



October 2, 2020

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Re: Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy [CMS-1734-P]

Dear Administrator Verma:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) notice of proposed rulemaking regarding changes to the Medicare Physician Fee Schedule (PFS), Quality Payment Program (QPP), and other federal programs for Calendar Year (CY) 2020 and beyond. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 163,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

We have summarized a subset of recommendations at the onset of this letter that reflect our top priority areas. Detailed explanations for each of these recommendations, along with a broader set of recommendations, are included in the main text of the letter. We are confident that these recommended changes would improve the strength of these proposals and help to promote access to affordable care for Medicare patients, while supporting physicians in their ability to deliver innovative care and protecting the integrity of the Medicare trust funds. We appreciate this opportunity to offer our feedback and look forward to continuing to work with the Agency to implement policies that support and improve the practice of internal medicine.

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**I. Summary of Top Priority Recommendations:**

**A. Payment and Documentation Proposals for Outpatient Evaluation and Management (E/M) Services**

- i. The American College of Physicians (ACP) strongly supports CMS' decision to move forward with changes finalized last year to ensure that Medicare payments to physicians better recognize the value of cognitive services in providing quality care to patients. ACP strongly recommends that CMS use its administrative authority to waive budget neutrality for the 2021 Medicare Fee Schedule RVU increases, provided that this would not result in a delay or in any way undermine CMS' decision to fully implement the E/M increases and other improvements on Jan. 1, 2021.

**B. Psychiatric Collaborative Care Model (CoCM) Services**

- i. We strongly encourage CMS to finalize this new G code, which will provide an important new resource for patients and their care teams.

**C. Proposed Add-On Code GPC1X**

- i. The College supports CMS' decision to establish the GPC1X add-on code, and we agree that the current GPC1X code descriptor fits its intended purpose and is well-defined. We support small changes to the GPC1X code descriptor, including ensuring the add-on code is available to both new and established patients.
- ii. We strongly recommend that no more than 23 percent of estimated claims should be the appropriate utilization estimate for the GPC1X add-on code.

**D. Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic**

- i. ACP strongly recommends that CMS finalize these values as proposed.
- ii. ACP encourages CMS to adopt the CPT revisions for the prolonged services codes exactly as recommended. The proposal under consideration by CMS has the potential to undercut efforts already underway to educate physicians about the changes to these codes.

**E. Telehealth**

- i. The College strongly encourages CMS to consider extending several policies promulgated during the COVID-19 Public Health Emergency (PHE) in order to address the many barriers to patient access and physician adoption and use of telehealth prior to the COVID-19 pandemic, and properly assess how to foster and strengthen longitudinal, patient-centered care delivery.
- ii. ACP recommends that CMS permanently extend the policy to waive geographical and originating-site restrictions after the conclusion of the PHE.
- iii. ACP supports CMS' proposal to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. In considering the factors proposed, however, the College urges CMS to remove the requirement for the use of two-way, audio/video telecommunications technology so that telephone E/M can continue to be provided to Medicare beneficiaries.
- iv. The College continues to recommend that following the end of the PHE, CMS should continue to provide flexibility in the Medicare and Medicaid programs for physician practices to reduce or waive cost-sharing requirements for telehealth services, while also making up the difference between these waived copays and the Medicare allowed amount of the service.
- v. The College continues to recommend CMS' interim policy allowing physicians to provide telehealth services across state lines, as long as specific licensure requirements and conditions are met, be extended through at least the end of 2021, with the option to extend even further.

- vi. The College strongly recommends that CMS maintain pay parity between telephone E/M claims and in-person E/M visits and between all telehealth and in-person visits even after the PHE is lifted.
- vii. The College recommends that CMS work to expand coding options for telephone E/M services through the use of G-codes or by working with the CPT Editorial Panel.
- viii. ACP continues to recommend that CMS establish clear guidelines around billing for telephone E/M claims.
- ix. ACP strongly encourages CMS to remove the requirement that telephone E/M visits not originate from a related in-person E/M visit within the past seven days or lead to an E/M visit/procedure within the next 24 hours.
- x. The College is pleased to see CMS respond to the needs of physicians by extending the flexibility to continue to provide direct supervision via interactive audio/video technology through the end of 2021. We strongly urge CMS to finalize this proposal with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these supervision flexibilities.

**F. Care Management**

- i. ACP encourages CMS to finalize the proposed changes to the remote physiologic monitoring and transitional care management services, including making permanent the policy to allow consent to be obtained at the time RPM services are furnished; allowing auxiliary personnel to furnish CPT codes 99453 and 99454 under a physician’s supervision; and allowing practitioners to furnish RPM services to patients with acute as well as chronic conditions.
- ii. The College strongly encourages CMS to extend its policy to allow RPM services to be furnished to patients without an established relationship on a permanent basis at least through the end of 2021, with the option to extend it even further or consider making permanent.

**G. Scope of Practice**

- i. We continue to encourage CMS to maintain the primary care exception modifications for a period of time after the PHE ends and until supervising physicians feel comfortable they are able to control the spread of infection rates.

**H. Immunization Administration**

- i. We strongly support the proposal from CMS to increase the valuation for vaccine administration codes, and we urge the Agency to finalize it.

**I. Changes to Policies re: Opioid Use Disorder (OUD)**

- i. ACP encourages CMS to work with medical societies and through the CPT Editorial Panel process to examine the different resource costs involved with treating different substance use disorders and determine the need for more stratified coding. In the meantime, CMS should finalize the proposal to ensure that more patients have access to these critical services.
- ii. The proposal to establish coding and payment for treatment of OUD in the emergency room with medication is a positive step, and we encourage CMS to finalize it.
- iii. ACP supports the inclusion of naloxone in the definition of medications to treat OUD, as well as payment for opioid overdose education. If adopted, this proposal will add additional tools for patients and their care teams to assist them on their journey to recovery. We encourage CMS to move forward with these proposals.

**J. Payment for Principal Care Management (PCM) Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)**

- i. While ACP supports allowing RHCs/FQHCs to provide these services, the College encourages CMS to examine and provide additional information about the estimated impact of these changes.

**K. Electronic Prescribing of Controlled Substances**

- i. ACP is supportive of the intent to facilitate efficiency, convenience, and better security. We encourage CMS to help achieve those goals by avoiding unreasonable burden imposed upon clinicians and delay compliance until at least January 1, 2023.

**L. Updates to CEHRT due to the 21<sup>st</sup> Century Cures Final Rule**

- i. ACP urges CMS to consider the fact that clinician groups, and hospital groups that clinicians belong to, will not be in a stable enough financial situation to implement and comply with the updates to CEHRT by 2022.

**M. Quality Payment Program**

- i. ACP encourages CMS to retain the *Query of Prescription Drug Monitoring Program* measure as an optional measure for CY2021 and is supportive of the proposal to increase its worth from five bonus points to 10 bonus points. We request the Agency focus on how information found within PDMPs can be easily and seamlessly integrated into health IT systems to avoid clinician burden.
- ii. The College encourages CMS to disincentivize participation in individual HIEs and rather incentivize the ability for information to flow across HIEs. Should the measure be finalized, ACP encourages CMS to be more inclusive by expanding the measure to include “HIEs, *exchange frameworks, or other organizations focused on bi-directional health information exchange*” since participation in a single HIE might not meet the need of the measure to support HIE for “every patient encounter, transition or referral.”
- iii. ACP supports CMS’ focus on interoperability and patient access to data, as well as its intention to give clinicians a greater flexibility while reducing their burdens. The College believes, absent a national, effective HIE infrastructure, that it would be wasteful and only result in greater clinician burden to propose an alternative HIE bi-directional exchange measure. In the event that CMS finalizes the proposed addition, ACP would recommend the measure permanently remain optional.

**N. MIPS Value Pathway (MVP)**

- i. ACP appreciates CMS acknowledging the need for a gradual transition, as ACP [previously suggested](#). As one of a handful of organizations to submit MVPs for 2021, ACP looks forward to continue engaging with CMS toward readying ACP’s own preventive care and chronic disease management [MVPs](#), and MVPs in general, for successful implementation. To this end, ACP calls on CMS to develop more focused cost measures, reimagine the Promoting Interoperability Category, have transparent, rigorous standards for performance metrics, and continue stakeholder engagement throughout development and implementation.

**O. MIPS**

- i. **COVID-19 Flexibilities and Performance Thresholds:** ACP appreciates the flexibilities proposed in this rule, but believes strongly that these alone are not enough. The College calls on CMS to finalize broad MIPS extreme and uncontrollable circumstances exceptions for the 2021 performance year, as it did for 2019 and 2020. To minimize burden, these exceptions should be automatic and prioritize the highest score. At a minimum, CMS should not increase the MIPS performance threshold; ACP recommends a 30-point threshold so clinicians that received hardship exemptions for 2019 and 2020 will not face a steep cliff.
- ii. **MIPS Quality Measure Inventory Changes:** ACP appreciates CMS’ efforts to improve the accuracy of performance measurement, including removing quality measures ACP [identified](#) as invalid.

However, the College believes additional clarity around what qualifies as a “substantive” change and further categorization beyond the “minor” versus “substantive” designation may help to more appropriately distinguish varying degrees of measure changes that could result in more scorable measures. ACP does not support the initial all-cause readmissions measure in its proposed form, particularly at the individual clinician level.

- iii. **Delay of Registry Vendor Requirements:** ACP strongly supports CMS’ delay of testing and data collection requirements, which ACP [previously raised](#) concerns as being extremely burdensome. We urge CMS to consider extending these requirements further, as it could add burden for physician practices to collect and submit data as they deal with the COVID-19 PHE. ACP strongly supports CMS’ proposal for a more gradual implementation for the testing requirement and asks CMS consider applying a similar approach to the data collection requirement as well.
- iv. **Cost Category:** ACP does not support any increases to the weight of the Cost Category until concerns about the validity and accuracy of existing cost measures are resolved. These include attributing costs at the group practice level or higher only, not attributing the same costs to multiple clinicians/groups, risk adjusting for social determinants of health, publishing detailed testing results, and holding all measures to strict standards for reliability, statistical significance, actionability, and impact on health outcomes. ACP supports counting telehealth toward existing cost measures, provided necessary changes are made to accommodate instances where the quality action cannot be completed during the telehealth and add telehealth modifiers for eQMs.
- v. **Promoting Interoperability Category:** ACP supports the proposed changes, including finalizing a permanent 90-consecutive day minimum reporting period, retaining the *Query of Prescription Drug Monitoring Program* measure as optional and increasing it from five to ten points, and introducing *Health Information Exchange Bi-Directional Exchange* measure as a new, optional measure. We have several technical concerns with both measures that impede their ability to apply to real-world practice settings that we would recommend CMS address before considering making either mandatory in the future. We reiterate [past recommendations](#) to convert performance measures to yes/no attestations and introduce additional measures to encourage other innovative uses of CEHRT and Health Information Technology.

**P. APM Performance Pathway (APP)**

- i. ACP supports the goals of the new APP to promote consistency across the QPP and to offer clinicians flexible reporting options. However, we worry requiring all clinicians to report the same six quality measures regardless of APM may inadvertently increase administrative burden. ACP additionally has several technical concerns with the measures proposed for inclusion and does not support them as proposed.

**Q. Medicare Shared Savings Program (MSSP) Quality Reporting Changes**

- i. ACP supports the intent behind these proposals, but worries about possible unintended consequences and the short timeline for implementation. The College urges CMS to delay any proposed MSSP quality reporting changes until at least the 2022 performance year, including removing Web Interface as an available reporting option, aligning MSSP quality benchmarks with MIPS benchmarks, and making changes to minimum scoring standards. We also strongly oppose eliminating the pay-for-reporting phase-in period.

**R. Medicare Diabetes Prevention Program (MDPP)**

- i. We support CMS’ proposal to require that all suppliers be authorized to furnish services in-person even if they are doing so virtually to minimize patient disruption and strengthen the patient-supplier relationship.

- ii. ACP strongly supports the significant flexibilities that CMS has provided for MDPP suppliers during the COVID-19 PHE and future health crises, and we believe many of them, including offering services via telehealth, could help to expand patient access, particularly for those that face transportation or mobility issues, and improve the overall success of the program. **For this reason, the College urges CMS to consider making many of these proposed MDPP flexibilities available on a permanent basis.**

**S. Advanced Alternative Payment Models (APMs)**

- i. **COVID-19 Flexibilities for Advanced APMs:** ACP appreciates model-specific flexibilities CMS previously finalized for several APMs and supports proposals not to reconsider a model's status as an Advanced APM or revoke QP status from any ECs due to model changes made in direct response to COVID-19. However, the College feels strongly that more broad scale protections for Advanced APM participants are warranted, similar to those finalized for MIPS ECs. Specifically, all Advanced APM participants should be held harmless from financial losses or penalties for the 2019 and 2020 performance years. Additionally, 2019 and 2020 performance data should not adversely impact shared savings or other model payments.
- ii. **New Advanced APM Options:** CMS should introduce new Advanced APMs to meet the anticipated increased demand for FFS alternatives due to COVID-19, with an emphasis on models that would address outstanding needs, including specialty-focused and multi-payer models. ACP implores HHS to prioritize ACP's Medical Neighborhood Model for testing and welcomes any opportunity to help ready the model for testing or implementation.
- iii. **Qualified APM Participant (QP) Thresholds:** ACP urges the HHS Secretary to exercise this statutory authority over the patient count threshold to retain it at 35 percent and 25 percent for QPs and partial QPs respectively for an additional two years, through at least performance year 2022.
- iv. **Revised Methodology for Advanced APM Incentive Payments:** ACP opposes CMS' proposed new approach to identifying and prioritizing TINs for making Advanced APM incentive payments because it minimizes the clinical care team model and moves further away from actions completed during the performance year. Making incentive payments earlier in the payment year would help by lessening the window for NPI-TIN changes. The College also strongly objects to CMS' proposed 60-day cutoff for new help desk requests for incentive payments owed. Instead, we recommend the date Advanced APM payments for the subsequent year are announced.
- v. **New Targeted Review Request Process for QP Determinations:** ACP greatly appreciates CMS' proposal to establish a targeted review request process for QP determinations, something ACP advocated for in the past. However, the College is concerned the scope of this proposal is far too limited and should include instances where clinicians believe CMS may have made a calculation error that may impact their status as a partial QP or QP.
- vi. **Partial QP Determinations:** ACP favors a minimally burdensome approach in which CMS would apply either the MIPS performance threshold score, or the score a clinician, practice, or APM Entity would earn based on data submitted, whichever is higher.

## II. PFS Detailed Recommendations:

### A. **Payment and Documentation Proposals for Outpatient Evaluation and Management (E/M) Services**

**CMS Proposal:** In the 2020 MPFS final rule, CMS finalized acceptance of the E/M codes, CPT guidelines, and RVS Update Committee (RUC) recommended values as implemented by the CPT Editorial Panel and submitted by the RUC for the 2021 payment year. These coding changes retained the existing five levels of coding for established patients, reduced the number of levels to four for office/outpatient E/M visits for new patients, and revised the code definitions.

CMS also confirmed in the 2020 final rule the decision to allow medical decision-making (MDM) or time to decide the level of office/outpatient E/M visits, along with updated CPT documentation guidelines for both options.

In the 2021 proposed rule, CMS proposes to adopt the actual total times (defined as the sum of the pre-visit, intra-visit, and post-visit times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215 while moving forward with the valuation and documentation changes adopted during previous cycles. As CMS notes, “In developing its recommendations to us, the AMA RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time.”

**ACP Comments:** **The American College of Physicians strongly supports CMS’ decision to move forward with changes finalized last year to ensure that Medicare payments to physicians better recognize the value of cognitive services in providing quality care to patients.** These changes are especially important at a time when many primary care practices in particular are under severe financial stress due to the COVID-19 pandemic and are at risk of closing their doors. Additionally, ACP notes that CMS applied a budget neutrality adjustment to the fee schedule to offset the increase in total spending that would have resulted from the changes in the RVUs for E/M and other services, as generally required by Medicare statute. While many physicians and specialties providing primarily undervalued E/M services will see major improvements in overall payments even with the budget neutrality adjustment, some will see reductions. **ACP strongly recommends that CMS use its administrative authority to waive budget neutrality for the 2021 Medicare Fee Schedule RVU increases, provided that this would not result in a delay or in any way undermine CMS’ decision to fully implement the E/M increases and other improvements on Jan. 1, 2021.** ACP looks forward to working with CMS to ensure that physicians have the tools they need to ensure they are ready for these changes.

### B. **Psychiatric Collaborative Care Model (CoCM) Services**

**CMS Proposal:** CMS proposes to establish a new code, GCOL1, which would describe 30 minutes of behavioral health care manager time. The code would be described as: *“Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other*

*qualified health care professional.*” CMS is proposing this code to reflect stakeholder concerns that a code did not exist to reflect shorter increments of time spent with patients.

**ACP Comments:** ACP is pleased that CMS is considering adopting a new G-code for psychiatric collaborative care model (PCCM) services, which would allow clinicians to bill for shorter increments of time. PCCM are important care management services that are aimed at improving overall patient health. These interim G codes will help to facilitate earlier implementation and will make transitioning to the CPT codes easier once they become available. **ACP strongly recommends CMS create the proposed temporary G code, which would allow clinicians to improve payment accuracy and incentivize the use of PCCM services, which will lead to improved patient care.** We encourage CMS to work with the CPT Editorial Panel to describe the services and create a CPT code to ensure this new service is available for billing by all payers.

