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September 24, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1715-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion

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 2020 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.
The College is providing CMS with two comment letters, which address two different components of the CY 2020 Medicare Physician Fee Schedule. On September 11, the ACC submitted a comment letter regarding the valuation of specific services and technical changes that drive payment in the House of Medicine, especially those services which impact cardiology. In this letter,

the ACC focuses on proposed programmatic changes and provides comments on the following key areas:

- Merit-Based Incentive Payment System **(**MIPS) Value Pathways Request for Information;
- Opportunities for Bundled Payments under the PFS;
- Enrollment Policies Related to Improper Prescribing and Patient Harm;
- Updates to Year 4 of the Quality Payment Program (QPP);
- Medicaid Promoting Interoperability Program Requirement for Eligible Professionals;
- Medicare Shared Savings Program; and
- Responses to other Requests for Information on the topics of the Patient Exchange Objective, EHRs and Health Data.

Opportunities for Bundled Payments under the PFS

Under the PFS, Medicare makes a separate payment for individual services furnished to a beneficiary, which requires CMS to establish payment for physicians' services based on the relative resource involved in furnishing the service. Identifying and developing appropriate payment policies that aim to achieve better care and improved health for Medicare beneficiaries is a priority for CMS. With that priority in mind, CMS is interested in identifying new paths to establish PFS payment rates and adjustments for services that are furnished together, such as establishing per-beneficiary payments for multiple services, procedure-specific or condition-specific episodes of care, which can be applied within the statutory framework of the PFS.

The ACC supports movement towards value-based care and believes that with the adequate time and resources provided, the development of a procedural or acute-care bundled payment system is possible. The ACC supports the possibility of structuring payment around a patient's care experience and believes such a system could support better care coordination and result in improved patient outcomes. The ACC also strongly supports CMS taking the necessary time to identify and fully comprehend the potential challenges to clinicians, health care systems, and related stakeholders that exist in the implementation of new or modified payment models. Further, the ACC strongly urges CMS to work collaboratively with the CPT Editorial Panel and the RUC, in order to *appropriately* value bundled services, as the Agency has experienced significant challenges doing so in previous proposed rules.

Currently, codes with assigned global periods of 010 or 090 days have multiple discrete services bundled into one payment amount. These services include: all pre-operative work performed within 24 hours of the surgery; the surgery itself; all post-operative work on the day of the procedure and for 010 or 090 days following the procedure, including hospital and office visits.

The RUC, via the Relativity Assessment Workgroup, identifies services that are inherently performed together by the same physician on the same day of service. The screen started with services reported on same date by same physician over 95% of the time with another service. The screen was then lowered for services reported together over 75% of the time to capture more services to be bundled. After five iterations of this screen, the CPT Editorial Panel has created code bundling solutions and the RUC submitted recommendations for approximately 340

services. The ACC worked on bundling services as part of these efforts, including codes for echocardiography, diagnostic catheterization, ablation, and myocardial perfusion imaging. However, since these efforts began in 2009, CMS has commonly disagreed with RUC recommendations. **Moving forward, the ACC strongly encourages CMS to collaborate with the CPT Editorial Panel, the RUC, and specialty societies to review the resources necessary in the provision of bundled services, and also recommends implementation be carried out in a phased manner.** Reconsidering the Agency's interpretation of the phase-in strategy established in the Protecting Access to Medicare Act of 2014 (i.e., allows for a two-year phase-in of payment reductions that exceed 20 percent) would make bundled payment implementation less disruptive to practices and patient access to care.

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 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period. **By aligning reporting requirements for multiple programs, CMS encourages participation and reduces the reporting burden of participation in these programs**. The College thanks CMS for undertaking this effort. CMS also proposes to retain the ability for Medicaid EPs to report on any six eCQMs that are relevant to their scope of practice. The College thanks CMS for providing EPs necessary reporting flexibility and providing continued program stability by continuing to allow Medicaid EPs to report on any six eCQMs that are relevant to their scope of practice.

CMS also proposes retaining the continuous 90-day reporting period for Medicaid EPs demonstrating meaningful use for the first for CY 2020. **The College once again thanks CMS for continuing to provide EPs with necessary reporting flexibility and program stability.** For returning EPs, CMS proposes a continuous 274-day reporting period within CY 2020. While the College is sympathetic to CMS' intent to allow states sufficient time to end the Medicaid Promoting Interoperability program, the ACC is concerned a 274-day (or 9 month) reporting period will be confusing and could inadvertently cause returning EPs to underreport or miss reporting deadlines. **Instead, the ACC believes CMS could further align the Medicaid Promoting Interoperability program with the Medicare program and allow a 90-day reporting period or propose a 180-day reporting period to ensure an appropriate length of time for program integrity purposes.** Either length should allow states to issue all Medicaid Promoting Interoperability payments to EPs by the December 31, 2021 statutory deadline while not needlessly complicating reporting period lengths for CY 2020.

Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm

Under new proposal, CMS would be able to revoke or deny enrollment, for any action, a state medical board takes or, alternatively, use a more targeted approach to focus on outliers. The ACC supports the Agency's efforts to ensure unqualified or potentially fraudulent individuals or entities are precluded from billing applicable programs. However, the ACC has serious concerns with the proposal to allow CMS to deny or revoke an enrollment for any action a state medical

board or equivalent entity takes that CMS determines led to patient harm (e.g., seeking treatment for a substance use disorder or mental health problem through a structured rehabilitation program in lieu of a disciplinary action). This proposal is a broad and unprecedented overreach, would significantly increase regulatory burden without efficiently targeting enforcement toward higher-risk providers and suppliers, and is partially duplicative of existing revocation authority. Accordingly, the **ACC recommends CMS reconsider the proposal and limit application only to providers and suppliers that are identified as outliers using data analytics.**

The College is concerned CMS included this proposal under the opioid treatment program section, and requests the Agency clarify if the proposal is to be strictly applied under the context of opioid programs or applies generally. Placement in this section of the proposed rule gives the appearance of potentially only applying to "high risk" Medicare-enrolled opioid treatment programs; however, the proposed change will likely impact all clinicians. Moreover, CMS does not consider the implications of a denial or revocation on a physician's practice. Revocations lead to a mandated cross-termination of participation in Medicaid and most payers will also remove a clinician from their provider network when CMS takes this action. Thus, if a physician agreed to abstain from drugs or alcohol and be subject to random drug testing to simply provide evidence that no addiction exists, CMS now gives itself the authority to revoke that physician's enrollment in Medicare, which includes a mandated cross-termination in Medicaid with most payers also following suit. In addition, adoption of this policy would be at odds with the nationwide effort to reduce the stigma associated with seeking treatment for substance use disorders. **The ACC urges CMS to withdraw its proposal, which also impacts state medical licensure, or, at a minimum, limit its application only to providers and suppliers that are identified as outliers using data analytics.**

Updates to the Quality Payment Program (QPP)

The ACC appreciates the opportunity to provide comments on Year 4 of the QPP. Participation in both tracks of the QPP –Advanced Alternative Payment Models (APMs) and Merit-based Incentive Payment System (MIPS)—has increased from 2017 to 2018. The number of Qualifying APM participants has almost doubled (99,076 to 183,306). In MIPS, 98 percent of eligible clinicians participated in 2018, a three percent increase from 2017. While the ACC is appreciative of the recently released participation data of the MIPS program, the ACC continues to desire participation data in a timelier manner so that participating clinicians can more quickly and meaningfully implement further refinements to the program.

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

- Continue efforts to prevent the QPP from being an administrative burden on clinicians;
- Finalize programs that adequately balance flexibility with quality patient care;
- Provide clinicians with meaningful measures appropriate to the patient population of interest;
- Provide enough time for the development of novel paths and frameworks to meet QPP performance goals in the following year and years to come;
- Continue to eliminate barriers to APM participation.

Merit-Based Incentive Payment System (MIPS)

Low-volume Threshold

The ACC thanks CMS for maintaining 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. Maintaining the threshold avoids increased reporting burden.

The College encourages CMS to continue monitoring the threshold annually to ensure that the low-volume threshold serves its intended purpose, exempting eligible clinicians for which the work of MIPS reporting outweighs the number of Medicare beneficiaries impacted.

Quality Performance Category

CMS proposes the reduction of the Quality Performance Category to 40 percent in 2020, 35 percent in 2021, and 30 percent in 2022. For performance year 2022, CMS proposes to remove 55 measures due to minimal adoption, duplication, and "topped out" status. The proposal also looks to add seven new specialty sets that address the eligible clinician groups that were added in CY 2019 final rule, changes 78 measures and adds four new measures addressing functional status, immunization status and pain management.

CMS is also proposing to establish a guideline to remove quality measures which do not meet the case minimum and reporting volume required for benchmarking after two consecutive years in the MIPS program. For 2020, CMS will continue to allow eligible clinicians and groups to submit a single measure via multiple collection types (e.g., MIPS CQMs, eCQM, QCDR measures and Medicare Part B claims measures). CMS may also consider a MIPS quality measure for removal if they determine it is not available for MIPS Quality reporting by or on behalf of all MIPS eligible clinicians (including via third party intermediaries).

As stated in previous comment letters, the College continues to oppose the removal of topped out measures from the QPP and asks CMS to exercise caution when eliminating measures. While there is good intention in reducing administrative burden by reducing the number of quality measures a physician must report under the Quality category, the removal could be completed in a phased approach. A phased or delayed approach would provide more time to measure stewards to provide input on the value of measures, and also provide clinicians with time to determine whether or not to continue reporting the measures. Drastic reduction goes against the goal to implement more outcome measures and also reduces the level of flexibility that clinicians are offered by limiting their selection to less clinically relevant measures to report. **The ACC encourages CMS to work with measure stewards to determine if removal is appropriate.**

Measure Updates

The College agrees with the CMS' proposal to allow for flat-percentage benchmarking for MIPS #236 (NQF #0018), Controlling High Blood Pressure, in order to avoid inappropriate

treatment. A one-size-fits-all blood pressure (BP) goal of < 140/90 mm Hg may erroneously suggest to patients and their healthcare providers that their treatment is adequate if they reach this goal. Providers should be able to apply individual judgement to exclude patients for whom more intensive BP lowering is contraindicated or not achievable for other valid reasons (e.g., patients who are unable to tolerate intensive BP lowering, patient refusal, etc.). The College also advises continued adherence to established guidelines for any measures related to blood pressure control.

In this proposal, CMS is also adding the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions (MCC) measure to the Quality performance category, beginning with the 2021 MIPS performance period. **The College has concerns with measure attribution at the individual level, as many unplanned readmissions are outside of the individual clinician's control. Should CMS move forward with implementation in 2021, the Agency must ensure that this measure is adequately risk-adjusted and reviewed under the Measures Under Consideration process through the Measures Application Partnership (MAP)** that is typically applied for all MIPS quality measures. The developers may want to consider raising the case minimum to ensure higher reliability of the measure. Attribution should be at the TIN level, with the requisite sample size for statistical reliability. Social determinants of health need to be factored in the calculation (such as transportation access, ability to afford medications, etc.).

