



September 26, 2019

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 2020 Revisions to Payment Policies under the Physician Fee schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations [CMS-1715-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 159,000 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. Evaluation and Management (E/M) Payment and Documentation Proposals

- **ACP applauds CMS for their updated E/M payment proposals and recommends the Agency finalize acceptance of the E/M codes, Current Procedural Terminology (CPT) guidelines, and Specialty Society Relative Value Scale Update Committee (RUC) recommended values exactly as implemented by the CPT Editorial Panel and submitted by the RUC.** ACP fully supports CMS' proposal to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel.
- The College greatly appreciates CMS working to address the significant problems with the documentation of E/M visits and proposing to allow the choice of medical decision making (MDM) or time to decide the level of office/outpatient E/M visit, along with updated guidelines for both. **We strongly support the proposal to eliminate use of history and/or physical exam for purposes of determining the level of E/M code.**
- **ACP recommends CMS provide additional clarity on what will be accepted for time-based and MDM-based documentation, either in the final rule or through sub-regulatory guidance.** Further, CMS should work to ensure that the auditing guidelines and procedures are updated and aligned to focus on both time-based and MDM-based notes, as well as applied consistently by all auditing organizations.

B. Practice Expense Direct Inputs

- **ACP respectfully disagrees with CMS' decision to decline to accept the desktop computer used in examination rooms as a direct medical expense.** The computer is dedicated to each individual patient throughout the visit to collect history, share and discuss lab and test results, and document the visit. It is an essential tool in conducting today's office visits and should be recognized as a direct medical equipment cost.

C. Care Management Services

- Physicians and their staff have been increasingly engaging in non-face-to-face services such as care management services because they are critically important to keeping patients healthy and saving costs down the road by reducing unnecessary hospital admissions, readmissions, and emergency room visits. ACP supports efforts to expand care management services to improve quality of care for more patients. CMS should expand use of these services by leveraging expected future savings to offset the cost of new reimbursable Principal Care Management (PCM) codes. **CMS could work with Congress to devise a plan to return funds saved in Medicare Part A back to Part B in the form of positive updates to the Medicare conversion factor, while maintaining the integrity of the valuation within the resource-based relative value scale (RBRVS).**

D. Additional Physician Fee Schedule (PFS) Recommendations

- **ACP recommends that requests to increase the valuation of E/M or other services be subject to additional survey and review. A list of these identified services should be published in the final 2020 PFS rule.** CMS should not make systematic adjustments to services without allowing for review by specialty societies and collaborating with the CPT Editorial Panel and RUC. Any valuation of codes should first require a review of the coding structure to assure it aligns with modifications to the corresponding office visits.
- ACP supports provisions in the proposed rule that would help in the fight to prevent opioid abuse and addiction, including increased access to treatment programs for opioid addiction and substance use disorders.
- ACP understands the importance of ensuring patient safety in all clinician and supplier settings. **However, ACP believes it is excessively severe to revoke or deny a physician or eligible professional's enrollment if he/she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care.** Finalizing the policy as written would allow for automatic revocation of billing privileges or enrollment denial based on very modest sanctions, without taking into account the nature of patient harm, possible misconduct, or severity of disciplinary actions imposed. **The College strongly encourages CMS to work with the physician community and stakeholders prior to finalizing any policy that would revoke or deny eligibility to participate in the Medicare program.**

E. Quality Payment Program (QPP) Recommendations

- **Do not mandate the Merit-based Incentive Payment System (MIPS) Value Pathway (MVP), especially in 2021.** Keep the MVP optional. At a minimum, create a multiyear pilot and offer MIPS credit for testing MVPs. Retain key flexibilities to smooth the transition and allow additional opportunities for stakeholder input.
- **Finalize a delay of the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure until 2021** to allow time to solicit stakeholder input and address past ACP concerns.
- **Remove unreliable, invalid measures, but do so only after working with stakeholders and measure developers to improve or increase reporting of the measure.** Consider whether removing a measure would adversely impact a particular specialty's ability to fully participate in MIPS.