At the same time, we note that the existing PCCM code set has been flagged by the RUC for review given significant increases in utilization since it was created. These increases in utilization raise questions about whether the code set is being billed appropriately. **We encourage CMS to work with the CPT Editorial Panel and the RUC to ensure that these services are being billed and utilized correctly.**

### **C. Proposed Add-On Code GPC1X**

**CMS Proposal:** The Agency is intending to finalize its proposal to implement a Medicare-specific add-on code for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient’s single, serious, or complex chronic condition. Additionally, the Agency seeks to finalize for payment year 2021 its proposal to increase the work RVUs for this code from 0.25 to 0.33, representing a 32 percent increase in work RVUs. The revised code descriptor will read, *“Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management.)”* CMS estimates that this add-on code will be billed with almost all office evaluation and management visits.

**ACP Comments:** The College agrees with CMS that the revised office visit E/M codes still do not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. We support CMS’ decision to establish the GPC1X add-on code to account for these resources, and we agree that the current GPC1X code descriptor fits its intended purpose and is well-defined. At the same time, we recommend that CMS should:

- Remove the comma between “single” and “serious” so that the GPC1X code descriptor reads: *“Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single serious, or complex condition.”;*
- Revise the estimated utilization assumptions to **no more than 23 percent of estimated claims;**
- Ensure the add-on code is available to both **new and established patients;** and
- Ensure the appropriate resource costs are accounted for in the code valuation.

ACP agrees that this new code is warranted and will ensure that physicians have the necessary resources to care for their patients.

The College encourages CMS to revisit the Agency's utilization assumptions for this add-on code. Currently, CMS projects that GPC1X will be applied to 75 percent of all office visit claims, an increase from the 50 percent projection in the 2020 rule. While CMS does not offer an explanation for this increased projection, the Agency's projection translates to about 187 million claims for GPC1X as found in utilization tables on the CMS website. However, it appears that if the intent is to append this add-on code to office visits related to ongoing care, CMS could examine past utilization history for Transitional Care Management (TCM) codes (99495 and 99496) and Chronic Care Management (CCM) codes (99387, 99489, and 99490). Both of these code sets serve as a helpful barometer for measuring the provision of "ongoing care." CMS previously estimated that there would be approximately 5.6 million claims for TCM. In fact, the actual utilization for TCM came in just under 300,000 the first year. Utilization for TCM was still less than one million after three years of implementation. 99495 and 99496 were respectively 22 percent and 20 percent of the 2019 claims volume when they became effective in 2013, with 99490 being 23 percent of the 2019 volume in its first year in 2015. Taken together, the combined 2019 utilization for 99495, 99496, 99387, 99489, and 99490 is just over 6 million claims. This is a very small fraction of the 187 million estimate from CMS. We agree with the RUC that 75 percent is a vast overestimate.

We also note that while the code will be widely applicable, GPC1X utilizations could be as low as five percent of initial TCM utilization in 2013 primarily because adoption will be slow at first given the necessity for medical societies to educate their members about appropriate use. Additionally, widespread uptake of GPC1X will be counterbalanced by the ongoing implementation of the revisions to the office visit code set. Not to mention, CMS has provided advance notice about an anticipated delayed issuance of the fee schedule final rule which will delay education and communication efforts, as well as electronic health records (EHRs) integration. Finally, the persistence of the COVID pandemic and the implementation of a national vaccination strategy will also slow down the adoption of this add-on code. We strongly encourage CMS to take this information into account when considering an appropriate utilization estimate. **We strongly recommend that no more than 23 percent of estimated claims should be the appropriate utilization estimate for the GPC1X add-on code.**

Additionally, the College notes that GPC1X should be available for **both new and established patients**. Finally, we encourage CMS to ensure that the following resources are accounted for in the valuation of GPC1X:

- Actions at assisted living/nursing homes that require a physician response;
- Time spent by care/referral/medical record coordinators that help manage the ongoing flow of information;
- Physician time that is unique to ongoing management and thus inadequately addressed in the revised E/M. This includes oversight of medication refills, evaluating appropriateness of current and new medications, including those initially prescribed by other providers (e.g., ER, specialists, hospitalists) and conduct medication-related monitoring and safety activities when these activities are not part of a visit;
- Forms and review of consultant reports lab and imaging reports that fall outside the 3 days prior and 7 days after the timeframe of an E/M visit, but do not necessitate a new visit;

- Assume responsibility for relevant electronic medical record systems to track preventive services; reminders to patients, scheduling, monitoring, tracking results of these services;
- Assume responsibility for chronic disease management tracking – individual patient and populations; and
- Physician and/or staff responsibility for time spent coordinating care.

The College appreciates the opportunity to comment on this important code, as well as the Agency's work to ensure that physicians and their teams have the resources needed to focus on caring for patients. We look forward to working with CMS to ensure that this code is implemented appropriately.

**D. Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic**

**CMS Proposal:** There are a number of codes that are directly cross-walked to office visit E/M codes. Due to the revaluing of the E/M office visit codes, CMS is proposing revalue codes that are directly cross-walked, including valuations for initial preventive physical examinations (G0402), annual wellness visits (G0438 and G0439), transitional care management (99495-96), and PCCM (99492-93).

**ACP Comments:** ACP appreciates CMS' proposal to update the valuations of codes that are directly cross-walked to E/M codes. This proposal will lead to increased valuations and will work to improve patient access to these services. **ACP strongly recommends that CMS finalize these values as proposed.**

*Prolonged Services*

**CMS Proposal:** The Agency is proposing to allow the billing of 99XXX when time is used to select the E/M office visit level of coding and when the minimum time for the level five office visit (99205 or 99215) is exceeded by at least 15 minutes. For example, practitioners could bill 99XXX in conjunction with 99205 (60-74 minutes of total time) when they have spent at least 89 minutes with the patient and with 99215 (40-54 minutes) when they have spent at least 69 minutes with the patient.

**ACP Comments:** ACP is concerned that this proposal by CMS will upend the work done by the AMA CPT Editorial Panel and the RUC to clarify the code descriptors and will make null and void education on appropriate use already underway. When the RUC surveyed this code, the medians and RUC recommended times to CMS for the purposes of valuation (and not coding) were 59 and 45 minutes respectively for 99205 and 99215. This meant that 99205 was outside the descriptor range (60-74 minutes) and 99215 was within the range (40-54 minutes), albeit at the lower end. However, CMS proposes to allow the prolonged services code to be billed only when time exceeds the upper bound time limits of 99205 (74 minutes) and 99215 (54 minutes) by 15 minutes. This would mean that physicians could not bill 99417 with 99205 until they have spent 89 minutes with the patient and with 99215 until they have spent 69 minutes with the patients. That is 30 more minutes for 99205 and 24 more minutes for 99215 than the median times recommended by the RUC for valuation.

Currently, the CPT coding structure requires two prolonged services codes to report initial and subsequent prolonged services. The CPT Panel's actions worked to ensure that 29 minutes of time beyond the upper bounds of 99205 and 99215 are recognized and that 30 minutes of additional time is not regarded just the same as 60 minutes of additional time. The CMS proposal would allow additional

time to be reported in increments of 15 minutes. Thus, 30 minutes of time would be recognized per the proposal, but 29 minutes of additional time would not as it is not a multiple of 15. **ACP encourages CMS to adopt the CPT revisions for the prolonged services codes exactly as recommended. The proposal under consideration by CMS has the potential to undercut efforts already underway to educate physicians about the changes to these codes.**

#### **E. Telehealth**

**CMS Proposal:** During the COVID-19 PHE, pursuant to authority granted, CMS waived the geographic and originating site restrictions for Medicare telehealth services. These flexibilities will remain in effect until the PHE ends, which is currently October 23, 2020. CMS does not propose to permanently extend the Medicare telehealth geographic and site of service originating site restrictions since it believes it lacks statutory authority. The Agency additionally does not explicitly address the need to expand access to and use of telehealth services in underserved urban areas, in addition to rural communities. Moreover, the Agency does not discuss the need to continue the interim flexibility allowing clinicians to reduce or waive cost-sharing for telehealth services, as well as making up the difference between these waived copays and the Medicare allowed amount of the service. In previous communications, ACP has called on CMS to extend all of these interim flexibilities and will continue with these efforts.

CMS is proposing to add a number of services to the list of available telehealth services (Table 8 in the proposed rule), including GPC1X (visit complexity) and 99XXX (prolonged E/M service). CMS distinguishes these codes on a Category 1 basis (services similar to services already on the telehealth list) and a Category 2 basis (services not similar to codes already on the telehealth list).

The Agency is not proposing to add any codes to the telehealth list on a Category 2 basis. However, CMS is proposing to create a new, Category 3 level that would add services to the telehealth list on a temporary basis through the calendar year in which the PHE expires. Factors CMS considers for Category 3:

- Whether, outside of the circumstances of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service;
- Whether, outside of the circumstances of the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care; and
- Whether all elements of the service could be fully and efficiently performed by a remotely located clinician using two-way, audio/video telecommunications technology.

A list of the temporary additions to the list of telehealth services can be found in Table 10 of the proposed rule.

**ACP Comments:** While ACP is pleased to see that CMS has defined a process for adding additional services to the telehealth list of services, the College strongly encourages CMS to consider extending several policies promulgated during the COVID-19 PHE in order to address the many barriers to patient access and physician adoption and use of telehealth prior to the COVID-19 pandemic, and properly assess how to foster and strengthen longitudinal, patient-centered care delivery.

As we have noted in previous communications, ACP supports CMS' policy changes during the PHE to pay for services furnished to Medicare beneficiaries in any health care facility and in their home — allowing services to be provided in patients' homes and outside rural areas. We equally agree that CMS should not jeopardize beneficiary access to added services that have been clinically beneficial. Although limited

access to care is prevalent in rural communities, underserved patients in urban areas have the same risks as rural patients if they lack access to in-person primary or specialty care due to various social determinants. These patients are more likely to reside in underserved communities that fall within the metropolitan statistical areas that are normally not included in Medicare telehealth reimbursement outside of the waivers offered through the PHE. Research has shown the extensive role that social determinants play in health and health equity, and the pandemic has highlighted how providing expanded access to telehealth services within underserved communities, rural and urban, is an important aspect for infection control, as well as addressing social determinants that exist outside of the pandemic. **It is essential to maintain expanded access to and use of telehealth services for underserved urban areas, as well as rural communities, and ACP recommends that CMS permanently extend the policy to waive geographical and originating-site restrictions after the conclusion of the PHE.**

The College supports CMS' proposal to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. We agree that the services added under the Category 3 should remain on the list through the calendar year in which the PHE ends. **However, ACP disagrees with the third factor considered by CMS as it is currently worded, in that it explicitly excludes telephone E/M. We urge CMS to consider removal of the requirement for the use of two-way, audio/video telecommunications technology so that telephone E/M can continue to be provided to Medicare beneficiaries through the CY in which the PHE ends.**

Additionally, ACP appreciates the flexibility provided during the PHE to allow clinicians to waive patient copays. However, it is critical that CMS provide the difference between the Medicare-allowed copay and the waived copay. Many physician practices have had to close their doors during the pandemic, at the expense of patients. **The College continues to recommend that following the end of the PHE, CMS should continue to provide flexibility in the Medicare and Medicaid programs for physician practices to reduce or waive cost-sharing requirements for telehealth services, while also making up the difference between these waived copays and the Medicare-allowed amount of the service. This extension should last at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these visits.**

Finally, ACP appreciates CMS' temporary waiver allowing physicians to provide telehealth services across state lines, as long as physicians meet specific licensure requirements and conditions. **ACP continues to recommend these changes remain in place at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these flexibilities.** These waivers offer an opportunity to assess the benefits and risks to patient care in addressing the pandemic as well as the ability to maintain longitudinal care for patients who move across state lines. While these waivers do not supersede any state or local licensure requirements, they provide the opportunity to promote state-level action that may further promote more streamlined licensure requirements across the country.

#### Payment for Audio-only Visits

**CMS Proposal:** CMS is not proposing to extend permanently coverage and payment for telephone E/M codes 99441-43 beyond the duration of the PHE. Instead, the Agency is seeking input on whether to

develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. Additionally, CMS is seeking feedback on whether to extend coverage and payment for telephone E/M services for a period after the PHE ends, or if it should be extended indefinitely.

**ACP Comments:** ACP wholeheartedly supports the Agency's actions to provide additional flexibilities for patients and their doctors by providing payment parity for telephone E/M services and adding these codes to the Medicare telehealth list. We additionally thank CMS for recognizing early in the COVID-19 pandemic the essential nature of telephone E/M to a sizable portion of Medicare beneficiaries who lack access to the technology necessary to conduct video E/M visits, including the requisite broadband and cellular phone network, or do not feel comfortable using video visit technology. These changes are instrumental in helping physicians make up for lost revenue and provide appropriate care to patients. **As we have stated before, the College strongly recommends that CMS maintain pay parity between telephone E/M claims and in-person E/M visits and between all telehealth and in-person visits even after the PHE is lifted. This extension should last at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with an option to extend it even further, or consider making permanent, based on the experience and learnings of patients and physicians who are utilizing these visits.**

**At the same time, rather than creating new coding for virtual check-ins, the College recommends that CMS work to expand coding options for telephone E/M services through the use of G-codes.** At the outset, we strongly disagree with CMS' proposal as it seems to conflate virtual check-ins, of any duration, with audio-only (telephone) E/M, which are completely different. Telephone E/M is not just a longer virtual check-in service, it *is* an E/M service. Relating to coding specifically, this structure should have five different levels and should mirror the five coding levels and coding descriptors for established patient office visit E/M codes. This change would help to ensure that telephone E/M visits are comparable to in-person visits. It would also provide practitioners with additional options to see patients in a manner that would effectively capture the work required by these services. We strongly urge CMS to establish the following G codes for telephone E/M visits:

- GXXX1: Telephone evaluation and management service for an established patient which does not require a video component; requires a medically appropriate history and/or examination by a physician or other qualified health care professional who may report evaluation and management services. Usually, the presenting problems are minimal. When using time for code selection, 5-10 minutes of total time is spent on the date of the encounter.
- GXXX2: Telephone evaluation and management service for an established patient which does not require a video component; requires a medically appropriate history and/or examination and straight-forward medical decision-making by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian. When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter.
- GXXX3: Telephone evaluation and management service for an established patient which does not require a video component; requires a medically appropriate history and/or examination and a low level of medical decision making by a physician or other qualified health care professional who may report evaluation and management services. When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter.

- GXXX4: Telephone evaluation and management service for an established patient which does not require a video component; requires a medically appropriate history and/or examination and a moderate level of medical decision making by a physician or other qualified health care professional who may report evaluation and management services. When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter.
- GXXX5: Telephone evaluation and management service for an established patient which does not require a video component; requires a medically appropriate history and/or examination and a high-level of medical decision making by a physician or other qualified health care professional who may report evaluation and management services. When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter.

Additionally, the recent changes to face-to-face E/M codes in terms of code descriptors and valuations means that most of the time accounted for in face-to-face E/M codes is intra-service time, rather than pre or post-service time. This change necessitates a change to the code descriptors for telephone E/M services which operate under outdated assumptions about typical times that will soon no longer be accounted for under revised E/M codes. Additionally, it is important that revised telephone E/M claims appropriately align with the guidelines for office visit E/M services and that the same number of coding levels apply to minimize physician burden and reduce billing complexity. Similarly, changes to these codes would be supported through family/caregiver/home health submission of data, vitals, and other information necessary for a patient exam.

At the same time, evidence suggests that patient visits to ambulatory practices have declined significantly and, despite a rebound, visits remain 30 percent lower than they were pre-pandemic. Given the uncertainty around the timeline for a COVID-19 vaccine or treatment, many expect that the virus will continue to spread well into 2021. Therefore, as the need to contain the virus and maintain appropriate social distancing protocols continues into next year, it is unlikely that in-person visits to practices will return to pre-pandemic levels as patients remain uncomfortable with making these in-person visits and physicians schedule fewer patients to be seen in the office. Second, patients have become accustomed to and appreciative of telehealth/telephone visits, and many appreciate the flexibility these visits provide. The transition from in-person visits to the greater use of telehealth and telephone visits during this PHE has provided patients a safe option of receiving equivalent or nearly equivalent care to what they otherwise would receive in an in-person setting in an effort to control the spread of COVID-19. Third, physicians will have to adjust their workflows and practices to allow for appropriate social distancing protocols and prevent patient infection. This again will mean that, in many cases, practices will not be able to maintain economic viability without maintaining payment for these remote services.