Cost Performance Category

CMS proposes to increase the weight of the Cost performance category to 20 percent in 2020, 25 percent in 2021, and 30 percent in 2022. Thus, the Quality performance category would make up 40 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year. The goal of these changes is to align Quality and Cost performance categories to create better value and to gradually work toward equal weighting, which is required by statute. CMS is also proposing to add 10 new episode-based measures and revise the Medicare Spending Per Beneficiary Clinician measure and the Total Per Capita Cost measure.

As the Cost category continues to increase under MIPS, CMS must ensure that clinicians are fairly measured. **The ACC continues to have concerns with use of the claims-based Total Per Capita Cost and Medicare Spend Per Beneficiary measures, as they may hold clinicians attributable for services outside of their control.** While the College appreciates efforts to revise these measures, additional work is needed to improve attribution methodologies used not only in the MIPS Cost category, but across all CMS programs.

The College supports the development of further episode-based group measures as a way to better assess clinician resource utilization. The ACC encourages CMS to continue the process of developing these measures with clinician engagement. However, the College reminds CMS that not all procedures and conditions will align under an episode-based measure model. Chronic conditions that involve multiple clinicians and variation among patients will be difficult to measure fairly at both the group and individual level**. The ACC recommends that CMS focus efforts on continuing to refine this category.** As part of this effort, clinicians must be given

transparent access to their own Cost performance data so they can review it, understand it, and better communicate any discrepancies back to the Agency.

Total Per Capita Cost Measure

We appreciate CMS' efforts to refine the Total Per Capita Cost (TPCC) measure, including the revised primary care attribution methodology, risk adjustment methodology, service and specialty category exclusions for clinicians that perform non-primary care services, and evaluating beneficiary cost every month rather than on an annual basis. Cardiology as a specialty will be included as a candidate for the measure, as these specialists are likely to be responsible for providing primary care to a beneficiary and frequently manage patients with chronic conditions. However, attribution will remain an issue for cardiology as well as other specialties. In addition, double-counting remains a potential issue when physicians are measured on episode-based cost measures, as well as the MSPB measure.

Medicare Spending Per Beneficiary Measure

The College appreciates the proposed modifications to attribution for the MSPB measure, specifically the distinction between medical and surgical episodes. **However, we remain concerned over issues of attribution and double-counting. CMS should consider a consolidation of the MSPB and TPCC measures, as there is potential for overlap.**

Improvement Activities Performance Category

CMS is maintaining the basic requirement of the Improvement Activities category; however, CMS is proposing to change the reporting requirements for group or virtual group reporters. In the past, groups could report an Improvement Activity as long as one member of the practice had completed the Improvement Activity. Starting next year, however, CMS is proposing to increase the requirement to a minimum of 50 percent of the group within the same 90-day period. CMS is also proposing the addition of two new Improvement Activities for the 2020 MIPS performance year. The Agency also plans to modify seven existing Improvement Activities and remove 15 other Improvement Activities. **While the College understands the need to increase the threshold, the College is concerned and believes 50 percent may not be the correct threshold.** For example, in a multispecialty group, cardiologists may not make up 50 percent of the NPIs under the same TIN. This may be the case for other specialists as well. This increased threshold disincentivizes specialties from picking Improvement Activities which are relevant to them. The College urges CMS to reassess this reporting requirement.

Promoting Interoperability Performance Category

CMS and ONC have continued to focus on methods for reducing administrative burdens directly related to reporting Promoting Interoperability and other programs. Additionally, proposed CMS and ONC Interoperability, Information Blocking, and Patient Access rules put forth a framework that would advance Certified Electronic Health Record Technology (CEHRT) requirements towards the realization of true interoperability. The ACC thanks CMS and ONC for their efforts to reduce administrative burdens and improve interoperability encourages continued work to

align reporting requirements across care settings, eliminating redundancies and streamlining objectives and measures. The ACC also believes CMS should continue to refine the Promoting Interoperability program and focus 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.

CMS proposes retaining the continuous 90-day period within the calendar year that occurs two years prior to the applicable MIPS payment year, up to and including the full calendar year (CY 2021). **The ACC thanks CMS for continuing the 90-day reporting period and encourages CMS to further align the Promoting Interoperability programs for the Medicare and Medicaid programs through common measures and reporting periods.** By providing continued program stability, CMS allows EPs to focus on caring for patients and improving interoperability rather than prescriptive reporting requirements.

Qualified Clinical Data Registries (QCDRs)

CMS is proposing to strengthen the QCDR measure standards for MIPS to require measure testing, harmonization, and clinician feedback to improve the quality of QCDR measures available for clinician reporting. These policies relate to CY 2020 and CY 2021 for QCDRs. CMS plans to grant QCDR measures that are potentially duplicative with another measure one year of conditional approval. The measures will be removed if they cannot be harmonized within that period. **The College has concerns regarding harmonization requirements. QCDRs were originally created such that they would have the ability to report their own individual measures. However, the harmonization requirements eliminate the ability for QCDRs to do so. The College asks CMS provide all impacted clinicians with more transparency regarding the process on how harmonization will be conducted, in addition to additional time for harmonization of measures. While the ACC understands CMS' need to generate a larger denominator, achieving harmonization is difficult.** There are instances when measures could have different data sources and/or timeframes. When attempting harmonization, there is question regarding who will own the changes and carry them out, as well as who the steward of the measure will be**. The College understands the need to obtain a better comparison of data across multiple registries, but believes harmonization places undue burden to reporting clinicians and eliminates the flexibility that had been originally built into QCDR measure reporting.**

