechanism, whether it may be reasonable to conclude that many visits included in the valuation of 10-day services are not occurring, whether visits may be performed by a different practitioner, whether the visits occur after the global period ends, and whether 99024 may be underreported despite the data collection effort.

The ACC agrees that the most likely reason for the findings is the lack of consistent reporting despite the data collection effort. The ACC does not think it would be appropriate for CMS to pursue an enforcement mechanism for providers who fail to report unpaid post-op visit code 99024. Specialty societies are prepared to jointly promote the effort—the ACC highlighted the project with it began but would also collaborate with CMS in ongoing outreach. If these or similar efforts are undertaken for a longer period, it may be possible to extract meaningful conclusions from at least a portion of the data.

A flawed approach would be to prematurely conclude that because 99024 is not reported that post-operative care is not provided. This data collection continues to be unique in comparison to the normal workflow for global surgery services, and adequate time should be taken to capture meaningful results.

Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

Under the proposed rule, CMS intends to align the electronic clinical quality measures (eCQMs) available for Medicaid eligible providers (EPs) in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. **By aligning reporting requirements for multiple programs, CMS encourages participation and reduces the reporting burden for participation in these programs**. The College applauds CMS for undertaking this effort.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

The ACC commends CMS for prioritizing the creation of a more transparent health care system that empowers patients and clinicians to make the best care decisions under a value-based payment environment. CMS must work with clinicians, hospitals, payers, and other stakeholders to ensure that any publicly released charge data are accurate and actionable. In addition, any increase in the transparency of cost data must be accompanied by robust measures of quality. Patients must be encouraged to seek care based on cost and quality, not cost alone.

As CMS undertakes this effort, the ACC encourages the Agency to consider how to achieve the goal of cost transparency without decreasing the quality of care and patient outcomes and increasing administrative burden. To better assist with the implementation of this effort, the College provided the following answers to the questions posed in the Inpatient Prospective Payment System (IPPS) proposed rule and reiterates them here in response to this proposed rule:

What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interfaces with these data?

Providing patients with standard charge lists will increase transparency but may do little to help patients make more informed decisions. Patients are most interested in understanding their real-time, actual out-of-pocket costs. The challenge of providing these data at the point of care is that out-of-pocket costs may differ based on a complexity of factors including the patient's insurance plan or lack of coverage, the site of service where care is delivered, and other discount and pricing policies. If CMS is to meaningfully implement transparency, data releases should be done in a way that is consumer-focused; patients should not be required piece together information in order to understand the cost of their care.

The ACC encourages CMS to use initiatives such as MyHealthEData to work with stakeholders to develop systems that can combine charge information, health plan information, and other key data in a standardized format to calculate and better predict out-of-pocket costs for patients.

Should health care providers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? What can be done to better inform patients of these obligations? Should health care providers play any role in helping to inform patients of what their out-of- pocket obligations will be?

The ACC supports conversations between patients and clinicians on the cost of care as part of shared decision-making. However, while ideal for clinicians and health care providers to inform patients on their out-of-pocket costs for a service before furnishing that service, this may be difficult to do based on the complexity of factors described above. While CMS should encourage that clinicians and heath care providers discuss out-of-pocket costs with patients, it should not be required at the expense of providing timely care. The development of real-time pricing tools and data sources may eventually support greater discussions of cost at the point of care; until then, CMS must ensure that clinicians focus on the care of the patient. As with patients, CMS should not assume that clinicians can easily navigate the complex health pricing system.

In addition to increasing transparency around the cost of care, CMS must work with health plans, benefit managers, states, hospitals, and other stakeholders to increase information around discount programs and other financial support so clinicians and healthcare providers can make this available to patients. The same stakeholders must also be transparent in providing clinicians and health care providers with information on utilization management policies such as prior authorization requirements that may impact a patient's ability to receive appropriate care.

If CMS does eventually require clinicians and health care providers to inform patients on their out-of-pocket costs, quality metrics and policies should be in place to recognize clinicians and providers for engaging in shared decision-making discussions involving the cost of care. In addition, CMS should ensure that an increase in these discussions

drive improved patient care rather than an unintended decrease in quality and outcomes. Improvements in measure stratification and socioeconomic and demographic data collection may support the ability for CMS to identify those patient populations where cost is a significant barrier to health. CMS must monitor performance on process and outcome measures; greater knowledge of out-of-pocket costs should empower patients, not drive avoidance of care based on cost.

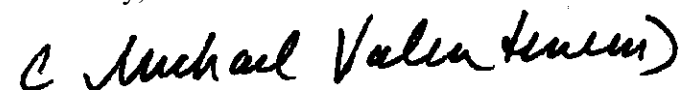
Should we require health care providers to provide patients with information on what Medicare pays for a particular service performed by a health care provider? If CMS were to finalize a requirement that this information be made available to beneficiaries by health care providers, what changes would need to be made by health care providers? What corresponding regulatory changes would be necessary?

As stated above, CMS should only require clinicians and health care providers to provide patients with information on what Medicare pays for a particular service if this information is accurate and actionable. CMS should not expect clinicians and health care providers to produce this information themselves. To relieve the administrative burden this requirement may place on clinicians and health care providers, the ACC expects that CMS would work with Medicare Administrative Contractors (MACs) and others to provide this information in a standardized format that can then be communicated to the patient.

Conclusion

The ACC looks forward to ongoing engagement with CMS to develop policies that support clinicians' ability to focus on delivering high-quality care to patients. The ACC acknowledges the tremendous thought and planning CMS is undertaking to improve the healthcare system. At this critical time, it is vitally important to continue offering innovative solutions that further the quadruple aim without harmful, unintended consequences. CMS consideration of the comments in this letter is appreciated. Should you or staff need additional information or have clarifying questions, please contact James Vavricek, Associate Director for Regulatory Affairs, at jvavricek@acc.org.

Sincerely,



C. Michael Valentine, MD, FACC
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