**ACP continues to recommend that CMS establish clear guidelines around billing for telephone E/M claims.** The Agency did note that the office/outpatient E/M level of selection for telehealth E/M services can be based on medical decision-making (MDM) or time, with time defined as all of the time associated with the E/M visit on the day of the encounter. We encourage CMS to allow clinicians to use the same aforementioned guidelines when billing telephone E/M claims. It is important that clinicians have similar rules and guidelines to minimize administrative complexity and maximize their time focused on delivering patient care. Given the unique challenges facing clinicians as noted above, **we again urge the Agency to allow these changes to remain in place at least through the end of 2021 to allow all stakeholders to work together to adapt to this new environment.**

Moreover, there is absolutely no difference between telephone E/M and video E/M in terms of clinician time, intensity, and work involved. All components are performed during both video and telephone E/M services, and clinician time should be compensated accordingly – resulting in an improvement in patient health, as well as communication and engagement. **ACP does not see any difference in practice expense between telephone and video E/M visits; therefore we recommend that telephone and video E/M visits be compensated equally.** The College believes that audio-only E/M visits have an added advantage over audio-visual visits by avoiding many issues associated with connectivity and broadband throttling. Additionally, the practical impossibility of excluding audio-only services must be noted. It is often the case that a patient, especially in a rural or disadvantaged community, cannot support audio-visual technology. The video visit must be converted to audio when this occurs, which would then deny the physician pay parity following the conclusion of the PHE. This could result in a deep equity issue across different populations as millions of beneficiaries could be left without care – individuals who benefit the most from audio-only services. **Audio-only has been one of the best use cases, and as parts of the country struggle with connectivity to broadband or do not have smartphone capabilities to support video visits, we encourage CMS to support our most underprivileged and rural communities.**

**We also strongly encourage CMS to remove the requirement that telephone E/M visits not originate from a related in-person E/M visit within the past seven days or lead to an E/M visit/procedure within the next 24 hours.** It is critically important that CMS work to remove barriers that may prevent patients from accessing the care they need at the time they need it. It is possible that patients will need follow-up visits to prevent the exacerbation of a condition or to monitor symptom presentation to determine the need for a COVID-19 test. For example, if a patient had an in-person visit in the last seven days where the physician determined that a follow-up visit was necessary but could be done remotely, this language would not allow a remote visit to be billable. Additionally, this language does not allow an in-person follow-up visit to be billed following a remote visit if that remote visit occurred within the previous 24 hours. We encourage CMS to ensure that the language in this code descriptor does not inadvertently subject patients to greater risk of COVID-19 infection due to the inability of practices to use in-person and telephone visits in concert with each other.

**Finally, the College notes that in our recommendation to extend pay parity to audio-only services, there should be the condition “if there are limitations on the patient’s end.”** Absent such, there could arise a situation where there is no incentive for clinicians to move to a video system – further disadvantaging our most vulnerable communities. ACP believes this is necessary since the anecdotal clinician experience has demonstrated that challenges presented by video visits are not unique to older populations or the digitally disinclined. Rather, there are definite disparities across the country in terms of accessibility to broadband. The College encourages CMS to allow reimbursement for audio-only services since the alternative will only exacerbate health disparities and further widen the digital divide as our most disadvantaged patients will no longer have access to care.

#### Direct Supervision

**CMS Proposal:** The Agency is proposing to extend until the end of 2021 the ability of supervising physicians or practitioners to use interactive audio/video real-time communications technology to supervise directly. “Direct supervision” in the office setting means the physician (or other supervising practitioner) must be present in the office and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision does not mean that the

physician/supervising practitioner must be present in the room. CMS is proposing that the presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only).

**ACP Comments:** The College is pleased to see CMS respond to the needs of physicians by extending the flexibility to continue to provide direct supervision via interactive audio/video technology through the end of 2021. **We strongly urge CMS to finalize this proposal with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these supervision flexibilities. ACP believes that providing for a permanent flexibility in this space supports the expansion of telehealth services and protects frontline workers by allowing appropriate social distancing measures.** Similarly, we believe that clinicians should feel empowered to supervise clinical staff virtually, at their discretion, regardless of whether there is a declared PHE.

## **F. Care Management**

### *Remote Physiologic Monitoring (RPM)*

**CMS Proposal:** CMS is proposing to make a number of modifications to RPM codes, including:

- Resuming the requirement that an established patient-physician relationship exist for RPM services to be furnished once the PHE ends;
- Making permanent the policy to allow consent to be obtained at the time that RPM services are furnished;
- Allowing auxiliary personnel to furnish CPT codes 99453 and 99454 services under a physician's supervision;
- Maintain the current requirement that 16 days of data each 30 days must be collected and transmitted to meet the requirements to bill CPT codes 99453 and 99454;
- Clarifying that RPM services are considered to be evaluation and management (E/M) services;
- Clarifying that only physicians and NPPs who are eligible to furnish E/M services may bill RPM services;
- Noting that practitioners may furnish RPM services to patients with acute conditions as well as patients with chronic conditions; and
- Clarifying that for CPT codes 99457 and 99458, an "interactive communication" is a conversation that occurs in real-time and includes synchronous, two-way interactions that can be enhanced with video or other kinds of data as described by HCPCS code G2012.

**ACP Comments:** **With respect to the proposals for RPM services, the College would like to thank CMS for filling the void of a lack of guidance on RPM services for Medicare.** RPM services have been a critical component of care, especially during the COVID-19 pandemic. ACP is pleased to see the Agency propose a number of policies that will be beneficial to both patients and their care teams. These changes expand access to services at an important time when patients and their care teams need additional resources to meet current challenges. These changes will help relieve physician burden and allow physicians more time to treat complex patient issues that require more than remote monitoring. **We strongly encourage CMS to finalize these proposals. We further encourage CMS to extend its interim policy to allow RPM services to be furnished to patients without an established relationship on a permanent basis at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with the option to extend it even further, or consider making permanent, based on the experience and learnings of patients and physicians who are utilizing these**

services. The College requests the same for CMS' interim policy allowing RPM services to be reported for periods of less than 16 days, but not less than two days, so long as the other requirements for billing the code are met.

#### Transitional Care Management (TCM)

**CMS proposal:** CMS is proposing to allow the concurrent billing of end-stage renal disease (ESRD) services and complex chronic care management (CCCM) alongside TCM services. The Agency is also proposing to increase the valuations of TCM services.

**ACP Comments:** ACP applauds CMS' decision to remove restrictions that prevent the concurrent billing of ESRD and CCCM with TCM services. If adopted, this change will lead to increased valuations and will work to improve patient access to these services. **ACP strongly recommends that CMS finalize these proposals.**

### **G. Scope of Practice**

#### Primary Care Exception Flexibilities

**CMS proposal:** During the COVID-19 PHE, CMS allowed all levels of outpatient E/M services to be provided in teaching hospitals by residents and billed by teaching physicians without the presence of a physician under the primary care exception rules. CMS is contemplating whether to extend this flexibility through the end of 2021. Before the COVID-19 pandemic, the primary care exception policy allows residents in teaching hospitals to provide and teaching physicians to bill for low- to mid-level complexity outpatient E/M services when a teaching physician is not present. The Agency is also seeking comment on whether specific services added under the primary care exception should be extended temporarily or made permanent. CMS is soliciting public comment on whether these services should continue as part of the primary care exception once the PHE ends.

CMS also notes that it is considering whether their interim final policy that PFS payment could be made to the teaching physician when residents furnish telehealth services under the primary care exception should be extended on a temporary basis or be made permanent.

**ACP Comments:** The College welcomes these proposals by the Agency that will grant attending physicians and residents/fellows additional flexibilities that prioritize patient safety and meets them where they are. These important steps promote efficient patient care and allows physicians and supervisees to work together unencumbered by social distancing restrictions. **We continue to encourage CMS to maintain these modifications for a period of time after the PHE ends and until supervising physicians feel comfortable they are able to control the spread of infection rates. This extension should last at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these supervision flexibilities.**

### **H. Immunization Administration**

**CMS Proposal:** In the proposed rule, CMS is planning to revalue the immunization administration codes by cross-walking the values of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000. This change will significantly increase the values of these services to levels

that preceded the earlier changes.

**ACP Comments:** The COVID-19 pandemic has underscored the importance of vaccines to the health and safety of the population at large. Vaccine payment is a critical component to ensuring that patients have access to vaccines. Current vaccine administration costs do not adequately cover the costs of purchasing, storing, monitoring, and administering vaccines. At the same time, the diversity in reimbursement models means that slight decreases in vaccine reimbursement amounts could pose significant consequences for physicians and patients. In last year's comments on the proposed rule, ACP stressed the importance of re-examining and retooling vaccine administration reimbursement. ACP is pleased that CMS has done so. **We strongly support this proposal from CMS to increase the valuation for vaccine administration codes, and we urge the Agency to finalize it.** This change is critically important to ensure that patients will have access to life-saving vaccines.

#### **I. Changes to Policies re: Opioid Use Disorder (OUD)**

##### *Bundled Payments under the PFS for Substance Use Disorders*

**CMS Proposal:** CMS is proposing to modify the code descriptors for G codes G2086, G2087, and G2089 to be inclusive of all substance use disorders (SUD) instead of just opioid use disorder (OUD). At the same time, the Agency is seeking feedback on whether there should be stratified coding to demonstrate any differences in the resource costs associated with providing different SUD services.

**ACP Comments:** While Medicare patients suffering from OUD now have access to an inclusive set of services, the existing code descriptors may close off access to treatment for patients who may be suffering from a SUD that is not OUD. At the same time, it is important to understand that SUDs manifest in different forms in terms of symptoms, underlying causes, psychology, and treatment needs. **Therefore, while this proposal is a step in the right direction, ACP encourages CMS to work with medical societies and through the CPT Editorial Panel process to examine the different resource costs involved with treating different SUDs and determine the need for more stratified coding. In the meantime, CMS should finalize this proposal to ensure that more patients have access to these critical services.**

##### *Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)*

**CMS Proposal:** Currently, statute defines covered OUD treatment services to include oral, injected, and implanted opioid agonist and antagonist treatment medications approved by the FDA for the treatment of OUD. CMS is proposing to revise that definition to include naloxone, which is used to treat opioid overdose. Should this proposal be finalized, patients would be able to receive treatment for opioid overdose at an OTP and this medication would be included in the OTP Medicare benefit. CMS is also seeking feedback on whether the definition of OUD treatment services under the OTP benefit should be revised to include opioid overdose education, and if so, whether payment for this service should be included in the weekly OTP bundled payment.

CMS is proposing two add-on codes, GOTP1 and GOTP2, to describe the take-home supply of naloxone. Additionally, the Agency is clarifying that in order to bill for HCPCS code G2077 (periodic assessments), a

face-to-face medical exam or biopsychosocial assessment would need to have been performed. CMS is also proposing to allow these assessments to be conducted via telephone for the duration of the PHE, but will permit them to be offered via telehealth even after the conclusion of the PHE.

**ACP Comments:** ACP is supportive of lifting barriers to ensure that patients receive access to medications to treat OUD and to reverse overdoses. OTPs are an essential component of care for many people recovering from a SUD. Additionally, opioid overdose education is important for patients to ensure they have the recovery tools needed to be successful. In fact, despite the absence of payment, opioid overdose education already occurs at most OTPs and may be part of treatment plans for patients who are given naloxone. **Therefore, ACP supports the inclusion of naloxone in the definition of medications to treat OUD, as well as payment for opioid overdose education. If adopted, this proposal will add additional tools for patients and their care teams to assist them on their journey to recovery. We encourage CMS to move forward with these proposals.**

#### **J. Payment for Principal Care Management (PCM) Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)**

**CMS Proposal:** CMS is proposing to add HCPCS codes G2064 (*at least 30 minutes of PCM services furnished by physicians or non-physicians during a calendar month with certain required elements*) and G2065 (*at least 30 minutes of PCM services furnished by clinical staff under the direct supervision of a physician or non-physician practitioner with certain required elements*) to G0511 (*a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month*) as a comprehensive care management service for RHCs and FQHCs starting January 1, 2021. The payment rate for HCPCS G0511 is the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491). CMS is proposing to add G2064 and G2065 to this list to determine the calculation of the G0511 payment rate.

**ACP Comments:** ACP agrees that PCM services are an important component of care and should be allowed to be billed by RHCs and FQHCs. At the same time, we note that given the formula used to determine the payment rate for G0511, adding G2064-65 to the formula would result in a net payment deduction, according to the 2020 RVUs for this service. Currently, the formula yields a payment rate of \$66.68 for G0511, while adding these two additional codes to the formula would yield a payment rate of \$66.40. While the reduction is not significant (-\$0.28), depending on the volume of G0511 services at an individual RHC/FQHC, this reduction could be significant when applied at the macro level. **While ACP supports allowing RHCs/FQHCs to provide these services, the College encourages CMS to examine and provide additional information about the estimated impact of this changes.**

#### **K. Electronic Prescribing of Controlled Substances**

**CMS Proposal:** The Drug Enforcement Administration has the primary responsibility of establishing requirements for prescribing and dispensing controlled substances. In 2010, DEA issued an Interim Final Rule, "Electronic Prescriptions for Controlled Substances" (EPCS), which provided practitioners with the option of writing prescriptions for controlled substances electronically and permitted pharmacies to receive, dispense, and archive these electronic prescriptions. Any electronic controlled substance prescription issued by a practitioner must meet the requirements in the 2010 DEA EPCS Interim Final Rule.

CMS adopted its first set of standards for e-prescribing in 2005, which included the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Version 5. CMS has since continued to adopt updated standards, and currently requires that Part D plans support the NCPDP SCRIPT standard version 2017071 for certain defined e-prescribing transactions as finalized in 83 FR 16440. Signed in 2018, Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act mandates that EPCS under Medicare Part D begin on January 1, 2021, subject to any exceptions, which HHS may specify. Balancing its intent not to provide too large of a burden on clinicians and to help ensure that the benefits of EPCS are realized quickly, CMS is proposing that all prescribers conduct electronic prescribing of Section II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 by January 1, 2022, except where the Secretary waives the requirement.

CMS is requesting comment on the feasibility for prescribers to meet the proposed January 1, 2022 deadline with minimal burden to those prescribers participating in the Part D program during and after the PHE, as well as the impact of this proposal on overall interoperability and the impact on medical record systems. In the Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information, CMS is requesting feedback on the appropriate waivers and whether CMS should impose penalties for noncompliance with the EPCS mandate (and what those penalties should be). Separate from the proposed rule, CMS intends to conduct future standalone rulemaking that would address these topics and believes the proposal to require EPCS by January 1, 2022 would allow time to solicit and consider feedback from the aforementioned RFI.

**ACP Comments:** ACP strongly supports reducing administrative burdens associated with the use of prescription drug monitoring programs (PDMPs), as well as other efforts to improve clinical workflow. The College appreciates CMS' recognition of the abundance of new technologies and functionalities, such as EPCS, that have the potential to enhance health IT usability and patient safety. While EPCS will likely reduce the potential for fraud and abuse, we remain concerned that CMS' proposal assumes these functionalities to be successful, when in actuality they still require significant fixes and delayed implementation timelines. Perhaps the biggest challenge clinicians will face is incorporating EPCS into their EHRs, and most clinician practices are not in a position to cover the costs and acquire the necessary resources for technical or system upgrades required by EHR vendors – especially rural and small practices. Due to the COVID-19 pandemic, many practices have been forced to delay or cancel implementation altogether of EHRs that support EPCS. Practices that do not even have the capability to prescribe electronically would be forced to purchase such a software. **ACP is supportive of the intent to facilitate efficiency, convenience, and better security, but we encourage CMS to avoid unreasonable burden imposed upon clinicians and delay compliance until at least January 1, 2023.**

#### **L. Updates to Certified Electronic Health Record Technology (CEHRT) due to the 21<sup>st</sup> Century Cures Final Rule**

**CMS Proposal:** The 21<sup>st</sup> Century Cures Act final rule established timelines for: (1) a transition period where technology certified to not-yet updated or updated versions of the same certification criteria would be considered certified; and (2) the date for which technology certified to only the updated version would be considered certified. ONC has finalized that health IT may be certified to the current 2015 Edition certification criteria or the 2015 Edition Cures Update for a period of 24 months from the publication date of the rule (May 2, 2022). In response to the COVID-19 PHE, ONC announced it will exercise enforcement discretion until three months after each compliance date and continue to allow

health IT certified to either version of the criteria to be considered certified. Therefore, CMS is proposing, during that same time period (up to 27 months from May 1, 2020, or until August 2, 2022), health care clinicians participating in the Promoting Interoperability (PI) Programs or QPP may use technology certified to either version and that health IT will be considered certified under the ONC Health IT Certification Program.

After the current transition period ends, in which health IT certified to either the existing 2015 Edition criteria or the 2015 Edition Cures Update is considered certified, health care clinicians must use technology certified to only the updated 2015 Edition Cures Update to meet the CEHRT definitions and meet PI objectives. This would include technology used to meet the 2015 Edition Base EHR definition, technology certified to the criteria necessary to be a meaningful EHR user under the PI Programs, and technology certified to the criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, as specified in the CEHRT definitions.

**ACP Comments:** The College is appreciative of CMS' flexibility to allow clinicians to use EHR technology that is certified to either criterion during this transition period. ACP believes this will be critical in allowing early adopters of the newly finalized criterion, as well as those using technology meeting the existing certification criterion, to be able to meet the requirements of the PI Programs and MIPS. However, when considering the proposed updates to CEHRT require clinicians to purchase upgrades for their systems, modernize system hardware, or hire new/additional staff, **ACP urges CMS to consider the fact that clinician groups, and hospital groups that clinicians belong to, will not be in a stable enough financial situation to implement and comply with these updates by 2022.** In its asks to the clinician community, the College encourages CMS to remain cognizant of the unfortunate reality that, as a result of the COVID-19 pandemic, clinicians across the United States are financially struggling and practices both small and large are at risk for going out of business. We do understand that, if finalized, these proposals will not go into effect until 2022, but we do not expect that clinicians will have recovered from the pandemic by that time. There are many unknowns in terms of the financial viability of practices, and ACP remains hopeful that CMS will take these into account when finalizing the implementation and compliance timeline for updates to CEHRT.