Further, beginning in the 2021 performance period, CMS is requiring QCDRs include information on how participants compare to other clinicians within the registry or QCDR cohort who submitted data on the same measures. In addition, QCDRs will have to license their measures to other QCDRs and have measure testing completed at the time they submit their application to CMS. **The College is concerned about this requirement, as the testing process can be significantly arduous**. **The College believes requiring that measure testing be completed at the time of the application submission is unrealistic and requests additional time be granted for QCDRs to comply with such a requirement.** One measure may take at least a year to develop, which requires considerable input and work from both physicians and society staff. Testing also takes additional time and can be very expensive. If outside parties are able to use the developed measures, specialty societies may no longer be able to dedicate

resources to QCDR measure development and some may eventually opt to not participate in the QCDR program.

Public Reporting on Physician Compare

CMS proposes to publicly report Physician Compare aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2. The **College supports public reporting of physician data when it is accurate and meaningful to clinicians and patients. The College supports first gaining experience with the MIPS data prior to publicly reporting it in aggregate,** as the Physician Compare data was not previously publicly reported under legacy programs. By beginning reporting in Year 2, CMS allows clinicians to first obtain feedback on past performance and provides more time to evaluate meaningful trends over time.

MIPS APMs

Application of Partial QP Status

Partial QP status is currently applied at the NPI level across all TIN/NPI combinations that a clinician may have. Under this policy, a clinician may be a Partial QP under one TIN may be excluded from participating in MIPS across all TIN/NPI combinations, regardless of whether the clinician is eligible to receive an incentive under one or more of those TINs. CMS is proposing that beginning in 2020, partial QP status would only apply to the TIN/NPI combinations through which an eligible clinician attains QP status. Therefore, any MIPS election for a partial QP would only apply to the TIN/NPI combination.

Currently, the election to be excluded from MIPS is not under the control of the individual clinician at the APM Entity. In this case, the eligible clinician could have reported to MIPS as a part of a group or as an individual under a separate TIN/NPI combination but would not have received any MIPS payment adjustment based on that reporting. **The ACC supports the Agency's decision to limit Partial QP status only to the TIN/NPI combination through which Partial QP status is reached, allowing clinicians to participate in MIPS under any remaining TIN/NPI combinations where they are MIPS-eligible.**

In implementing this proposal, CMS should ensure that clinicians are provided with clear and timely information as to which TIN/NPIs they are practicing under, and under which of those combinations they are exempt from MIPS as a Partial QP or are MIPS-eligible. CMS should monitor implementation to ensure that this well-intended proposal does not result in greater confusion and administrative burden.

Medicare Shared Savings Program under MIPS

The ACC cautiously supports the proposal to replace the Medicare Shared Savings Program (MSSP) quality performance score with the MIPS quality score for ACOs in MSSP tracks that do not qualify as Advanced APMs. Currently, the MIPS quality score is based on measures reported by the ACO via the CMS Web Interface and CAHPS for ACO survey for participants in MSSP tracks that do not meet the definition of an Advanced APM

(Track 1, BASIC Levels A, B, C, D). Utilizing the MIPS quality performance score for both the ACO performance and MIPS APM performance could lessen confusion and eliminate the burden of tracking two quality scores across two different programs. **However, CMS should monitor any unintended consequences that may arise, especially as the MSSP program and QPP undergo annual updates that may disrupt this alignment.**

Allowing MIPS Eligible Clinicians Participating in MIPS APMs to Report on MIPS Quality Measures

The ACC supports the Agency's proposal to allow MIPS eligible clinicians to receive a score for the quality category through individual or group level reporting, based on the highest score submitted. The APM Entity would then be scored based on the average of the highest scores for each MIPS eligible clinician in the entity. This flexibility allows clinicians in select APMs the ability to select the preferred-clinically relevant measures that they would like to be scored against, rather than applying scores on the same group measures to all clinicians in the entity.

APM Quality Reporting Credit

CMS proposes that where APM quality data cannot be used for MIPS purposes, a minimum score of 50 percent should be applied under the MIPS Quality performance category for certain APM entities that are participating in MIPS. CMS is proposing that this score be referred to as an "APM Quality Reporting Credit." This proposal recognizes the equal or greater investment in quality through the APM.

This proposal is based on the belief that MIPS APMs require an equal or greater investment in quality which cannot be reflected in a MIPS quality performance category score. Currently, if a MIPS APM participant does not provide quality measure data through the model, their score is based on Promoting Interoperability (75 percent) and Improvement Activities (25 percent) and not on Quality. The ACC supports the proposal to allow certain APM entities to submit MIPS Quality data through MIPS when their APM quality data cannot be used. This proposal recognizes the importance of quality under a value-based payment program. CMS should provide clear notice on this credit to APM entities and their impacted clinicians so they can ensure the collection of quality measure data and work with their vendors to submit data to CMS.

APM Scoring Beyond 2020

The ACC strongly encourages CMS to engage stakeholders in ongoing discussion on MIPS APM scoring approaches for 2020 and beyond. As the QP threshold increases in future years, more clinicians are expected to fall under the MIPS program, especially if additional Advanced APM opportunities are not implemented.

While the College supports flexible scoring and incentives for MIPS APM participants, understanding the policies that apply to these participants remains highly complex. It has become difficult for clinicians in APMs to understand when bonus credit is applied, when MIPS performance category weights are adjusted, and differences in MIPS-eligible and MIPS-excluded status. Granted, some of this is attributable to the variety of APM tracks and the need to take the differences of each these programs into consideration. The College encourages CMS to

continue to seek ways to simplify policies for MIPS APMs so that clinicians can properly understand how to participate under this pathway.