- **Reverse proposals to reject Qualified Clinical Data Registry (QCDR) measures if the developer does not sign a licensing agreement or it is not fully tested prior to implementation. Encourage development and reporting of new measures** by setting prospective benchmarks or awarding improvement activity credit or bonus points.
- **Transform the Promoting Interoperability (PI) Category into attestation-based menu measures** that align with the other categories; support emerging Electronic Health Record (EHR) capabilities; and encourage transferring relevant, actionable data at the point of care. Award credit for leveraging Certified EHR Technology (CEHRT) to report quality and cost data or perform improvement activities.
- **Do not increase the data completeness requirement for quality measures from 60 to 70 percent**, which would increase reporting burden on clinicians with no clear benefit to patient care at a time of great volatility with the impending MVP changes. This change would disproportionately impact small practices and make practices less able to overcome temporary reporting glitches.
- **Increase the minimum reliability threshold for all measures, particularly cost measures. ACP recommends a minimum of at least 0.75.** Evaluating clinicians on unreliable measures is dangerous and could result in myriad unintended consequences.
- **Overhaul risk adjustment and patient attribution methodologies.** Hierarchical condition category (HCC) coding fails to adequately capture social and other important risk factors. ACP supports voluntary, prospective assignment, particularly through the use of patient relationship codes, and urges CMS to develop and implement these codes with all due expediency.
- **Eliminate the Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost (TPCC) measures, which inappropriately attribute broad downstream costs to clinicians and practices.** Condition- or specialty-specific measures more effectively gage the costs clinicians are able to influence.
- **Refrain from increasing the weight of the Cost Category while it is undergoing a major transformation.** Maintain current category weights or reweight Cost to zero until the implications of these changes can be evaluated and better understood.
- **Before increasing MIPS performance and exceptional performance thresholds, CMS has a responsibility to address the deeply concerning performance gap for small practices**, which in 2017 was 30 points lower than the average overall MIPS performance score. It is clear CMS must take a more comprehensive approach to supporting small practices, such as evaluating small practices separately within MIPS, or establishing separate MIPS performance and Qualified APM Participant (QP) thresholds.

- **Do not increase the threshold for groups to attest to completing an improvement activity from one clinician to 50 percent of the group’s clinicians.** Often, activities that are supported by one clinician can greatly benefit the entire practice and its patients.
- **Reverse several proposals that would add substantial confusion and reporting burden for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs),** including replacing the MSSP quality score with the MIPS quality performance score, raising the minimum quality threshold to determine if an ACO is eligible to share in savings, and eliminating a one-year exemption from minimum quality requirements.
- **Avoid proposals that only seek to limit the number of clinicians that earn QP status,** including excluding certain expected expenditures from counting toward the benchmark for purposes of evaluating financial risk, excluding “small” losses from marginal risk calculations, and requiring private sector medical homes to formally partner with CMS in order to qualify under the medical home standard for the All-Payer Combination Threshold Option.
- **Reverse plans to only apply Partial QP status to the taxpayer identification numbers (TIN) through which a clinician achieves partial QP status,** which would mean clinicians would still be expected to participate in MIPS or face a penalty for any non-Alternative Payment Model (APM) TINs. ACP urges CMS to instead apply a policy similar to its facility-based scoring approach in which it would automatically apply the most advantageous score.
- **Offer clinicians whose QP status would be impacted by an APM Entity that terminates prematurely a one-year exemption from MIPS to encourage clinicians to experiment with participating in new APMs.** Individual clinicians have virtually no control over whether their APM Entity terminates and would have little recourse to participate in MIPS if the APM Entity terminates and fails to report on their behalf during or after the performance year.

II. PFS Detailed Recommendations:

A. Determination of Practice Expense Relative Value Units (PE RVUs)

CMS Proposals: In the Proposed Rule for CY 2019, CMS used their authority under Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) to initiate a market research contract with a consulting firm, StrategyGen, to update the direct practice expense (PE) inputs for supply and equipment pricing. Based on the report from StrategyGen, CMS proposed to update pricing for 2,017 supply and equipment items currently used as direct PE inputs. Market research resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis. CMS proposed to update supply and equipment pricing over a four-year phase-in period.