#### **M. Quality Payment Program (QPP)**

**CMS Proposal:** The Agency proposes to retain Query of Prescription Drug Management Program (PDMP) as an optional measure for PY 2021 but proposes to increase it from five to 10 bonus points to reflect its significance.

CMS proposes to add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as an optional alternative to two existing measures: 1) Support Electronic Referral Loops by Sending Health Information; and 2) Support Electronic Referral Loops by Receiving and Incorporating Health Information. Clinicians may choose to report the two existing measures (and associated exclusions) or report the new measure. The new HIE Bi-Directional Exchange measure would be worth 40 points and reported via yes/no attestation. Clinicians who report the measure would attest to the following:

- "I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period."

Notably, the new measure would require bi-directional engagement for all new and existing patients and patient records seen by the EC regardless of known referral or transition status, or the timing of any potential transition or referral. It would not allow for exclusion, exception, or allowances for partial credit. This is equivalent to achieving a score of 100 percent on both existing measures, while completing required actions for additional cases beyond the scope of the denominators for both existing measures. CMS does propose to use a flexible interpretation and notes in the rule that there are numerous certified health IT capabilities that can support bi-directional exchange with a qualifying HIE using 2015 CEHRT Cures Update to transmit Consolidated Clinical Document Architecture (C-CDA) documents to the HIE, or using certified Application Programming Interface (API) technology to enable an HIE to obtain data in the Common Clinical Data Set (CCDS) or United States Core Data for Interoperability (USCDI) formats from a participant's EHR.

- “The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs and does not engage in exclusionary behavior when determining exchange partners.”

Certain HIE arrangements may not have the capacity to enable bi-directional exchange for every patient transition or referral made by clinician, and thus would not meet necessary requirements. Examples include exchange networks that only support information exchange between affiliated entities, such as clinicians that are part of a single health system, or networks that only facilitate sharing between clinicians that use the same EHR vendor.

- “I use the functions of CEHRT for this measure.”

Physicians would be required to use only technology considered certified under the ONC Health IT Certification Program according to the timelines finalized in the 21st Century Cures Act final rule. Physicians may use the current 2015 Edition EHRs and/or 2015 Edition Cures Update EHRs until August 2, 2022. After August 2, 2022, technology that has not been updated in accordance with the 2015 Edition Cures Update would no longer be considered certified.

**ACP Comments: ACP encourages CMS to retain the Query of Prescription Drug Monitoring Program measure as an optional measure for CY2021 and is supportive of the proposal to increase its worth from five bonus points to 10 bonus points.** The College appreciates CMS' focus on addressing the opioid crisis and agrees that prescription drug monitoring programs (PDMPs) play an important role in that effort. We additionally agree that this proposed increase emphasizes the importance of the measure as it relates to improved patient safety and incentivizes clinicians to expand the use of PDMPs. **We remain concerned, however, that until information found within PDMPs is easily and seamlessly integrated into health IT systems, this type of EHR-functional-use measure will be burdensome and require multiple actions outside of the clinical workflow.**

ACP is enthusiastic about CMS' continued attempts to simplify and align the PI performance category; however, there is still much more that needs to be done. Although the use of bi-directional exchange, and the ongoing capability for such, is critical to the advancement of effective interoperability, **the College believes the proposed addition of a new Health Information Exchange (HIE) Bi-Directional Exchange measure is unworkable in real-world practice settings and likely to be cumbersome to clinicians.** This new proposed measure does little to promote interoperability or help clinicians move forward with health IT innovation and utilization. CMS' proposed attestations also assume clinicians

know what HIEs their hospital uses, and its particular usage, which generally is not the case and puts the clinician in a position of having to defer to others with this knowledge – an unnecessary and onerous task that increases burden.

**Similarly, the College is disappointed that this new alternative measure requires “all-or-nothing” performance and fails to account for the significant expense to clinicians who wish to report. This measure additionally fails to account for the clinical relevance and value at the point of care, as there is no value in querying for data all the time.** HIEs are expensive, often requiring monthly or yearly subscription fees, and due to the substantial impact of the COVID-19 pandemic on practices, this is a heavy lift for clinicians. Furthermore, given the substantial cost, this disadvantages rural clinicians and small practices during a period when these populations are already suffering great challenges.

**The College is concerned that CMS’ proposed additional measure fails to account for the implications absent a certified HIE on a national level.** In regions of the country there are multiple competing HIEs, and often there are HIE silos within states. This creates, for instance, the possibility for a situation where one HIE receives the data but the other does not. For a clinician practice, then, this results in a burdensome administrative task to complete the exchange. **We encourage CMS to disincentivize participation in individual HIEs and rather incentivize the ability for information to flow across HIEs. Should the measure be finalized, the College encourages CMS to be more inclusive by expanding the measure to include “HIEs, exchange frameworks, or other organizations focused on bi-directional health information exchange” since participation in a single HIE might not meet the need of the measure to support HIE for “every patient encounter, transition or referral.”**

In addition to different HIEs being in existence, there are challenges in clinicians ensuring they have a business agreement with each one or risking that the HIE may not be able to interface well with their EHR. Even absent the COVID-19 pandemic, this is an expensive and unrealistic ask for a practice.

**Generally, ACP supports CMS’ focus on interoperability and patient access to data, as well as its intention to give clinicians a greater flexibility while reducing their burdens. The College believes, absent a national, effective HIE infrastructure, that it would be wasteful and only result in greater clinician burden to propose an alternative HIE bi-directional exchange measure. In the event that CMS finalizes the proposed addition, ACP would recommend the measure permanently remain optional.**

#### **N. MIPS Value Pathway (MVP)**

##### Implementation Delay

**CMS Proposal:** CMS proposes to delay initial implementation of the MVP until at least the 2022 performance year due to the COVID-19 PHE. The Agency acknowledges in the rule the importance of transitioning to MVPs gradually without immediately eliminating the current MIPS program, but reiterates that it may eventually require participation in MIPS through either an MVP or the new APM Performance Pathway (APP) and will monitor physician readiness accordingly.

**ACP Comments:** While ACP supports implementation of optional MVPs as soon as possible, we recognize the unique circumstances due to the COVID-19 PHE. We also appreciate the Agency’s recognition of the importance of a gradual transition period that would retain MIPS as clinicians begin to voluntarily transition to MVPs, which ACP [has called for previously](#). A gradual implementation will be critical for clinicians to familiarize themselves with new requirements and achieve long-term success under this new pathway. Maintaining MIPS as clinicians transition to MVPs will also help to minimize

reporting disruptions. ACP reiterates our belief that mandatory participation in MVPs is not necessary and should not be rushed. Provided MVPs fulfill their promise of creating more cohesion between the categories, using more clinically targeted metrics, and reducing overall reporting burden, we believe this should be a sufficient incentive to draw clinicians into MVPs voluntarily.

#### Reducing Complexity and Burden; Creating Alignment within MIPS

**CMS Proposal:** CMS reiterates its primary goals for the MVP, namely reducing the complexity and burden of MIPS; reducing the siloed nature of MIPS by creating more alignment across the four MIPS performance categories; and making metrics and feedback more meaningful by connecting measures across the categories that are relevant to a particular specialty, medical condition, or patient population. As part of its consideration criteria, CMS includes “does the improvement activity complement and/or supplement the quality action of the measures in the MVP, rather than duplicate it?”

**ACP Comments:** ACP supports the overarching goals of the MVP, which align with longstanding ACP priorities of [reducing administrative burden](#) and [more accurate, actionable performance measurement](#). The College submitted two of its own MVPs for consideration earlier this year. In that [proposal](#), ACP also made several recommendations to inform overall MVP implementation. ACP believes that a critical component to reducing the siloed nature of MIPS is aligning clinical goals across the performance categories. For example, reporting eQMs through CEHRT simultaneously demonstrates use of CEHRT, which should earn credit under the Promoting Interoperability Category, as well as collecting data towards the quality measure. In this case, the measures remain distinct, but performing one action can simultaneously demonstrate use of CEHRT and provide CMS with the necessary quality data. Quality measures are intended to capture meaningful differences in performance to ultimately improve patient outcomes, which in many cases are a direct result of complementary improvement activities. The point of the MVP is to streamline reporting. Aligning quality measures and improvement activities to eliminate unnecessary box checking should be a primary objective of MVPs, not consciously avoided.

#### Promoting Interoperability (PI) Category as a Foundational Component

**CMS Proposal:** CMS continues to consider the PI Category a “foundational component” and proposes to include the entire set of PI measures in the MVP.

**ACP Comments:** ACP believes maintaining the PI category in its current format conflicts with CMS’ stated goal of creating more alignment between the performance categories and using more meaningful metrics. **ACP implores CMS to take a more innovative approach and convert the PI Category to a set of attestation-based measures that capture a wider array of innovative CEHRT and Health Information Technology (HIT) uses**, similar to the Improvement Activities (IA) category. The current set of functional use measures are cumbersome and do little to spur innovation. Clinicians should not be evaluated on how many times they use a system or the volume of data they submit, but on how effectively they leverage CEHRT and other HIT to meaningfully improve patient care. Moreover, many of the existing measures do not have meaningful distributions in performance or are not yet at a point where they are ready to be evaluated on a performance basis due to current EHR platform limitations, inadvertently penalizing physicians for technological limitations that are beyond their control. CMS could easily address these concerns while maintaining many of the existing measures by converting them to a yes/no attestation, a precedent set by the proposed Health Information Exchange (HIE) measure. Reinventing the PI Category in this fashion would also afford CMS the opportunity to introduce new

measures that capture HIT innovations as they evolve and promote strategic priorities, such as awarding PI credit for participating in the development of new eCQMs. Rather than purposefully keeping this category separate from all the others by labeling it as “foundational,” CMS should embrace its own goal of creating more alignment between the performance categories by awarding credit in the PI Category when other categories inherently intersect. For example, if an Improvement Activity inherently involves use of CEHRT, or when quality measures are reported electronically.

#### Prioritization of Administrative Claims Measures

**CMS Proposal:** CMS says it is “looking into ways to mitigate” stakeholder concerns with the reliability and validity of administrative claims measures, but continues to prioritize them as a way to improve patient outcomes, have more consistent metrics, and minimize reporting burden.

**ACP Comments:** ACP appreciates the advantages of administrative claims measures, most notably reducing burden. However, evaluating clinicians on inaccurate or unreliable metrics is potentially worse than not measuring them at all because it may result in perverse incentives and adverse consequences, such as penalizing practices that treat at-risk patient populations and most importantly, potentially jeopardizing patient safety. Measures should not be used to impact clinician payments without passing consistent, transparent, and rigorous standards for minimum reliability, clinical relevance, actionability, and a proven ability to improve patient care. In the past, ACP has [recommended](#) a minimum reliability of 0.75.

While ACP appreciates the potential value of consistent metrics, the College believes this value is overstated, particularly relative to clinical relevance. The primary goal of performance measurement should always boil down to leveraging data to improve patient outcomes. This requires metrics that are accurate, within a practice’s ability to influence, and with a proven ability to improve patient care. Using broad, downstream metrics such as hospital readmissions for the sole purpose of broadly applying them to all clinicians, regardless of their ability to meaningfully influence them, sacrifices clinical relevance and a chance to move the needle on improving patient care for the sake of data collection and comparison. Holding clinicians accountable to metrics irrespective of their ability to influence the outcomes also opens the door to a number of potential adverse consequences including patient access issues and undermining clinician confidence in value-based programs. **ACP calls on CMS to leverage this important opportunity to create more meaningful performance measurement by using targeted metrics that are statistically valid, clinically relevant, actionable, and have a proven ability to positively impact patient care.**

#### Cost Measures

**CMS Proposal:** CMS seeks feedback on cost measures that should be prioritized for future development and inclusion in the MVP, including potential condition-specific measures.

**ACP Comments:** **ACP strongly supports the development of cost measures targeted to specific specialties, patient populations, and conditions, and we strongly believe they should be attributed at the group practice level or higher.** As noted above, the current use of one-size-fits-all cost metrics fails to account for varying abilities to control certain costs. While every clinician plays an important role in controlling costs, their ability to influence costs at different points in the process can vary widely. It is ineffective to attempt to evaluate all clinicians, regardless of specialty, on the same cost metrics. The vast majority of current cost metrics focus on downstream costs (i.e. hospital readmissions, total per

capita costs, etc.). This systematically disadvantages upstream clinicians, namely internists, due to their more limited ability to meaningfully influence broad, downstream costs such as hospital readmissions. CMS should invest in developing cost metrics that would more accurately reflect the types of costs internists have an ability to influence, even if this focuses on a narrower scope. Clinically irrelevant cost measures are one of the chief concerns ACP hears from its members and one of the primary sources of frustration and lack of confidence in performance measurement. Addressing this concern could pay dividends in terms of clinician confidence and willingness to invest in MVPs and value-based programs more generally.

In the interim, **ACP has outlined several tangible improvements we believe would drastically improve the Total Per Capita Cost measure.** Namely, these include attributing at the group practice level or higher only; not attributing the same costs to multiple clinicians/groups; risk adjusting for social determinants of health; meeting robust, consistent minimum standards for average reliability, statistical significance, actionability, and demonstrated impact on health outcomes; having detailed testing results published to the public; and providing insights into year-over-year cost reduction.

#### Sub-TIN Reporting and Clinician-Level Feedback

**CMS Proposal:** CMS proposes to allow sub-TIN reporting and emphasizes the importance of meaningful data at the individual clinician level.

**ACP Comments:** **ACP supports flexibility in reporting, including the option to submit data at the sub-TIN level.** ACP agrees that providing performance feedback at the individual clinician and group practice levels and providing meaningful comparative data to similar clinicians and practices offers critical insights that practices can leverage to inform interventions to improve patient care. At the same time, the College reiterates our [support](#) of the clinical care team-based approach, noting that many innovations occur at the group practice level. We also maintain our stance that performance measurement, particularly for cost, is generally more accurate at the group practice level. Therefore, **ACP recommends value-based payment programs move away from “check the box” performance requirements toward a limited set of actionable, evidence-based measures for public reporting and payment purposes, while supporting the use of additional clinically meaningful measures for internal quality improvement purposes.**

#### Incorporation of QCDR Measures into MVPs

**CMS Proposal:** CMS continues to support development of QCDR measures and their possible inclusion in MVPs. The Agency proposes that beginning with PY 2022, only QCDR measures that were approved in the previous year may be considered for inclusion within a candidate MVP. Candidate MVPs must also be proposed and finalized through rulemaking. Therefore, QCDR measures would be eligible for two-year approval for inclusion in an MVP. CMS intends to establish a formal process for QCDRs and qualified registries to identify which MVPs they plan to support and seeks comment on this.

**ACP Comments:** **ACP continues to believe QCDR measures are an important source of more specialty and condition-specific quality (and potentially cost) measures.** We wish to express our concerns that the proposal to only consider QCDR measures that were approved in the previous year for inclusion within a candidate MVP may inadvertently delay the development of new MVPs, particularly with new QCDR measure testing requirements. To clarify, ACP is not seeking CMS to relax standards for statistical

rigor or clinical relevance. To the contrary, one of ACP's top performance measurement priorities includes subjecting every measure to rigorous, consistent, and transparent standards for reliability, validity, actionability, clinical relevance, and impact on patient outcomes. However, ACP does believe there is a solution to expedite the development of MVPs without sacrificing clinical or statistical rigor. Specifically, **ACP suggests CMS consider allowing stakeholders to submit MVPs that include QCDR measures that are simultaneously undergoing approval with final inclusion pending their meeting full testing and reliability requirements and receiving final approval.** Should the measure ultimately not be approved, it could be removed from the final MVP in or prior to publication of the final rule. However, allowing these two approval processes to occur simultaneously will shorten the timeframe for developing MVPs. ACP also notes that allowing some degree of quality measure selection (i.e. having six available to report for a given MVP but requiring only three) would provide some flexibility and help to avert situations where approval of the entire MVP would hinge on the outcome of a single QCDR measure.

#### MVP Development Process

**CMS Proposal:** CMS proposes modifications and additions to the MVP guiding principles and development criteria to emphasize the importance of patient voices and supporting the transition to digital quality measures. Beginning with PY 2022, CMS proposes that stakeholders must include patients in their MVP development process and formally submit MVPs utilizing a standardized template, which would be published in the QPP resource library. CMS seeks feedback on MVP development criteria and the development process, including how to make it more transparent, with possible review by a third party advisory committee or technical expert panel. The Agency does not intend to communicate to stakeholders whether an MVP candidate has been approved, disapproved, or is being considered for a future year prior to the publication of the proposed rule.