As CMS has noted, the QP threshold will increase in future years, while the MIPS performance threshold will increase annually. Many clinicians who have invested in Advanced APM participation may be discouraged if they can no longer meet the QP threshold and are placed in MIPS, where currently, available incentives may not be significant enough to support further participation in the APM. CMS should ensure that policies provide clinicians with a stable path toward APM participation rather than a moving target.

In addition, CMS must also acknowledge that there are still clinicians who cannot participate in APMs for reasons such as lack of infrastructure, lack of patient volume, and lack of clinically relevant model. The MIPS pathway must be available to them as a way to engage in value-based payment. While MIPS APM participants should be incentivized, CMS should ensure that MIPS APM participants are not the only clinicians who are able to succeed under MIPS.

MIPS Value Pathways Request for Information

CMS is proposing a new way to simplify MIPS and integrate measures and activities that are meaningful to all clinicians (e.g., spanning specialists to primary care clinicians) by creating the MIPS Value Pathways (MVPs) framework to future proposals beginning in 2021 MIPS performance year. The MVP framework would remove APM participation barriers and reduce the number of performance measures and activities clinicians may select to decrease clinician burden and improve performance data quality. Ultimately, all MIPS eligible clinicians would have to participate through an MVP or MIPS APM. CMS presented the following guiding principles it will use to define MVPs:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
3. MVPs should include measures that encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

The ACC supports the need to capture meaningful data and agrees that there would be value in obtaining comparative data within and across specialties. The College understands that legacy programs (e.g., Meaningful Use, etc.) have not been successful in improving quality care, reducing costs, and producing efficient outcome processes. However, the ACC has some concerns with the CMS guidelines and timeline for MVPs and details concerns below.

Selection of Measures and Activities

CMS proposes to require that beginning with the 2020 Call for measures process, MIPS quality measure stewards link their MIPS quality measures to existing and related cost measures and improvement activities. Starting as soon as 2021, CMS envisions MVPs would utilize a *limited* set of measures and activities that incorporate a foundation of promoting interoperability and administrative claims-based population health measures with specialty/condition specific clinical quality measures to create uniformity and simplicity in measure reporting. **The College is supportive of the development of more meaningful measures and activities that truly capture increased quality patient care.** However, the College is concerned about the additional burden that would be imposed on clinicians, administrative clinical staff and society staff that participate in the creation of *new* measures in the current MIPS system. The proposed rule already drastically reduces the amount of available measures in the QPP program. The anticipated reduction of measures in the MVP could negatively impact participating clinicians even more so and could lead to less than ideal participation in MVPs over the next few years**. As such, the College recommends a gradual reduction of measures, as the MVP framework is finalized, and supports a simultaneous development of new measures that are specialty-, sub-specialty- and setting-specific.** Initiating a program as soon as 2021 is unrealistic and burdensome, given the amount of time and work that is necessary in the development of new measures.

CMS could commence by using the current set of measures in circulation. For example, the Agency would link clinicians with a facility site of service on their claims to that facility (e.g., inpatient or outpatient). In this manner, participating clinicians or groups would be evaluated on measures used in the hospital quality program (e.g., readmission rates, patient satisfaction, MSPB, etc.). By following this pattern, those clinicians who do not already participate in group reporting, would learn to identify as a group and work together to develop improvements to patient outcomes. Overtime, CMS would recognize trends and participation patterns to determine group requirements, such as size, and could also modify measures as necessary.

MVP Assignment

CMS proposes to assign clinicians to MVPs to reduce the administrative burden that could be associated to the wide selection of measures and reporting options already established in the MIPS program. **The ACC believes that MVP assignment should be voluntary and self-assigned, and clinicians should have the flexibility to participate in MIPS, MVPs, or APMs over the next few years.** Self-assignment would also allow multi-specialties to select one or more MVPs that are most relevant to the specialty mix within the group. The MIPS program has seen benefits to the "Pick Your Pace" approach. **Similarly, clinicians should have the option to move towards MVPs when they are adequately prepared (structurally, administratively or otherwise).** By offering a flexible approach to eligible clinicians, CMS is more likely to see a positive transition towards MVPs and gives the diverse House of Medicine time to adjust and adapt to a new environment.

Transition to MVPs

Clinicians have already invested considerable resources in preparation of and participation in the QPP and current Advanced APMs. As such, the College recommends a phased approach to the implementation of MVPs. The College believes a pilot period is necessary to help physicians and CMS understand the evolving reporting requirements and related necessary systemic changes. The ACC calls for pilot programs to test the validity of measures that will form the basis of MVPs. The pilot program could begin with a handful of specialties that report with the current set of available measures and activities. Test groups and individuals should be identified from various sites of services and should cut across all demographics, including small and rural practices. The MVP framework appears to implement a "one size fits all" approach, which is unrealistic. By implementing a pilot period, CMS will be able to gauge participation and reporting challenges or shortcomings. The College believes it is possible to develop or identify measures that could result in valuable comparative data comparing a few MVPs but believes that it may be challenging to identify measures that are comparable across *all* MVPs.

A phased approach would also provide third parties, like EHR vendors, the opportunity to update their systems to meet MVP requirements, develop, test and finalize the necessary capabilities into their systems. The ACC also believes CMS should clearly outline processes, scoring, and performance requirements before requiring clinician participation. A timeline for approving MVPs and new measures should also be clearly delineated prior to implementation. Once the processes, scoring, performance requirements, and MVP nomination process is more clearly defined, the ACC recommends CMS work with stakeholders through notice, rulemaking, and work groups to finalize the framework.