**ACP Comments:** ACP has been a vocal advocate of the importance of patient-centered care and believes incorporating patient voices is critical to developing any strong performance indicator. That said, ACP has concerns that adding a number of additional criteria, though well-intentioned, may cause significant delays in the MVP development process. **ACP believes that it would be more efficient for CMS to take all of the MVP candidates it collects and subject each to a robust screening process that includes patient perspective, rather than putting the onus on developers to do so.**

ACP believes transparency and accuracy are of paramount importance and generally supports performance metrics being subject to review by an independent third party for this reason. However, CMS must balance this with the tradeoff of delaying the process for implementing new MVPs. CMS notes in the rule that any QCDR measures included in an MVP must have already been approved through the separate QCDR measures approval process. **Provided all of the individual measures included in an MVP have already been reviewed by a third party and are deemed reliable, valid, and actionable, ACP does not believe that an additional, separate screening process for the MVP bundles is necessary.**

Maintaining ongoing stakeholder communication is critical to the successful development and implementation of MVPs, particularly with organizations that are sponsoring MVPs. As noted previously, ACP was pleased to be one of only a few stakeholders who submitted MVP candidates in advance of the 2021 performance year. We appreciated the productive dialogue with CMS throughout and felt the development process was stronger for it. While we appreciate CMS staff bandwidth is an important

consideration, we worry CMS' proposal not to inform MVP candidates of where their proposal stands may jeopardize stakeholder confidence and willingness to submit MVPs, particularly if their MVP is not selected and they are unsure why. ACP understands that CMS will not be able to approve every MVP candidate that is proposed, but **maintaining open lines of communication with stakeholders is an important way to build confidence and encourage stakeholders to develop and submit MVPs.** CMS and stakeholders share the same goal of bringing MVPs to fruition; there is no reason to sever communication at a critical point in the development process. **At a minimum, CMS should not prohibit itself from informing developers of where their MVP proposals stand.**

## O. MIPS

### COVID-19 PHE Flexibilities

**CMS Proposal:** CMS does not propose any broad-scale MIPS extreme and uncontrollable circumstances exception for the 2021 performance year.

**ACP Comments:** While ACP supports many of the individual changes CMS proposes in this rule to improve the accuracy of 2021 performance evaluations, these alone are not enough. Practices are still in the midst of the COVID-19 pandemic. The recovery and rebuilding process will not take place overnight; it will be gradual and long. Service delivery patterns will continue to shift as a direct result of this pandemic for many months, if not years, to come. Patients who avoided scheduling their regular check-up appointments will be making up many of those services in 2021. Those who skipped preventive care services or chronic disease management check-ins in 2020 due to the pandemic will likely have exacerbated conditions or be in poorer health when they reprise their normal routines. We have only just begun to see the full impacts of this pandemic unfold. CMS must finalize broad MIPS extreme and uncontrollable circumstances exceptions for the 2021 performance year, just as they did for 2019 and 2020. To minimize burden, these exceptions should be automatic and prioritize the highest score (either the MIPS performance threshold or the score based on data received). Many physician practices across the country are struggling to stay financially viable; a nine percent cut on top of this would potentially be devastating, particularly for small, independent, and rural practices, which are disproportionately likely to receive a penalty and often serve vulnerable patient communities.

### MIPS Scoring and Payment Adjustments

**CMS Proposal:** CMS proposes a MIPS performance threshold of 50 points, which is five points higher than 2019 but 10 points lower than previously finalized for PY 2021. CMS proposes to maintain the exceptional performance threshold at 85 points. As defined under statute, the maximum MIPS penalty would be nine percent. CMS projects MIPS positive payment adjustments would maximize near six percent, as opposed to 1.5 percent in past years.

**ACP Comments:** ACP appreciates CMS recognizing the need to lower the MIPS performance threshold from previously finalized levels. However, we do not believe this does enough. **ACP recommends CMS maintain the current MIPS performance threshold of 45 points for the 2021 performance year. ACP also reiterates its calls for CMS to establish a broad extreme and uncontrollable circumstances hardship exception for PY 2021 due to the COVID-19 PHE.** The projected sharp increase in bonuses spells out more money collected in penalties, which disproportionately impacts small practices. These penalties compound the financial stress practices are already under due to the COVID-19 pandemic. An additional nine percent penalty could be devastating. **Should CMS not approve a broad exception, it**

**should lower the MIPS performance threshold to 30 points, the 2019 MIPS performance threshold.**

That way, clinicians who experienced significant hardships for the 2019 and 2020 performance years due to the COVID-19 PHE and received exceptions will be picking back up seamlessly along CMS' trajectory—rather than facing a steep increase from 2018 MIPS performance threshold level of 15 points.

Quality Category: Using Performance Year Data for Scoring

**CMS Proposal:** CMS proposes to use actual performance year data as opposed to historic data to score quality measures for PY 2021 (only) due to the COVID-19 PHE.

**ACP Comments:** ACP generally [supports](#) the use of prospective benchmarks based on past data to score measures so clinicians are aware in advance of targets they are aiming for so they can set internal metrics and monitor progress. However, ACP also understands that the COVID-19 PHE has created a unique and unprecedented disruption in the delivery of medical services, which will impact quality performance. Accordingly, **we believe that making a one-time exception to use actual performance year data to evaluate measures is an appropriate solution to avoid unfairly penalizing practices for variations in performance compared to pre-pandemic data from past performance years. That said, ACP reiterates that this and other piecemeal accommodations to 2021 reporting alone are insufficient.**

Quality Category: Sunsetting the Web Interface Reporting Option

**CMS Proposal:** CMS proposes to sunset the web interface reporting option, including for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs). The Agency considered continuing to allow groups and virtual groups to report via web interface while ACOs would transition to the APM Performance Pathway. CMS considered sunsetting web interface for groups and virtual groups only, since ACOs account for more than 80 percent of web interface reporters. The Agency notes in the rule that it is “not fiscally viable, feasible, or sustainable” to continue web interface as a data collection type.

**ACP Comments:** **ACP strongly opposes CMS' proposal to sunset the web interface reporting option for the 2021 performance year.** First, ACP has concerns about potential adverse consequences of completely aligning MSSP reporting with MIPS reporting, which we expand on in the MSSP section of our comments. Not finalizing this change for performance year 2021 would give CMS more time to engage with stakeholders and consider the impact of some of these effects. Beyond that, with the additional challenges practices are navigating due to the COVID-19 PHE, now is not the right time to enact major changes to MIPS reporting such as eliminating a reporting mechanism, particularly one that served as the only option through which ACOs were allowed to report up to this point. Practices cannot simply flip a switch; they need time to evaluate other reporting options, talk to vendors, sign contracts, align their internal infrastructure with the new system and measure inventory, train staff, and test and troubleshoot issues. This cannot occur within the proposed timeline, which is further compounded by the delayed release of both rules. Rushing this process risks serious disruptions that could impact reporting on upwards of 12 million Medicare beneficiaries that are served by MSSP ACOs alone.

Quality Category: Bonuses and Scoring Flexibilities

**CMS Proposal:** CMS proposes to continue scoring policies and flexibilities for the Quality Category, including the three-point floor for measures that meet case minimum and data completeness requirements; improvement scoring policies; and bonus points for treating complex patients, reporting

high-priority measures, and end-to-end electronic prescribing. CMS proposes temporarily scoring flexibilities for PY 2021 due to COVID-19, including removing the cap on complex patient bonus points and only applying the seven-point cap for “topped out” measures if the measure is considered topped out for two or more years based on 2020 benchmarks *and* PY 2021 data. Total bonus points would continue to be capped at 10 points.

**ACP Comments: ACP supports these policies as proposed.** These scoring policies provide important protections for clinicians and promote strategic priorities of CMS. As CMS points out in the rule, consistency is also critical, particularly this year. The temporary flexibilities on scoring caps provide practices with additional flexibilities that are appropriate and warranted given the circumstances. We believe that continuing to cap the overall bonus points for the Quality Category at 10 points appropriately balances recognizing practices for serving patients with complex needs, particularly this year, while preserving the integrity and rigor of MIPS scoring.

*Quality Category: Measure Inventory Changes*

**CMS Proposal:** As it does every year, CMS proposes changes to the Quality Category measure inventory including “substantive changes” (changes to the specifications, title, and/or domain) to 112 measures, removal of 14 measures, and two new administrative claims measures. CMS proposes additions and changes to specialty measures sets based on stakeholder feedback.

**ACP Comments:** Having accurate, high-validity measures is paramount to accurate performance evaluation, and is a top priority of the College’s. For the past several years, ACP’s Performance Measurement Committee (PMC) has been independently reviewing MIPS quality and cost measures and rating them as valid, invalid, or of uncertain validity. ACP appreciates CMS’ removal of measures with validity, accuracy, or other integrity or clinical concerns. Specifically, we are pleased to see that CMS has removed 11 measures ACP rated as invalid with an additional measure proposed for removal in CY 2021, i.e. MIPS 390 (Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options).

Of the 56 existing measures currently included and two new measures proposed for inclusion in the internal medicine specialty set, ACP’s PMC [rated](#) 25 as valid, 13 as uncertain validity, and 18 as invalid. Two have not yet been reviewed. The Committee found that many measures aimed to capture outcomes that were extremely relevant to high quality patient care, but were flawed in their technical approach. Specific shortcomings included insufficient numerator or denominator thresholds, inaccurate intervals, and a general lack of detail, among other reasons. The PMC noted that in many cases, modest technical changes could help improve the validity of the measure and offered specific revision suggestions in many of these cases. ACP supports the removal of the 18 measures the PMC rated as invalid unless technical improvements are made (see Appendix I).

**The College believes additional clarity around what qualifies as a “substantive” change and further categorization beyond the “minor” verses “substantive” designation may help to more appropriately distinguish varying degrees of measure changes and could result in more scorable measures.** As an example, adding telehealth encounters to MIPS #006 (Coronary Artery Disease: Antiplatelet Therapy) is far different in scope from the significant number of modifications made to MIPS #236 (Controlling High Blood Pressure). Beyond helping to direct stakeholder attention to changes that are truly substantial, ACP is concerned about potential scoring implications. For PY 2021, 92 measures would have their benchmarks removed due to “substantive” changes to the measure. We are concerned that the

continuation of a dichotomous variable for measure modifications (i.e. minor versus substantive) is not sufficiently nuanced to capture the full range of modifications that could be instituted.

Finally, ACP urges CMS to temporarily halt the removal of “topped out” measures for the 2021 performance year to provide clinicians with consistency as they recover from the COVID-19 PHE, particularly those that may be aligned with future MVPs.

Quality Category: Measure Accuracy Adjustments

**CMS Proposal:** If warranted due to significant changes to clinical guidelines, measure specifications, or codes during the performance year that would impact a clinician’s ability to submit accurate data, CMS proposes to assess the measure based on nine months of data (as opposed to 12). If nine consecutive months of data were not available, CMS would suppress the measure by reducing the total available number of points for the Quality Category by 10 points for every impacted measure submitted. CMS would publish a list of measures requiring a nine-month assessment period on the CMS website as soon as technically feasible, but no later than the beginning of the data submission period, which is January 2, 2021 for PY 2020.

**ACP Comments:** ACP supports efforts not to penalize clinicians for an inability to submit data based on external factors such as significant changes to clinical guidelines or codes, including suppressing non-scorable measures. However, without more information, it is difficult for us to determine the effect that this type of change would have, or how many measures it would impact. The College is concerned that classifying too many changes as “substantive” may result in a lack of scorable measures. ACP reiterates its recommendation above that CMS create a more graduated classification that expands on the current dichotomy of minor versus substantive changes. We ask that CMS provide more detailed information about the expected scale of the impact of this change, including how many measures are expected to be impacted and how performance would shift, and to work with measure stewards to determine the most appropriate course of action in each case to yield the most accurate data.

Quality Category: Administrative Claims Measures

**CMS Proposal:** CMS proposes two new administrative claims quality measures. The hospital-wide 30-day all-cause unplanned readmission rate measure would replace the all-cause readmission measure, and an additional administrative claims-based measure for hip/knee complications would be added. The new readmission measure would have a minimum of 200 cases and apply only to groups. The hip/knee complications measure would have a minimum of 25 cases and apply to individual clinicians and groups. In all other instances, case minimums would remain at 20. The total hip/knee arthroplasty complications measure would have a three-year performance period that would start on Oct. 1 of the calendar year three years prior to the applicable performance year and conclude on Sept. 30 of the calendar year of the applicable performance year with a three-month numerator assessment period followed by a two-month claims run-out period. CMS proposes that different performance periods be considered on a case-by-case basis for administrative claims measures since they do not require active data reporting.

**ACP Comments:** ACP has [expressed concerns](#) with administrative claims measures that have been used to-date based on concerns of minimum reliability, clinical relevance, and actionability, particularly at the individual clinician level.

ACP's Performance Measurement Committee [supported](#) the initial all-cause readmission measure (1789), noting some evidence that readmission measures have reduced rates at the margins and improved population health. However, measure 1789 was designed and tested for application at the level of the facility and integrated delivery system. **The all-cause readmission measure is not suitable for attribution at the clinician or group level.** Readmissions are due to complex factors, including social determinants of health, availability of appropriate physicians for timely follow-up care, etc. that are not adequately accounted for in the risk adjustment methodology. In addition, reliability varied widely across specialties in testing and case minimums were insufficient, particularly the individual clinician case minimum of 25. Attributing the same readmission to multiple groups (i.e., plurality of inpatient care, discharging physician group, and outpatient primary care clinician) worsens rather than resolves the attribution problem as none have complete control over readmissions, particularly the discharging clinician. When the newer version of the measure was submitted for NQF consideration, a number of professional organizations disapproved of applying the measure at either the individual clinician level or group practice level. **For these reasons, ACP does not support the initial all-cause readmissions measure in its current form.**

While ACP can appreciate the issues that low-volume procedures pose for reliable and valid quality measurement, we would caution against a multi-year performance period for quality measures. A three-year performance period is far too long to provide meaningful, timely data that would help to inform quality improvement activities and convert it to a data reporting exercise.

Quality Category: CAHPS for MIPS Survey

**CMS Proposal:** For the 2021 CAHPS for MIPS Survey, CMS proposes to: 1) add a new measure to assess patient-reported use of telehealth; and 2) add telehealth services to the list of codes used for beneficiary assignment.

**ACP Comments:** ACP would support a new CAHPS measures to assess patient-reported use of telehealth, provided it is related to the use of the services only. We think it would be premature to include a measure assessing patient satisfaction with the service and would oppose using such a measure to evaluate a physician's performance. ACP generally supports using telehealth services for beneficiary assignment. Particularly given the recent eruption of telehealth services during the COVID-19 PHE, we believe this would be an appropriate way to maintain regular service patterns. However, this should be closely monitored and potentially re-evaluated in future years as the breakdown between in-person and telehealth services begins to normalize.

Quality Category: Third Party Intermediaries

**CMS Proposal:** CMS proposes to codify that as a precondition of approval, all Qualified Clinical Data Registries (QCDRs) and qualified registries must conduct annual data validation audits for all performance categories and all submission types for which it reports data. Should any data deficiencies or errors arise, the vendor would be required to perform a targeted audit to identify root causes and correct any and all deficiencies prior to submitting data to CMS. Vendors would be required to provide the results of any and all audits, as well as clinical documentation to validate that the actions or outcomes measured actually occurred or were performed. CMS also proposes new criteria for corrective action plans, which includes: (1) issues contributing to non-compliance; (2) scope of clinician impact/harms; (3) corrective actions; and (4) a detailed timeline for achieving compliance.

CMS had previously finalized that QCDRs must: 1) fully develop and test measures with complete results at the clinician level; and 2) collect data on all measures prior to submitting the measure starting with PY 2021. In its [May 8 IFR](#), CMS delayed both requirements until PY 2022. In response to stakeholder concerns, the Agency proposes in this rule a more gradual implementation approach for the first requirement regarding development and testing. Specifically, in order to be approved for PY 2022, a QCDR measure would have to be “face valid.” To be approved for PY 2023 and future years, a QCDR measure would have to be face valid for the initial MIPS payment year for which it is approved and fully tested for the second and any subsequent MIPS payment year for which it is approved. Timing for the second data collection requirement would remain PY 2022.

**ACP Comments: ACP appreciates CMS’ efforts to monitor the integrity of QCDR and qualified registry vendors and the data they submit. However, we do think it is important the Agency balance this interest with excessive reporting burden that could be passed onto practices.** For example, rather than requiring all vendors to provide clinical documentation to validate that the actions or outcomes measures for audits actually occurred or were performed, CMS may consider having vendors prepared to provide such documentation upon request, as it does for other audits. This would minimize burden on behalf of the vendors, practices they contract with, and CMS, while upholding the integrity of these audits. ACOs seek more information on the proposed new criteria for corrective action plans and how they would be quantified, particularly scope of clinician impact and/or harms.

**ACP strongly supports CMS’ delay of testing and data collection requirements, which ACP [previously raised](#) concerns as being extremely burdensome. We urge CMS to consider extending these requirements further.** Measure testing and data collection is a multi-year process that could add burden for physician practices to collect and submit this data in 2020 and 2021 as they are still dealing with the COVID-19 PHE. **ACP also strongly supports CMS’ proposal for a more gradual implementation approach for the testing requirement wherein a QCDR measure would have to be “face valid” for its initial payment year and fully tested for future payment years.** This will help to expedite the development of QCDR measures while preserving their integrity and accuracy. We ask CMS to consider applying a similar approach to the second data collection requirement.

#### Cost Category: Weighting

**CMS Proposal:** CMS proposes to increase the weight of the Cost Category (and decrease the weight of the Quality Category) by five percent compared with performance year 2020. Under current statute, CMS is required to weight the Cost Category at least 30 percent starting with PY 2022.

**ACP Comments: ACP does not support any increases to the Cost Category until concerns about the validity and accuracy of the current cost measures are resolved.** While we appreciate recent changes to the Total Per Capita Cost and Medicare Spending per Beneficiary measures, outstanding issues remain. Specifically, ACP reiterates its [past recommendations](#) that all cost measures: 1) only be attributed at the group/practice level or higher; 2) not attribute the same costs to multiple clinicians/groups; 3) risk adjust for social determinants of health; 4) meet robust minimum standards for average reliability, validity, and statistical significance; 5) be reasonably within the practice’s ability to influence; 6) have a proven impact on health outcomes; 7) provide insights into year-over-year cost reduction; and 8) have detailed testing results published in a public domain.

#### Cost Category: Inclusion of Telehealth Services

**CMS Proposal:** CMS proposes to include costs associated with telehealth services towards existing cost measures. Some telehealth services are already included. Additional proposed codes were not originally included because they were newly added to the Medicare telehealth services list in the March 31 and May 8 Interim Final Rules (IFRs), or because they were not previously billed widely prior to the COVID-19 PHE. CMS seeks comment on permanently adding remote evaluation of recorded video and/or images submitted by an established patient including interpretation with follow-up and brief communication technology-based service. CMS believes outside the context of the PHE for the COVID-19 pandemic, these monitoring/check-in services for established patients will no longer replace primary care services because these services describe a check-in directly with the billing practitioner to assess whether an office visit is needed. CMS did not consider including telephone E/M visits because these are non-covered services outside of the COVID-19 PHE.

**ACP Comments:** **ACP supports the inclusion of telehealth service costs within existing cost measures, provided necessary methodology changes are made based on a number of ACP concerns.** First, in terms of denominator eligibility, there are clear ways to identify whether a claims/registry MIPS measure applies to the telehealth setting with the use of telehealth modifiers. For those measures, if a measure does not explicitly exclude such modifiers, it will apply to physicians seeing patients in a telehealth environment. For eQMs, CMS has identified 42 out of 47 measures that are telehealth-eligible for the 2020 performance period, 39 of which are telehealth-eligible for the 2021 performance period. Current eQM standards do not allow for the use of modifiers and therefore do not clearly include or exclude telehealth encounters when these “telehealth-eligible” CPT and HCPCS codes are used.” Given the growing use of telehealth, we would strongly encourage the refinement of those standards to accommodate such distinctions. In terms of numerator compliance, [CMS guidance](#) has stated that there may be instances where the quality action cannot be completed during the telehealth visit. If an EC is providing services via telehealth but unable to complete the quality action in the numerator via telehealth, ACP strongly believes that measure should be excluded from the list of telehealth eligible measures. For example, if a physician sees a patient with POAG via telehealth but cannot complete the numerator action of the optic nerve evaluation via telehealth, the physician would fail the measure for patients being seen via telehealth since they would have a denominator eligible visit. Another example would be the flu measure, which allows for current administration of the vaccine or previous receipt. For patients that did not previously receive the flu vaccine, the measure cannot be met via telehealth. As a result, the physician would fail the measure for patients seen via telehealth since they would have a denominator eligible visit.

ACP has called for and supports the removal of measures that are unreliable and of uncertain validity based on findings by its Performance Measurement Committee (PMC), which found that only one third of 2019 MIPS measures relevant to internal medicine were valid. The PMC recently reviewed the 33 measures rated as valid for applicability to the telehealth environment, of which 23 were found to be applicable, eight were not, and two were removed from consideration. Of note, four of the eight measures that were not applicable are currently in the program as telehealth eligible and seven of the 23 measures that were determined to be applicable are not currently in the program. ACP strongly urges CMS to consider the implications for practicing physicians and make necessary adjustments so that measures that cannot be met during telehealth encounters be excluded from telehealth reporting, starting with the list provided by the PMC (see Appendix II).

*Improvement Activities (IA) Category*

**CMS Proposal:** CMS proposes that moving forward, stakeholders can nominate IAs for the duration of any PHE, including outside of the standard nomination for new activities timeframe. The Agency also proposes to consider HHS-nominated IAs on a rolling basis in order to address HHS initiatives in an expedited manner. Any HHS-nominated IAs would be subject to the same criteria and proposed through rulemaking and subject to public comment. In addition to previously finalized criteria, CMS would consider whether submitted IAs are linked to existing quality and cost measures. CMS proposes to modify “Engagement of patient through implementation of improvements in patient portal” (IA\_BE\_4) by including caregivers as potential users of the patient portal, specifying that the portal should be used for bidirectional information exchange between the patient and their provider,” and noting that the primary use of the portal should be clinical, not administrative.

**ACP Comments:** ACP supports efforts to promote the more rapid approval of new IAs, particularly during PHEs. This will help to spur innovative, timely responses that benefit patients and public health initiatives. We encourage CMS to continue to develop and adopt more IAs that encourage participation in activities intended to improve patient care during the COVID-19 PHE and help bring about an end to the pandemic. ACP supports the proposed modifications to IA\_BE\_4. We believe involving caregivers is a critical component of patient-centered care, and we also support the use of patient portals to facilitate a meaningful exchange of bidirectional, clinical information between physician and patient.

*Promoting Interoperability (PI) Category: 90-day Performance Period*

**CMS Proposal:** CMS proposes to establish a PI performance period of 90 continuous days up to and including the full calendar year, which aligns with the proposed reporting period for the Medicare PI Program for eligible hospitals and critical access hospitals (CAHs).

**ACP Comments:** **ACP remains supportive of the 90-day reporting period for the PI program and would further recommend that CMS maintain the 90-day reporting period beyond 2022.** The College believes this is a sufficient amount of time to capture the necessary information required for the PI performance category and allows for the opportunity to update or implement new and innovative technology through the course of the CY without fear of negatively impacting performance data. Likewise, this 90-day period allows flexibility for participating practices and physicians who are upgrading or replacing their health IT systems.

*PI Category: Query of Prescription Drug Monitoring Program (PDMP) Measure Remains Optional*

**CMS Proposal:** CMS proposes to retain Query of PDMP as an optional measure for PY 2021, but proposes to increase it from five to 10 bonus points to reflect its significance.

**ACP Comments:** **ACP supports CMS’ proposal to retain the *Query of Prescription Drug Monitoring Program* measure as optional for CY 2021 and supports increasing it from five to 10 points.** The College appreciates CMS’ focus on addressing the opioid crisis and agrees that PDMPs play an important role in that effort. We additionally agree that this proposed increase emphasizes the importance of the measure as it relates to improved patient safety and incentivizes clinicians to expand the use of PDMPs. **We remain concerned, however, that until information found within PDMPs is easily and seamlessly integrated into health IT systems, and this type of EHR functional-use measure will be burdensome and require multiple actions outside of the clinical workflow. ACP urges the Agency to retain this measure as optional until these concerns are addressed.**

PI Category: New Health Information Exchange (HIE) Bi-Directional Exchange Measure

**CMS Proposal:** CMS proposes to add a new HIE Bi-Directional Exchange measure as an optional alternative to two existing measures: 1) Support Electronic Referral Loops by Sending Health Information; and 2) Support Electronic Referral Loops by Receiving and Incorporating Health Information. Clinicians may choose to report the two existing measures (and associated exclusions) or report the new measure. The new measure would be worth 40 points and reported via yes/no attestation. It would require bi-directional engagement for all new and existing patients and patient records seen by the EC regardless of known referral or transition status, or the timing of any potential transition or referral. It would not allow for exclusion, exception, or allowances for partial credit. CMS would apply a flexible interpretation, and the Agency notes numerous certified health IT capabilities can support bi-directional exchange with a qualifying HIE from a participant's EHR. Certain HIE arrangements may not have the capacity to enable bi-directional exchange for every patient transition or referral made by a clinician, and thus would not meet necessary requirements. Examples include exchange networks that only support information exchange between affiliated entities, such as clinicians that are part of a single health system, or networks that only facilitate sharing between clinicians that use the same EHR vendor. Physicians would be required to use only technology considered certified under the ONC Health IT Certification Program according to the timelines finalized in the 21<sup>st</sup> Century Cures Act final rule. Physicians may use the current 2015 Edition EHRs and/or 2015 Edition Cures Update EHRs until August 2, 2022. After August 2, 2022, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

**ACP Comments:** ACP is enthusiastic about CMS' continued attempts to simplify and align the PI performance category. However, more needs to be done. Although bi-directional exchange is critical to the advancement of interoperability, **the College worries the proposed new HIE Bi-Directional Exchange measure is unworkable in real-world practice settings and is likely to be cumbersome. ACP also has concerns with several of the technical requirements of the measure,** as described below.

- CMS' proposed attestations assume clinicians know what HIEs their hospital uses, and its particular usage. This generally is not the case and puts the clinician in a position of having to defer to others with this knowledge – an unnecessary and onerous task that increases burden.
- The measure perpetuates “all-or-nothing” performance, which ACP opposes because it fails to recognize and reward meaningful performance improvement.
- The measure fails to account for the significant expense to clinicians who wish to report. HIEs are expensive, often requiring monthly or yearly subscription fees. The substantial cost can be a substantial barrier to a practice's ability to meet this measure, particularly those impacted by the COVID-19 PHE, or small, rural, or independent practices.
- The measure would require constant querying of data, which comes at huge burden and expense with little to no clinical value.
- The measure fails to account for the implications absent a certified HIE on a national level. In regions of the country, there are multiple competing HIEs. Often, there are HIE silos within states. This creates scenarios where one HIE receives the data but the other does not, requiring burdensome follow-up on behalf of the practice in order to complete the exchange. ACP encourages CMS to shift the focus from participation in individual HIEs to information flow across HIEs. Should the measure be finalized, the College encourages CMS expand the measure to include “HIEs, exchange frameworks, or other organizations focused on bi-directional health

*information exchange*” since participation in a single HIE might not meet the need of the measure to support HIE for “every patient encounter, transition or referral.” Even if a clinician engages in multiple HIEs, they may not have business agreements in place with each one. Interfacing with EHRs adds an additional layer of complexity, as well as an expensive and time-consuming undertaking for a practice. ACP supports CMS’ focus on interoperability and patient access to data, as well as its intention to give clinicians a greater flexibility while reducing their burdens. However, absent a national HIE infrastructure, this alternative HIE bi-directional exchange measure would encourage waste and add additional burden and expense for practices as currently designed.

This all said, the fact that this measure would be optional affords it important flexibilities considering its methodological imperfections. **Should CMS finalize the measure, ACP recommends it remain optional permanently, pending significant changes to address the concerns outlined above.**

**ACP also strongly supports that this measure would be yes/no attestation-based and urges CMS to continue moving in this direction for the category by introducing additional attestation-based measures.** Doing so will help minimize the reporting burden associated with reporting while encouraging innovative uses of CEHRT and other HIT. We urge CMS to consider ACP’s [past recommendations](#) to shift the category away from functional use measures that encourage the transferring of potentially copious amounts of data towards a set of more targeted, attestation-based measures that focus on how that data is leveraged to improve patient care. Importantly, this approach would introduce variety and capture other innovative uses of CEHRT and HIT as they evolve and be more targeted to specific specialties, which could facilitate the evolution to MVPs.

#### **P. APM Performance Pathway (APP)**

**CMS Proposal:** CMS proposes to terminate the MIPS APM Scoring Standard and replace it with the new APP starting in performance year 2021. The APP is designed to be an optional, complementary pathway to the MVP. Data could be reported at the clinician, group, or APM Entity level. The highest available TIN/NPI level score would apply. The final score earned by the group or APM Entity would be applied only to clinicians who appear on a MIPS APM’s Participation List or Affiliated Practitioner List on an applicable snapshot date during the performance year. Cost would be weighted zero percent; PI: 30 percent; IA: 20 percent; and Quality: 50 percent.

**ACP Comments:** ACP supports efforts to promote consistency across the QPP and to offer clinicians flexible reporting options, which reduces burden. **We support the proposal that data could be reported at the clinician, group, or APM Entity level and that the highest available TIN/NPI level score would apply.** We believe this appropriately awards credit that the clinician/practice has earned by participating in these innovative arrangements while minimizing a potentially burdensome and confusing nomination process. **However, we feel the rigidity of the design of the new APP, particularly concerning quality measurement, may inadvertently create more administrative burden,** as explained below.

#### Quality Reporting

**CMS Proposal:** All clinicians scored under the APP would be scored on the same six quality measures (described below). Measures that fail to meet specified patient population or minimum case thresholds would not be counted. Scoring caps for “topped out” measures would not apply, though those measures may be removed in future performance years.

**ACP Comments:** ACP believes having some selection of measures is critical to quality measurement that is accurate and clinically relevant and appropriate for a range of specialties and patient populations. Additionally, while ACP appreciates an effort to create overlap with required measures for various APMs such as the Comprehensive Primary Care Plus Program, these six measures are not universally required across all APMs. Accordingly, the APP would constitute an additional reporting burden beyond existing quality reporting requirements for various APMs, which each have their own distinct quality reporting requirements. While ACP appreciates the important goal of streamlining duplicative reporting, trying to fit all APMs into a one-size-fits all box of reporting has the opposite effect by stacking additional quality reporting requirements on top of existing quality reporting requirements that are specific to each APM. The only APM which CMS specifically addresses overlap of the APP for in this rule is the MSSP. It is unclear how and if quality reporting requirements for the dozens of other APMs would be affected. For these reasons, **ACP opposes CMS' proposed quality reporting approach for the new APP that would require all clinicians in MIPS APMs to report on the same six measures.**

**In addition, ACP has technical concerns with several of the measures that CMS specifically proposes for inclusion and does not support them as proposed.** Five of the six measures proposed for inclusion [were rated](#) as invalid by ACP's PMC for a variety of reasons including reliability concerns, insufficient risk adjustment – particularly when it comes to incorporating social determinants of health – and application at the individual clinician level, which is often not appropriate. We explain our specific concerns regarding each of the proposed measures in greater detail below. ACP's PMC has not yet reviewed the Risk-Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs. Generally, ACP supports and encourages the development of episode-based cost measures at the group practice level or higher for chronic conditions, which represent a substantial portion of U.S. health care expenditures.<sup>1</sup>

- **ACP does not support MIPS measure 321: CAHPS Clinician & Group Surveys.** Improving patient experience is an admirable goal. However, we question the validity of the survey process and the impact of survey results on improving patient outcomes. Specifically, implementation could promote overuse of unnecessary treatments where the potential benefits do not outweigh the risk of harms (e.g., opiate prescriptions, imaging studies). Additionally, there has not been any evidence presented to form the basis of the measure. Finally, survey results are likely to suffer from response bias and be subject to factors that are beyond physician control (e.g. parking, wait times, etc.) and be an overall poor gauge of true clinician performance.
- **ACP does not support MIPS measure 001: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9%).** While a large proportion of patients with an HbA1c >9% can indicate poor quality care, there is insufficient evidence to support the specific cutoff between acceptable versus unacceptable levels of poor HbA1c control. In addition, the measure specifications should include appropriate exclusion criteria for patients where the potential harms outweigh the benefits of treatment (e.g., patients with dementia, patients aged > 80 years, etc.). Developers should also risk-adjust for socioeconomic status and other unmodifiable factors to avoid penalizing clinicians who disproportionately treat a large percentage of patients who cannot easily achieve HbA1c measurements below nine percent.
- **ACP does not support QPP measure 134: Preventive Care & Screening: Screening for Clinical Depression and Follow-Up.** The denominator should exclude patients currently under the care

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<sup>1</sup> [www.cdc.gov/chronicdisease/about/costs/index.htm#ref1](http://www.cdc.gov/chronicdisease/about/costs/index.htm#ref1)

of a mental health specialist for comorbid illness or severe cognitive impairment and patients not seen for a face-to-face visit during the current calendar year. In addition, measure specifications do not define an appropriate screening frequency.

- **ACP does not support QPP measure 236: Controlling High Blood Pressure.** Implementation may result in measurable and meaningful improvements in clinical outcomes. There is also a known performance gap in the area of blood pressure control. However, the measure specifications do not stratify patients into well-defined risk groups (i.e., comorbid disease diagnosis). ACP additionally recommends numerator specifications include an average of several measurement results. Doing so would increase the accuracy of the measurement results and reduce the potential for overtreatment. Finally, the measure was created to assess system-level performance from a variety of settings. It is not appropriate for accountability at the individual clinician level.
- **ACP does not support the Hospital Wide, 30-Day, All-Cause Unplanned Readmissions Measure Rate.** ACP's Performance Measurement Committee [supported](#) the initial all-cause readmission measure (1789), noting some evidence that readmission measures have reduced rates at the margins and improved population health. Measure 1789 was designed and tested for application at the level of the facility and integrated delivery system. The all-cause readmission measure is not suitable for attribution at the clinician or group level. Readmissions are due to complex factors, including social determinants of health, availability of appropriate physicians for timely follow-up care, etc. that are not adequately accounted for in the risk adjustment methodology. In addition, reliability varied widely across specialties in testing and case minimums were insufficient, particularly the individual clinician case minimum of 25. Attributing the same readmission to multiple groups (i.e., plurality of inpatient care, discharging physician group, and outpatient primary care clinician) worsens rather than resolves the attribution problem as none have complete control over readmissions. The explanation for including discharging clinicians is particularly inadequate. When the newer version of the measure was submitted for NQF consideration, a number of professional organizations disapproved of applying the measure at the individual clinician level or group practice level for these reasons.