Small and Rural Practices Participation in MVPs

The College recommends facilitating small and rural practice participation in MVPs. Similar to accommodations made in MACRA implementation, the College recommends modified reporting requirements, exemptions, and potentially lower reporting thresholds. Technical support and training may also be beneficial to these practices. The College is concerned solo practitioners and practices, particularly small and rural, may feel forced to participate with large groups. To aid this transition, the ACC supports added attention to small practices for success in MVPs.

Population Health Measures in MVPs

The ACC acknowledges the Agency's interest in incorporating population health measures such as all-cause hospital readmissions into MVPs. These measures would be claims-based, which would reduce administrative burden for clinicians and allow CMS to provide claims-based performance data back to clinicians. In addition, these measures would align with current population health measures currently implemented in many APMs. **However, the College strongly urges CMS to use the MVPs as a pathway for maintaining clinical quality measures, such as those reported through QCDRs. CMS should not use population health measures alone, nor should these comprise the majority of the MVP score. As CMS attempts to create MVPs that increase clinician engagement, they must include quality measures that reflect patient populations specific to an MVP area.**

Incorporating QCDRs and QCDR Measures into MVPs

The ACC supports the development of QCDR MVPs. The ACC requests CMS consider the administrative and technical burden that is incurred in the development of MVPs. The ACC and other organizations already face challenges in obtaining performance data results in a timely manner, and the ACC believes omitting QCDR measures would be detrimental and negate all the work that has already been invested in the development of these measures.

Scoring MVP Performance

The College believes that scoring MVP performance should also follow a phased approach, much like MIPS. As clinicians become more comfortable with MVPs, the size of penalties and rewards could increase over time. In the proposal, CMS notes that they will ensure equity in MVPs so that clinicians are not advantaged in reporting in one MVP or another. In the same vein, the **College recommends CMS use caution in developing scoring such that the maximum amount does not encourage clinicians to stay in an MVP rather than progress to an Advanced APM.**

An MVP could cap the negative payment adjustment, as well as the total payment increase. In this manner, the MVP program could remain budget neutral, as the rest of the Medicare Physician Fee Schedule was designed to be.

Promoting Interoperability Component of MVPs

Since the creation of the Promoting Interoperability component of MIPS, the ACC has called on the Agency to work with clinicians to develop activities that truly promote and measure interoperability. The recently proposed CMS and Office of the National Coordinator for Health Information Technology (ONC) Interoperability, Information Blocking, and Patient Access rules put forth a framework that would advance Certified Electronic Health Record Technology (CEHRT) requirements towards the realization of true interoperability. However, there is still progress to be made. The ACC thanks CMS for acknowledging the need for continued progress to promote the use of health information technology (IT) and interoperability and the **ACC encourages CMS to use both the PI program and MVP programs to promote the appropriate, purposeful and accurate use of health IT solutions, rather than mandate completion of tasks**.

Currently, there are objectives and measures that aim to appropriately promote interoperability such as the "Provide Patients Electronic Access to their Health Information" and "Support Electronic Referral Loops By Receiving and Incorporating Health Information." However, as CEHRT requirements evolve in future years under the new rules, **CMS should also use PI objectives and measures to focus on 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.** For example, CMS could develop and deploy PI measures and Improvement Activities as part of the MVP program that aim to improve EHR safety through incentives to improve EHR training and workflow. CMS could also work with ONC to develop methods and incentives for EPs to provide real world, user-reported

feedback on CEHRT systems. Usability and interoperability will only improve when clinicians can provide feedback to ONC and Health IT vendors that will directly contribute to the certification and maintenance of an EHR system and the MVP program affords the incentives and flexibility to directly impact CEHRT usability and safety.

Advanced Alternative Payment Models (Advanced APMs)

The ACC acknowledges CMS' interest in moving towards Advanced APMs that encourage clinicians to coordinate care for a population under a two-sided risk model. As CMS moves toward this goal, the College strongly recommends that CMS continue to view the movement as a glide path toward value that should not be marked with sudden policy changes that disrupt practice stability and the delivery of care.

CMS should continue to develop Advanced APMs that provide opportunities that support the meaningful engagement of specialty clinicians. The College is pleased with the efforts to implement specialty-focused Advanced APMs, such as Bundled Payments for Care Improvement Advanced (BPCI Advanced), and ongoing work to incorporate recommendations from the Physician-Focused Payment Model Technical Advisory Committee (PTAC) into recent models. As CMS develops additional Advanced APMS, the Agency must engage the clinician community in the implementation of clinically-relevant performance metrics that truly support the quality of patient care. Without a focus on quality, a two-sided risk model cannot fully achieve the goal of value.

In addition, the ACC reiterates the request that CMS work with Congress to reduce the payment and patient thresholds for the Qualified Provider (QP) determination. As these thresholds increase, they will become increasingly difficult to meet. CMS acknowledges this trend in the proposed rule and predicts that in future years, some QPs may revert to being MIPS-eligible clinicians. These thresholds are set in statute and a revision would require an act by Congress; however, the ACC encourages CMS to determine whether the current laws governing the QP threshold pose a barrier to policies that support greater participation in Advanced APMs.

Amending the Definition of "Expected Expenditures"

The ACC supports the Agency's effort to revise definitions under the Advanced APM pathway based on current experiences with the models. **In particular, the College supports revising the definition of "expected expenditures" to "the beneficiary expenditures for which an APM Entity is responsible under an APM" and recognizing the target episode price as "expected expenditures" under any episode payment model.** The ACC agrees that amending the definition of "expected expenditures" will provide more clarity in assessing levels of financial risk for participants.