**ACP supports CMS' proposals not to count measures that do not meet specified minimum case thresholds and not to impose scoring caps.** ACP maintains that CMS should establish transparent, consistent standards for robust performance measurement. The College recommends a minimum reliability threshold of 0.75 be instituted across all measures, and case minimums be set accordingly. CMS should prioritize measures that have been proven to have the most meaningful impact on patient care and that have been independently vetted by a third-party organization such as ACP's PMC, the Measures Application Partnership (MAP), or the Core Quality Measures Collaborative (CQMC). Stakeholder input throughout measure development and implementation is paramount for accurate and effective performance measurement. **In lieu of the six quality measures proposed for inclusion in the APP, ACP encourages CMS to consider maintaining the existing 23 measures, as well as those included in [ACP's MVP proposals](#) and/or aligned with the [CQMC core set](#).**

#### MSSP ACOs

**CMS Proposal:** MSSP ACOs would be required to report through the APP for purposes of assessing their quality performance within the MSSP, as well as MIPS. Participating clinicians would have the option to report within or outside the APP at an individual or group level for being scored under MIPS.

**ACP Comments:** ACP appreciates the intent behind this proposal to create alignment across Medicare value-based program requirements. However, we have concerns about several possible unintended consequences that may result from attempting to completely align quality reporting under the MSSP and MIPS, as outlined in greater detail in the MSSP section of our comments. ACP supports the proposal to allow reporting at the clinician, group practice, or ACO level for purposes of MIPS, as it would allow clinicians more flexibility and for them to be appropriately recognized for work they are doing to improve the value of patient care both inside and outside the context of the ACO.

#### Extreme and Uncontrollable Circumstances Hardship Applications

**CMS Proposal:** Beginning with the 2020 performance year, APM Entities may submit applications for reweighting due to extreme and uncontrollable circumstances. Such applications would apply to all four MIPS performance categories and all eligible clinicians (ECs) in the APM Entity. APM Entities would have to demonstrate that 75 percent or more of its ECs are eligible for reweighting for the PI Category. If the request is approved, all ECs participating in the APM Entity would be exempted from MIPS reporting for the applicable performance period, and the APM Entity would receive a final score equal to the performance threshold and a neutral payment adjustment, notwithstanding any data submitted. CMS considered allowing an APM Entity to submit reweighting applications for individual performance categories, but rejected this approach.

**ACP Comments:** ACP strongly supports allowing APM Entities to submit applications for reweighting due to extreme and uncontrollable circumstances. However, we oppose CMS' proposal to automatically reweight all four performance categories and urge CMS to allow APM Entities to select some or all performance categories instead. This would be consistent with its reweighting policy for non-APM Entity applications and encourages data submission in cases where data for only one or a few categories are affected, such as issues related to a practice's CEHRT. ACP urges CMS to adopt the MIPS performance threshold or the score based on data submitted, whichever is higher, to avoid a potentially burdensome and confusing attestation process.

#### **Q. Medicare Shared Savings Program (MSSP)**

##### Quality Reporting and Scoring

**CMS Proposal:** As noted earlier, MSSP ACOs would be required to report through the APP for purposes of assessing both their quality performance within the program, as well as MIPS. Quality scores would be calculated based on MIPS benchmarks, as opposed to MSSP specific benchmarks. Scoring caps for "topped out" measures would not apply, though those measures may be removed in future performance years. Web Interface would be removed as a reporting option, so MSSP ACOs would select one of the other available mechanisms to report quality data. Under the new APP, all MSSP ACOs would be scored on six static quality measures (instead of 23) and actively report three measures (instead of 10). The CAHPS for MIPS survey, which currently counts as 10 separate measures and comprises 25 percent of the MSSP quality score, would count as one measure.

**ACP Comments:** In general, ACP appreciates the spirit of this proposal to streamline quality reporting and minimize burden on MSSP ACOs. We also support a number of the individual proposals. However, we do have concerns with some proposals about several potential unintended consequences.

Most acutely, we are concerned about the proposed implementation timeline, particularly given the delayed release of the final rule and the COVID-19 PHE. **ACP urges CMS to delay any proposed MSSP quality reporting changes until the 2022 performance year, particularly removing Web Interface as an available reporting option.** MSSP ACOs have been reporting via web interface since the program's start. Many may have limited familiarity with other reporting options. Moreover, many ACOs are complex networks of different practices, hospitals, and health systems. It will take time to evaluate alternative options, sign a new vendor contract, and implement a coordinated roll out across all of these entities. Less than 60 days' notice is an insufficient window of time to implement these changes successfully, especially during a global pandemic. Additionally, Web Interface requires reporting on a sample of the first 248 consecutively assigned patients. The majority of other reporting methods require reporting on 60-70 percent of all eligible patients across payers, which would represent a massive increase in reporting burden, which again, comes at a particularly inopportune time with the COVID-19 pandemic. This would mean ACOs would have to collect this data from each of its participating TINs, which would likely entail transitioning them all to the same EHR, QCDR, or qualified registry platform – a potential logistical nightmare with untold rippling effects on expense and reporting disruption that may force practices to re-evaluate their participation in the ACO. Removing the Web Interface reporting option and finalizing the other MSSP quality reporting changes within the proposed timeframe risks possible wide-scale quality reporting disruptions for MSSP ACOs.

We are also concerned about potential implications that evaluating MSSP ACOs on MIPS benchmarks would have both for ACOs and other MIPS eligible clinicians, which is exacerbated by the fact that Web Interface would no longer be an available reporting option. Currently, all ACOs are required to report via Web Interface and are scored on identical performance benchmarks, whereas MIPS quality measure benchmarks are based on the reporting modality and can vary widely, even for the same measure. ACOs are large, sophisticated, and complex systems with unique attributes that distinguish them from individual clinicians or group practices. Including them in benchmarks calculations for other MIPS reporting modalities may drastically alter benchmarks for other MIPS eligible clinicians and further exacerbate the performance gap between small practices and larger health systems. At the very least, for a change of this magnitude, the Agency should provide more data, ideally modeling past performance data that compares how benchmarks under the proposed new methodology would compare to the current methodology, both for MSSP ACOs and general MIPS benchmarks. CMS should also give stakeholders time to evaluate this information, consider the full impact of these proposals, and provide more detailed feedback. **At this time, we urge CMS to reverse its proposal to align MSSP quality benchmarks with MIPS benchmarks.**

As noted in the APP section, ACP has concerns about the inflexibility of CMS' proposal to require all clinicians reporting under the APP to report the same six quality measures. While ACP greatly appreciates CMS being responsive to stakeholder calls to reduce reporting burden, we worry that reducing the MSSP quality measures set from 23 to six measures in one performance year is a drastic change with an unforeseeable impact on quality scoring for ACOs. It also omits entire categories of quality assessment that help to drive positive patient outcomes, such as vaccinations or cancer screenings. **The College suggests a more gradual, phased reduction in which CMS would remove measures in rounds based on level of priority and evaluate the impact before proceeding with removing additional measures.**

ACP also has technical concerns with the six specific measures proposed, as explained in our comments on the APP. The following measures in the current ACO measure set were rated by ACP’s PMC as valid. **ACP encourages CMS to prioritize inclusion of these measures in any new ACO or APP measure set.**

ACO Measure #	Measure Title
ACO-8	Risk-Standardized, All Condition Readmission
ACO-14	Preventive Care and Screening: Influenza Immunization
ACO-17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
ACO-19	Colorectal Cancer Screening
ACO-20	Breast Cancer Screening
ACO-42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Data Completeness Requirements

**CMS Proposal:** ACOs would no longer automatically receive zero points for the Quality Category if they fail to report completely on all required measures, but they would receive zero points for each measure they fail to report. ACOs would receive a score between three and 10 points for each measure that meets the data completeness and case minimum requirements. Under the APP, measures that fail to meet specified patient population or minimum case thresholds would not be counted.

**ACP Comments:** **ACP does not support all-or-nothing approaches to quality scoring and supports CMS’ proposal to no longer automatically give ACOs zero points for the entire Quality Category if they fail to report a single required measure.** We feel that awarding zero points for failure to report applicable, required measures is an appropriate compromise. **We also support CMS’ proposal not to count measures that fail to meet patient population or case minimum requirements.** ACP reiterates its calls for CMS to establish consistent, rigorous standards for minimum reliability, validity, and clinical relevance that would apply across all quality measures for the MSSP and otherwise.

Minimum Scoring Standards

**CMS Proposal:** CMS proposes to eliminate the pay-for-reporting phase-in period for new measures; all six measures would be scored on a pay-for-performance basis for all ACOs regardless of contract year. The Agency would raise the minimum quality performance standard from the 30<sup>th</sup> percentile on at least one measure per domain to a total Quality score at or above the 40<sup>th</sup> percentile for all MIPS Quality scores, excluding facility-based scoring. In addition to terminating an ACO’s participation agreement if it fails to meet the quality performance standard for any two consecutive years, CMS proposes that it may also do so if an ACO fails to meet the quality performance standard for any three years within the same five-year agreement period. This new policy would also apply to “re-entering ACOs,” e.g. 50 percent or more of the participants were in the same ACO within a five-year lookback period.

**ACP Comments:** **ACP strongly opposes CMS’ proposal to eliminate the pay-for-reporting phase-in period for new measures.** This period is critical to allow ACOs time to familiarize themselves with new measures and for CMS to study the impact and make potential adjustments before using these measures to impact physician payments to help avoid potential adverse consequences. The impact and importance of this would be magnified if CMS does reduce the quality measure set in the future. While

ACP supports rigorous quality standards to ensure patients are receiving the best possible care, we do not think it is advisable for CMS to increase minimum quality standards during a global health crisis. **We urge CMS to delay any changes to minimum scoring standards until at least 2022, possibly longer, as the COVID-19 PHE crisis evolves.**

#### All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions Measure

**CMS Proposal:** CMS would use the revised All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure, which uses slightly revised measure specifications to align the ACO MCC measure with the MIPS MCC measure by: (1) adding a diabetes cohort; (2) excluding any admissions within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility; and (3) adjusting for the AHRQ socioeconomic status index and specialist density social risk factors.

**ACP Comments:** ACP's PMC has not yet reviewed the all-cause readmission for patients with multiple chronic conditions measure. However, we generally support measuring outcomes for patients with multiple chronic conditions at the group practice level or higher and also support the specific methodological changes proposed, particularly incorporating additional risk factors related to socioeconomic status and social risk factors, which has been a top advocacy priority of ACP's for many years.

#### Extreme and Uncontrollable Circumstances Policy

**CMS Proposal:** CMS proposes to adjust the extreme and uncontrollable circumstances policy so that it would apply the higher of the affected ACO's quality score or the 40<sup>th</sup> percentile MIPS Quality score, as opposed to the mean ACO score. CMS solicits feedback on alternatives that would continue to incentivize reporting, such as adjusting savings similar to losses by multiplying the maximum possible savings by the percentage of total months and beneficiaries affected.

**ACP Comments:** While ACP appreciates CMS' goal to incentivize reporting, **ACP strongly opposes CMS' changes to the MSSP extreme and uncontrollable circumstances policy as proposed**, which would effectively lower the protections for impacted ACOs and comes at a particularly tumultuous time with COVID-19. **ACP would support a similar policy that would apply the higher of either score, provided the Agency maintains the same baseline level of protection, i.e. the mean ACO score.** This would maintain current levels of protection, which is particularly critical during the midst of a global pandemic, while incentivizing ACOs to report data to improve their quality scores.

#### Adding to Covered Primary Care Services List used for Patient Assignment

**CMS Proposal:** CMS proposes to add several services to the list of primary care services for patient assignment and for other purposes. These include online digital E/M services i.e. "e-visits," assessment of and care planning for patients with cognitive impairment, chronic care management (CCM) services, non-complex CCM services, principal care management services, and psychiatric collaborative care model codes (if finalized). CMS also proposes to exclude advance care planning services when billed in an inpatient care setting because it may attribute beneficiaries based on inpatient care rather than their regular primary care clinician.

**ACP Comments:** ACP generally supports the addition of these codes to the list of primary care services, including telehealth services. We agree adding these codes will help to improve the accuracy of patient

attribution. We also agree with CMS' proposal to exclude inpatient advance care planning services to reinforce the relationship between a patient and his/her regular primary care clinician.

#### Repayment Mechanism Flexibilities

**CMS Proposal:** For renewing ACOs that wish to use their existing repayment mechanism for a new agreement period, CMS proposes to discontinue the policy that currently requires them to maintain existing repayment mechanism amounts if higher than the amount specified for the new agreement period. Starting with the 2022 application cycle, such ACOs would only be required to meet the remaining criterion, i.e. an amount equal to: (1) one percent of total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the most recent calendar year; or (2) two percent of total Medicare Parts A and B FFS revenue of its ACO participants for the most recent calendar year, whichever is less. Renewing ACOs could still choose to switch repayment mechanisms for the new agreement period. In these cases, the ACO would maintain its existing repayment mechanism at the previously required amount until it is able to terminate the first repayment mechanism, after which only the new mechanism for the ACO's current agreement period would remain. CMS is considering finalizing an additional policy that would require renewing ACOs to maintain existing, higher repayment mechanism amounts until they have fully repaid any shared losses owed for the most recent performance year. CMS is also considering finalizing provisions that would specify "re-entering ACOs" as the same legal entity as an ACO that previously participated in the program, and may therefore use that ACO's existing repayment mechanism to support its participation in a new agreement period in the MSSP. CMS proposes to allow ACOs whose agreement periods began July 1, 2019 or Jan. 1, 2020 a one-time opportunity to elect to reduce the amount of their repayment mechanisms if they elected to use an existing repayment mechanism, the original amount was greater than the new amount, and the recalculated amount for performance year 2021 is less than the existing repayment mechanism amount. If finalized, CMS will notify applicable ACOs of this opportunity to reduce their repayment mechanism amounts after the start of the 2021 performance year. Interested ACOs would submit such an election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS, likely within 30 days from the date of the written notice from CMS.

**ACP Comments:** ACP supports CMS' proposals to institute new repayment mechanism flexibilities. We agree that other enforcement mechanisms, such as possible pre-termination actions and accruing interest for not repaying shared losses, are sufficient to warrant timely repayment of shared losses. We generally support these policies as proposed, including the provision that would allow re-entering ACOs to use the original ACO's existing repayment mechanism. However, we urge CMS to consider allowing 2019 and 2020 ACOs longer than 30 days to submit elections to reduce their repayment mechanism amounts, particularly given the circumstances of COVID-19.

#### **R. Medicare Diabetes Prevention Program (MDPP)**

**CMS Proposal:** In this rule, CMS proposes to expand on and clarify flexibilities under its earlier Interim Final Rule and expand these flexibilities through the duration of the COVID-19 PHE, as well as all future health emergencies. CMS proposes that MDPP beneficiaries in their first year of MDPP services at the start of an emergency would have the choice to either restart the set of MDPP services at the beginning or resume with the relevant attendance session after the emergency period has ended. MDPP beneficiaries in their second year of MDPP services at the start of the emergency event would have to resume the set of MDPP services with the relevant attendance session. All sessions, including the first

core session and those furnished to achieve both attendance and weight loss goals, may be offered virtually during the remainder of the COVID-19 PHE and future emergency events. The limit normally placed on the number of virtual make-up sessions would not apply during applicable emergency events, so long as the virtual services are furnished in a manner consistent with all applicable CDC and other standards. MDPP suppliers could obtain weight measurements from beneficiaries through the following methods: (1) in-person; (2) via digital technology, such as “Bluetooth™ enabled” scales; or (3) self-reported weight measurements from an at-home digital scale via video. Given these new flexibilities, the Agency would end the previously finalized temporary waivers for minimum weight loss requirements. Thus, effective January 1, 2021, all MDPP beneficiaries would be required to achieve and maintain the required five percent weight loss goal in order to be eligible for the ongoing maintenance sessions, even if the COVID-19 PHE remains in place. An exception for continuing in-kind beneficiary engagement incentives would apply in cases where contact has lapsed due to a qualifying emergency event, the MDPP beneficiary is receiving services virtually, and services eventually resume or restart. All MDPP suppliers must be authorized to furnish services in-person, even if they elect to do so virtually during emergencies. This is intended to minimize disruption when the emergency ends.

**ACP Comments:** ACP strongly supports the significant flexibilities that CMS has provided for MDPP suppliers during the COVID-19 PHE and future health crises. While these flexibilities are particularly critical to the continuation of this program in a safe way during this and future public health crises, we believe that many of them, including offering services via telehealth, could help to expand patient access, particularly for those that face transportation or mobility issues, and improve the overall success of the program. **For this reason, the College urges CMS to consider making many of these proposed MDPP flexibilities available on a permanent basis.** We do support CMS’ proposal to require that all suppliers be authorized to furnish services in-person even if they are doing so virtually to minimize patient disruption and strengthen the patient-supplier relationship.