RFI on a Metric to Improve Efficiency of Providers within EHRs

The College appreciates the Agency's continued interest in improving EHR usability, including improving efficiency of providers within EHRs. As CMS evaluates methods for improving EHR

efficiency, it is important that CMS not increase the burdens placed on providers through additional reporting requirements. Clinicians have actively sought to work with health IT vendors to improve EHR efficiency through increased usability. However, many providers resort to custom modifications after an EHR system is installed to improve efficiency and usability.

In comments previously submitted to ONC, the ACC recommended ONC account for usability and user-centered design criteria in the certification process, including the capture of user-reported criteria on usability, user-centered design, and EHR system interoperability. Including user-reported data in the EHR certification and maintenance process will assist in shifting user-centered design to the focus of the EHR design and implementation process. Specific human-computer interface evaluations methods include but are not limited to heuristic techniques, keystroke level models that sum up the time taken to perform tasks in a system, and comparative analysis between similarly commercially available systems.

Additionally, several user-reported criteria that ONC should consider for inclusion in the EHR certification and maintenance process and published comparison reports including Work-after-work (WOW) time per provider (time spent on an EHR following conclusion of the work day); Measurements of time spent logged into an EHR versus the number of patients seen; Ease of displaying user-defined report formats; and Total time extracting and manipulating health information transferred from external data source. Increasing the availability of this data, those measured by ONC and those reported by end users, to clinicians and health IT decision makers would greatly expand the number of variables to be factored into the EHR procurement process and enable group practices and healthcare systems to make better informed decisions. In turn, EHR vendors would be forced to consider the needs of the end-user when developing EHRs, leading to improved products, decreased frustration and burden for clinicians and patients, and increased time for discussions between clinicians and patient. **The ACC supports the implementation of specific usability and user-centered design criteria into the EHR certification process as one specific method for increasing health IT usability.**

RFI on the Provider to Patient Exchange Objective

In the proposed rule, CMS seeks comment on whether MIPS eligible clinicians should make patient health information available immediately through an open, standards-based API, no later than one business day after it is available to the MIPS eligible clinicians in their CEHRT. Current technological capabilities, privacy concerns, workflow, and administrative staffing often do not allow for same-day responses. **Until technology that allows for safe, secure, automated information extraction is widely available and no longer cost-prohibitive, ONC should not place undue administrative burdens on clinicians, their clinical staff, or other entities by requiring infeasible timelines.** While the ACC is sympathetic to patient's rights to access their health information, by placing artificial time constraints on clinicians to make patient health information available, CMS risks patients receiving sensitive health information before their provider can discuss and explain the results. While some basic results may be available sooner and patients could responsibly receive the information without explanation, CMS should allow for exceptions and build in necessary nuances to ensure patients and providers can decide which information could be delivered electronically in a shared decision-making process. Finally, CMS

should allow providers to develop clear policies that provide specific, feasible timelines for responses that allow patients to know when they should expect a response.

In addition to forcing providers and their staff to make patient health information available before it may be ready, it is important for CMS to align the provider to patient exchange objective and patient request requirements under the proposed ONC Information Blocking and Interoperability proposed rules. Under the proposed rule, ONC states actors are required to respond to requests in a timely manner. While the proposed rule does say information blocking may be invoked if a health care provider has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient's health care provider, but takes several days to respond, this requirement has not been finalized, and if it was, would be burdensome. Instead, CMS and ONC should coordinate efforts, allow clinicians and patients to determine a feasible and safe timeline for information exchange that affords clinicians and their staff sufficient time to ensure information is correct and provided to a patient in a responsible and ethical manner.

Under the request for information, CMS seeks comment on developing a possible bonus under the Promoting Interoperability performance category for early adoption of a certified FHIR-based API in the intermediate time as well as creating an alternative measure under the Provider to Patient Exchange objective that would require clinicians to use technology certified to the EHI criterion to provide the patient(s) their complete electronic health data contained within an EHR. The ACC has long called on CMS to focus the PI program on a limited handful of high value initiatives that aim to promote true interoperability, 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. By developing bonus or alternative measures that seek to encourage the adoption of FHIR-based APIs or use technology certified to the EHI criterion, CMS would encourage providers to adopt technology that gets us the goal of true interoperability. **However, because the technology and policies requiring these capabilities are still in their infancy, it is important CMS make any potential measures and objectives optional only.** By providing incentives for providers to adopt updated technology early, CMS can avoid the pitfalls of the Meaningful Use Stages 1 and 2, and instead foster good will without increasing costs or burdens on providers and their staff.

Finally, CMS seeks comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy. While the ACC is supportive of efforts to remove prohibitions from using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual, **CMS and ONC should continue to work to adopt methods that provide patient matching solutions through technological innovation and collaboration with external stakeholders.** As a recent report from the Government Accountability Office (GAO) indicates[1], stakeholders across the country are developing patient matching applications that utilize algorithms to patch records across care settings and organizations. While these applications show promise, it is important that ONC and CMS work with standards development organizations (SDOs) and health IT vendors to ensure these programs operate with a very high degree of certainty before

[1] GAO, *Heath Information Technology: Approaches and Challenges to Electronically Matching Patients' Records Across Providers*, January 2019. https://www.gao.gov/assets/700/696426.pdf

they are deployed into the care setting. ONC and CMS should work with SDOs and health IT vendors to set an ambitious, yet attainable match rate for all patient matching algorithms to ensure patients are not exposed to undue harm caused in part by matching errors.
In addition to this needed high degree of certainty, it is vital that SDOs and health IT vendors develop patient matching applications in an open and accessible process. Much like the development of health IT standards put forth in these proposed rules, transparency will provide all stakeholders both the ability to provide input in the developmental stages to ensure unique use-cases are properly considered as well as the needed confidence in both the process and the product created. A transparent and open process led by SDOs and health IT vendors will also ensure technological advances are incorporated into patient matching solutions. For example, as biometric authenticators continue to advance at a rapid pace and are widely accepted across industries, SDOs and vendors should account for the proliferation of this technology.
Patient matching solutions will only serve their intended purpose and successfully protect patients from unintended harm if they are trusted by the vendors, health systems and clinicians who install and utilize them. As ONC and CMS continue to work on patient matching solutions, the ACC encourages a transparent process which incorporates stakeholder feedback throughout development and deployment.

RFI on Integration of Patient-Generated Health Data into EHRs Using CEHRT

The continued creation of additional methods for generating and transmitting patient-generated health data (PGHD) promises to allow patients and providers alike the ability to monitor their health in real-world settings and provide a more complete picture of a patient's health. While patient-generated health data can help provide a more complete picture of a patient's health and generate additional insights, it is important that this data provide useful data in a standardized format. The addition of patient-generated health data in a non-standardized format will contribute to clinical record note bloat and make it harder to providers to find useful clinical information in the EHR. **The College encourages CMS to consider methods to promote technical solutions or approaches for capturing patient-generated health data and incorporating it into CEHRT using standards-based approaches. This includes bonus points for health care providers or incentives under the Promoting Interoperability program for health IT vendors developing devices that generate and transmit patient-generated health data.**

Finally, in the same way CMS began paying for virtual check-ins and remote evaluation of patient images/video in CY 2019 rulemaking, CMS must also be forward-thinking as it considers how best to compensate systems clinicians for the increased time and complexity of incorporating PGHD into patient care. Too often these tools are viewed as indirect infrastructure costs, when in fact they require direct expenses that can be attributed to an individual patient encounter or time period.

RFI on Engaging in Activities that Promote the Safety of the EHR

The College is encouraged by CMS' continued interest in promoting activities that promote the safety of the EHR and supports efforts to reduce medical errors directly or indirectly attributable to EHRs. The College believes incentivizing health IT vendors, hospitals, and providers to

promote activities that help to reduce errors, such as more in-depth EHR training or standardized implementation guides, is one way to make drastic improvements in EHR safety. As previously mentioned, CMS could develop and deploy PI measures and Improvement Activities as part of the MVP program that aim to improve EHR safety through incentives to improve EHR training and workflow. CMS could also work with ONC to develop methods and incentives for EPs to provide real world, user-reported feedback on CEHRT systems. Usability and interoperability will only improve when clinicians can provide feedback to ONC and Health IT vendors that will directly contribute to the certification and maintenance of an EHR system and the MVP program affords the incentives and flexibility to directly impact CEHRT usability and safety.

CMS could also work with ONC to use the Conditions and Maintenance of Certification components of the Promoting Interoperability program as additional policy levers to increase EHR safety through improved usability and user-centered design. The inclusion of **functionality-based criteria such as usability and user-centered design into the Promoting Interoperability Conditions and Maintenance of Certification process would have a positive direct impact on the real-world applications of health IT systems and improve EHR safety.** Numerous studies, including research published by the MedStar Health's National Center for Human Factors in Healthcare, have shown medical errors and patient harm is directly attributable to poorly designed EHR systems. Including user-reported data in the EHR certification and maintenance process will assist in shifting user-centered design to the focus of the EHR design and implementation process. Factoring these components into the initial design will assist in keeping the total cost of ownership for EHR systems down, enabling practices and health systems to more accurately plan for the resources required for EHR system purchase, installation, training and maintenance.

When undergoing real-world testing in clinical settings, it is also important for HHS to consider the inclusion of user-reported criteria. Practitioners can provide unique insights into the real-world applications of EHR and health IT systems and ONC should incorporate this input into the certification process. The inclusion of user-reported data into the real-world testing and certification process for health IT promises to provide additional pressure for continued progress in addressing the concerns of the clinical community. **Usability and interoperability will only improve when clinicians can provide feedback to ONC and Health IT Vendors that will directly contribute to the certification and maintenance of an EHR system.**

Finally, it is important that HHS and developers are transparent regarding real-world testing performed on certified health IT systems. Making real-world testing data available will provide needed context to ensure health IT acquisition personnel make informed decisions when upgrading or purchasing a new system. **ONC should incorporate real-world testing data into any EHR comparison reports and should emphasize development of a marketing strategy and educational resources to increase awareness of and access to such important comparison tools.** Development of interactive online and application-based resources that allow for side-by-side comparisons and real-time user input and reviews would provide much-needed accessibility and context to the decision-making process.

Conclusion

The ACC appreciates the opportunity to comment on the CMS notice of proposed rulemaking regarding the CY 2020 Medicare Physician Fee Schedule. The ACC looks forward to collaborating with CMS to further develop meaningful approaches and pathways to promote a healthy physician environment and quality patient care. The ACC urges CMS to consider the recommendations detailed in this letter. Should you or your staff require additional information or clarifications, please contact Claudia Vasquez, Associate Director of Medicare Payment & Quality Policy, at cvasquez@acc.org.

Sincerely,

Richard Kovacs, MD, FACC
President