## **S. Advanced Alternative Payment Models (APMs)**

### COVID-19 PHE Flexibilities

**CMS Proposal:** Alternative Payment Model (APM) flexibilities to date have mostly been made on a model-by-model basis and are summarized in this [chart](#). They include a number of delays and adjustments to quality reporting and financial methodologies. CMS does propose in this rule to exercise enforcement discretion for Advanced APM determinations. Specifically, the Agency will not reconsider a model’s status as an Advanced APM for CY 2020 even if the APM makes changes to its governance structure or operations in such a way that it would no longer meet the criteria. Furthermore, changes made in direct response to the COVID-19 PHE will not prevent the APM from qualifying as an Advanced APM for future performance years. Aside from this, CMS proposes no additional changes to Qualified APM Participant (QP) determinations due to the COVID-19 PHE. Finally, in the event that Participation Agreement end dates are moved up in response to the COVID-19 PHE, CMS proposes not to treat this as termination from an Advanced APM and would not revoke QP status from any eligible clinicians (ECs) on that basis. CMS anticipates that the COVID-19 PHE may warrant additional APM-related changes, which the Agency may publish through additional regulations or amended Participation Agreements.

**ACP Comments:** ACP greatly appreciates the number of model-specific flexibilities CMS previously finalized for several APMs, particularly the MSSP. The College supports CMS’ proposals not to reconsider a model’s status as an Advanced APM for CY 2020 or future performance years should the APM make

changes to its governance structure or operations due to COVID-19 that would impact its ability to meet the criteria. ACP also supports CMS' proposal not to treat decisions to move up Participation Agreement end dates due to the COVID-19 PHE as termination from an Advanced APM and not to revoke QP status from any ECs on that basis. These important flexibilities will provide clinicians important assurances and protections.

However, **the College feels strongly that a more cohesive set of protections are warranted for Advanced APM participants, similar to those finalized for MIPS ECs.** ACP applauds CMS for rising to the occasion and finalizing broad-scale MIPS hardship exceptions for the 2019 and 2020 performance years due to COVID-19. The College believes CMS should issue similar protections to clinicians who are leading the transition to Advanced APMs, and in many cases have more at stake financially than clinicians in MIPS. **Specifically, ACP calls on CMS to hold all Advanced APM participants harmless from financial losses or penalties for the duration of the COVID-19 PHE, at least the 2019 through 2021 performance years. Additionally, we recommend 2019 through 2021 performance data not be used to adversely impact shared savings or other model specific payment calculations.** In all risk-bearing models, clinicians only retain a portion of the savings they themselves generate for Medicare, so this policy is unlikely to result in losses to Medicare. Importantly, it is a critical step to preserving the investment CMS and other public and private payers have made over the last several years to encourage clinician participation in APMs, particularly risk-bearing APMs. If CMS does not offer Advanced APM participants the necessary protections to weather this crisis, it may deter future clinician buy-in for Advanced APMs.

The COVID-19 PHE has shed a light on the instability of the current Medicare FFS system. ACP anticipates this may drive increased clinician interest in Advanced APMs and other innovative payment arrangements that offer more predictable payments. **CMS should be working to introduce new Advanced APMs to meet the anticipated increased demand for FFS alternatives due to COVID-19, with an emphasis on models that would address gaps in the current offering of Advanced APMs.** This includes those that engage specialty clinicians, create alignment across payers, offer opportunities for prospective payments, and encourage coordination and continuity of care across settings. The PTAC (Physician-Focused Payment Model Technical Advisory Committee) recently voted to recommend ACP's [Medical Neighborhood Model \(MNM\)](#) for testing. The MNM is a multi-payer model developed in collaboration with the National Committee for Quality Assurance (NCQA) that would offer specialty practices prospective payments for meeting advanced clinical care requirements and coordinating care with primary care partners in Medicare's CPC+ or Primary Care First programs. Importantly, the model would address each of the aforementioned strategic priorities for new APMs. **ACP implores HHS to prioritize ACP's Medical Neighborhood Model for testing. We would welcome an opportunity to work with the Department to ready the model for testing or implementation,** including addressing any outstanding concerns to improve the model's design.

#### Qualified APM Participant (QP) Thresholds

**CMS Proposal:** CMS estimates between 196,000 and 252,000 clinicians will become QPs in Advanced APMs and therefore be excluded from MIPS and qualify for the five percent Advanced APM Incentive Payment. This number is lower than estimates for 2019 and 2020, due mostly to an increase in the QP performance thresholds from 50 percent to 75 percent for the payment threshold and 35 percent to 50 percent for the patient count threshold. CMS considered, but ultimately did not propose, changes to the QP determination methodology due to the COVID-19 PHE out of concern that said changes may inadvertently pick winners and losers.

**ACP Comments:** ACP appreciates that CMS is under certain statutory obligations when it comes to QP thresholds. ACP is actively working to pursue statutory changes that would afford the Secretary of HHS more discretion in setting these thresholds in 2021 and future performance years. However, **ACP believes it is within the current statutory authority of the Secretary to change the patient count threshold. We urge the Secretary to exercise this authority to retain the current patient count threshold at 35 percent and 25 percent for QPs and partial QPs, respectively, for an additional two years through at least performance year 2022.** QP thresholds were designed to increase gradually over time to match the pace of APM development and growth. The HHS Secretary was consciously granted additional authority over the patient count threshold specifically so he/she could factor in APM development and growth in real time. Unfortunately, APM development and participation is advancing slower than originally anticipated. In 2015, the year MACRA passed, HHS [announced](#) a goal of tying 50 percent of Medicare FFS payments to APMs by 2018. According to a Health Care Learning and Action Network [report](#), the actual number was 33.6 percent, with 29.8 percent still built on a FFS architecture. From 2017 to 2020, only one national new Medicare Advanced APM was announced, the Bundled Payments for Care Improvement Advanced model. The pace has recently picked up with the Primary Care First, Direct Contracting, Kidney Care Choices, and Community Health Access and Rural Transformation (CHART) Models, set for implementation in 2021 or 2022. However, just as clinicians are gaining experience with these models, they will face steep, maximum QP thresholds. Also, the majority of these models are geared towards primary care clinicians and large integrated health networks. Before HHS allows thresholds to increase, it must provide ample opportunities to participate in Advanced APMs, particularly for practices that currently do not have such opportunities, such as specialists and small or independent practices. Additionally, [2018 QPP experience reports](#) showed average QP threshold scores for the MSSP was 44 percent for the payment threshold score, and 45 percent for the patient threshold. The Next Generation Model was similar at 49 percent and 51 percent. This would mean roughly half of current ACOs risk losing their QP status, which is especially concerning considering these two programs comprise the bulk of current Advanced APM participants. Finally, we would be remiss not to mention that maintaining the current QP thresholds for an additional two years would provide clinicians with much needed consistency as they continue to recover from the COVID-19 PHE.

#### *Revised Approach for Identifying TINs for Making Advanced APM Incentive Payments*

**CMS Proposal:** CMS proposes a revised approach to identifying TIN(s) for purposes of making Advanced APM incentive payments. Under this approach, when the QP is no longer affiliated with the original TIN through which they achieved QP status, CMS would pay TINs with which QPs are affiliated at the time the APM Incentive Payment is made. CMS also proposes to introduce a cutoff date of November 1 of each payment year, or 60 days from the day on which the initial round of APM Incentive Payments is made, whichever is later. After this point, CMS will no longer accept new helpdesk requests for payments, and clinicians will forfeit any payments earned.

**ACP Comments:** **ACP objects to CMS' proposed revised approach for identifying TINs for purposes of making Advanced APM incentive payments.** CMS explains in the rule that this change would reduce the potential burden on payee TINs to find QPs no longer affiliated with them in order to disburse the APM Incentive Payment amount, as well as payment delays. While ACP appreciates this point, strategic decisions and financial investments related to APM participation are typically made at the TIN or APM Entity level, and this structure persists as individual clinicians come and go. CMS recognized as much when it decided to pay MSSP shared savings at the ACO Entity level. Like shared savings payments, Advanced APM bonuses are often factored into the financial calculations of starting or joining an

Advanced APM, and TINs rely on this to recoup up-front investments and continue reinvesting back into the infrastructure that is necessary to support an Advanced APM. ACP believes moving payments further from the TIN that made the original strategic decision and financial investment to join the APM would run counter to the clinical care team model that the College strongly supports. ACP appreciates CMS' point that numerous NPI-TIN reassignments may occur over the timeframe between performance year and when incentive payments are made. To this, we offer alternative solutions we believe would be preferable to making payments to a TIN that had nothing to do with the APM through which a clinician attained his/her QP status. For example, rather than default to a clinician's current payment year TIN in the hierarchy, CMS could defer instead to the TIN through which the clinician was assigned during the relevant performance year, even if the NPI is no longer affiliated with that TIN. This would solve CMS' problem of searching for TIN/NPI combinations that no longer exist and tracking down new TIN-level assignments while reinforcing the clinical care teams model. It may also give practices more assurance to join Advanced APMs if attrition of incentive payments from individual NPIs is no longer a concern. In any case, making incentive payments earlier in the payment year which would help to shorten this period and lessen the window for NPI-TIN changes.

**ACP strongly objects to CMS' proposed 60-day cutoff for new help desk requests for Advanced APM incentive payments earned.** This cutoff appears both arbitrary and far too short, particularly given the way APM incentive payments are made, i.e. to the payee TIN in a one-time lump sum as opposed to a percentage-based payment adjustment that clinicians would have all year to notice. If payment is not received, the payee TIN must immediately realize this and coordinate with all participating downstream clinicians and TINs to fully assess the scope of the situation. Sixty days does not provide a sufficient window within which to orchestrate all of this. CMS' proposal to change the APM incentive payment methodology stands to obfuscate this process even more. **ACP recommends an alternative cutoff as the date Advanced APM payments for the following performance year are announced.** This will provide a clear cutoff point and avoid incentive payments from rolling over year-to-year while providing Advanced APM Entities and participating clinicians ample time to realize if they were owed an incentive payment that was not paid. Once again, making Advanced APM incentive payments earlier in the year would be advantageous on both sides, as it would allow CMS to close their books on the previous year faster.

#### *New Limited Targeted Review Request Process for Qualified APM Participant (QP) Determinations*

**CMS Proposal:** CMS proposes to establish a new limited targeted review request process for QP determinations solely for cases in which an EC or APM Entity believes in good faith that, due to a CMS clerical error, an EC was omitted from a Participation List used for purposes of QP threshold determinations. CMS may request additional information, which must be provided and received by CMS within 30 days. Otherwise, a final decision will be made based on information available. If CMS identifies a pattern of error affecting EC(s) not directly involved in the initial review request, CMS would correct any identified errors for all ECs. If CMS determines a clerical error was in fact made, the Agency would assign the impacted EC the most favorable QP status determined for that APM Entity for the relevant QP Performance Period. CMS would not recalculate the QP Threshold Score for the entire APM Entity. The timing for the QP Determination targeted review process would align with the MIPS targeted review process, after which there would be no opportunities for further review or appeal. CMS does not propose to conduct targeted reviews of potential omissions for Other Payer Advanced APMs.

**ACP Comments:** ACP greatly appreciates CMS' proposal to establish a targeted review request process for QP determinations, which is something ACP has advocated for in the past. However, the College has concerns that the scope is too limited. Specifically, we believe clinicians should be able to submit

targeted reviews both if they believe they were arbitrarily omitted from a participation list, as well as if they believe CMS may have made a calculation error that could impact their status as a partial QP or QP. Additionally, if an error in the participation list was discovered that may make the difference for an APM Entity to qualify as a QP or partial QP, a recalculation of the QP threshold score should occur. Clinicians should not miss an incentive payment they rightfully earned, often at significant expense and effort, due to a clerical error. ACP supports CMS' proposal to apply the most favorable QP status determined. We believe this will simplify the process and minimize potential adverse consequences.

#### Partial QP determinations

**CMS Proposal:** To date, CMS' method for contacting Partial QPs has been to send letters to APM Entity contacts. The Agency is considering options to make the Partial QP election process less burdensome. CMS seeks comment on whether to allow an APM Entity to make the Partial QP election on behalf of all of its ECs and how to handle potentially conflicting elections.

**ACP Comments:** ACP appreciates CMS' desire to make the Partial QP election process less burdensome and agrees that this is important to consider at this time as more clinicians will likely be falling into this category as a result of the proposed increase in QP thresholds. **ACP favors a minimally burdensome approach in which CMS would apply either the MIPS performance threshold score, or the score a clinician, practice, or APM Entity would earn based on data submitted, whichever is higher.** This aligns with CMS' facility-based scoring policy and would appropriately recognize clinicians for their efforts to advance value-based objectives to improve patient care while minimizing possible adverse consequences and avoiding a potentially burdensome, confusing election process.

#### **In Conclusion**

Thank you for this opportunity to comment on CMS' notice of proposed rulemaking regarding changes to the Medicare Physician Fee Schedule and Quality Payment Program for Calendar Year 2020 and beyond. We are confident these recommended changes would improve the strength of these proposals and help promote access to affordable care for Medicare patients, while supporting physicians in their ability to deliver innovative care and protecting the integrity of the Medicare trust funds. We appreciate this opportunity to offer our feedback and look forward to continuing to work with the Agency to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Director, Regulatory Affairs for the American College of Physicians, at [boutland@acponline.org](mailto:boutland@acponline.org) or 202-261-4544 with comments or questions about the content of this letter.

Sincerely,



Ryan D. Mire, MD, FACP  
Chair, Medical Practice and Quality Committee  
American College of Physicians

## **Appendix I:**

### **Measures Found Not to be Valid in IM Specialty Set As Reviewed by ACP's Performance Measurement Committee**

1. MIPS 009: Anti-Depressant Medication Management
2. MIPS 126: Diabetic Foot & Ankle Care, Peripheral Neuropathy—Neurological Evaluation
3. MIPS 130: Documentation of Current Medications in the Medical Record
4. MIPS 154: Falls: Risk Assessment
5. MIPS 155: Falls: Plan of Care
6. MIPS 181: Elder Maltreatment Screen and Follow-up Plan
7. MIPS 277: Sleep Apnea: Severity Assessment at Initial Diagnosis
8. MIPS 279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy
9. MIPS 305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment
10. MIPS 317: Preventive Care & Screening: Screening for High Blood Pressure and Follow-up Documented
11. MIPS 318: Falls: Screening for Future Fall Risk
12. MIPS 370: Depression Remission at Twelve Months
13. MIPS 374: Closing the Referral Loop: Receipt of Specialist Report
14. MIPS 383: Adherence to Antipsychotic Medications for Individuals with Schizophrenia
15. MIPS 398: Optimal Asthma Control
16. MIPS 401: Hepatitis C: Screening for Hepatocellular Carcinoma in Patients with Cirrhosis
17. MIPS 441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)
18. MIPS 468: Continuity of Pharmacotherapy for Opioid Use Disorder

## Appendix II:

### MIPS Quality Measures Applicable for Telehealth Reporting Based on Review by ACP's Performance Measurement Committee

#### Measures approved for telehealth applicability

- MIPS 243; NQF 0643: Cardiac Rehabilitation: Patient Referral from an Outpatient Setting
- MIPS 112; NQF 2372: Breast Cancer Screening
- MIPS 113; NQF 0034: Colorectal Cancer Screening
- MIPS 005; NQF 0081: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker Therapy for Left Ventricular Systolic Dysfunction
- MIPS 008; NQF 0083: HF: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction
- MIPS 007; NQF 0070: Coronary Artery Disease (CAD): Beta-Blocker Therapy - Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)
- MIPS 107; NQF 0104: Adult major Depressive Disorder (MDD): Suicide Risk Assessment
- MIPS 117; NQF 0055: Diabetes: Eye Exam
- MIPS 119; NQF 0062: Diabetes: Medical Attention for Nephropathy
- MIPS 387: Annual Hepatitis C Virus Screening for Patients who are Active Injection Drug Users
- MIPS 400; NQF 3059e: One-Time Screening for Hepatitis C Virus for Patients at Risk
- MIPS 338; NQF 2082: HIV Viral Load Suppression
- MIPS 275: Inflammatory Bowel Disease: Assessment of Hepatitis B Virus Status Before Initiating Anti-Tumor Necrosis Factor Therapy
- MIPS 418; NQF 0053: Osteoporosis Management in Women who had a Fracture
- MIPS 039; NQF 0046: Screening for Osteoporosis for Women 65-85 Years of Age
- MIPS 438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease
- MIPS 402: Tobacco Use and Help with Quitting Among Adolescents
- MIPS 226; NQF 0028: Tobacco Use: Screening & Cessation Intervention
- MIPS 431; NQF 2152: Unhealthy Alcohol Use: Screening & Brief Counseling
- MIPS 176; NQF 2522: Rheumatoid Arthritis: Tuberculosis Screening
- MIPS 177; NQF 2523: Rheumatoid Arthritis: Assessment of Disease Activity
- MIPS 178; NQF 2524: Rheumatoid Arthritis: Functional Status Assessment
- MIPS 050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65+

#### Measures NOT recommended for telehealth applicability

- MIPS 444; NQF 1799: Medication Management for People with Asthma
- MIPS 116; NQF 0058: Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis
- MIPS 320; NQF 0658: Appropriate Follow-Up for Normal Colonoscopy in Average Risk Patients
- MIPS 309; NQF 0032: Cervical Cancer Screening
- MIPS 443: Non-Recommended Cervical Cancer Screening in Adolescent Females
- MIPS 419: Overuse of Neuroimaging for patients with Primary Headache and a Normal Neurological Evaluation
- MIPS 333: Adult Sinusitis: CT for Acute Sinusitis (Overuse)
- MIPS 110; NQF 0042: Influenza Immunization