ACP Comments: ACP recognizes that this pricing update is the first comprehensive review of supply and equipment prices since 2004/2005. The RUC PE Subcommittee does not evaluate pricing. Rather, it collects the information and submits it to CMS as part of the RUC recommendation process. This process, although not comprehensive, represents collaboration between physicians and CMS. ACP agrees with CMS that there is a need for comprehensive review of supply and equipment pricing and, in general, supports CMS' efforts to this effect. However, ACP is concerned that supply and equipment pricing will quickly become outdated once the transition to updated prices is complete in 2022. **Therefore, ACP recommends CMS move to an ongoing process for updating costs for all supplies, equipment, and clinical labor staff that would be open for public comment through the formal rulemaking process.**

CMS Proposals: In the Proposed 2020 PFS Rule, CMS received invoice submissions for approximately 30 supply and equipment codes from stakeholders as part of the second year of the market-based supply and equipment pricing update. The invoices were reviewed and researched by StrategyGen and based on this research, CMS is proposing to update the prices of 36 supply and equipment items as listed in Table 9.

ACP Comments: ACP believes it is extremely important to identify supply and equipment items that may be inaccurately priced. To this end, **ACP strongly encourages CMS to continue to carefully consider *all* pricing data, including invoices and other supporting evidence that they receive from the specialty societies throughout this comment period and the entirety of the four-year transition period.**

B. Care Management Services

Care management services provide patients with high quality care and play a large role in preserving the Medicare trust funds by reducing hospital admissions, readmissions and, emergency room visits. For this reason, physicians and their staff have been increasingly engaging in non-face-to-face services. ACP supports efforts to increase utilization of these services by expanding care management services to additional patients. CMS should account for the future savings these services generate in decreased hospital visits and emergency visits

by using them to offset the cost of developing new, reimbursable Primary Care Management (PCM) codes. **CMS should work with Congress to devise a plan to return funds saved in Medicare Part A back to Part B in the form of positive updates to the Medicare conversion factor, while maintaining the integrity of the valuation within the RBRVS.**

In finalizing a policy to allow additional reporting of concurrent care management codes, **ACP recommends the Agency issue very clear guidance to assist physicians in understanding what each code represents to avoid overlapping the use of multiple codes in describing the same service.** For example, when reporting time-based codes, the same minute should only be counted once. **ACP is willing to work along with the Agency in preparing this guidance.**

In the proposed rule, CMS lists the following care management service codes as available to physicians:

- Care Plan Oversight (Healthcare Common Procedure Coding System (HCPCS) Codes G0181, G0182)
- ESRD Monthly Services (CPT Codes 90951-90970)
- Transitional Care Management (CPT Codes 99495, 99496)
- Chronic Care Management (CPT Codes 99487, 99489, 99490, 99491)
- Advance Care Planning (CPT Codes 99497, 99498)
- Behavioral Health Integration (CPT Codes 99484, 99492, 99493, 99494)
- Assessment/Care Planning for Cognitive Impairment (CPT Code 99483)
- Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (CPT Codes 99358, 99359)
- Remote Patient Monitoring (CPT Code 99091)
- Interprofessional Consultation (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452)

i. Transitional Care Management (TCM) Services

CMS Proposals: CMS examined studies which concluded that patients who receive TCM services have lower hospital readmission and mortality rates and therefore incur lower costs. Based on these findings, CMS seeks to increase the utilization of TCM services and expand payment for care management in general. To incentivize additional utilization, CMS would modify billing requirements to allow TCM codes to be reported concurrently with other codes. CMS also proposes to increase the work relative value unit (RVU) of TCM services from 2.11 to 2.36 for CPT code 99495 and 3.05 to 3.10 for CPT code 99496, as recommended by the RUC.

ACP Comments: **ACP appreciates CMS' proposal to adopt RUC recommendations that will lead to increased valuation of TCM services and strongly recommends CMS finalize these values as proposed.**

ii. Chronic Care Management (CCM) Services

CMS Proposals: CMS proposes to adopt a new add-on code for CCM services that would allow clinicians to bill incrementally. In conjunction with the creation of the new add-on code, CMS proposes to replace the single existing CCM CPT code 99490 and replace the current CPT codes for complex CCM services (99487 and 99489) with G codes. CMS requests comment on whether to implement G codes for these expanded CCM codes for 2020 or wait for anticipated changes to CPT in 2021. CMS also proposes to clarify the language describing the comprehensive care plan required for all CCM codes. Specifically, they propose to clarify that care plans may include but are not limited to the following elements:

- A problem list
- Expected outcome and prognosis
- Measurable treatment goals
- A cognitive and functional assessment
- Symptom management
- Planned interventions
- Medical management
- Environmental evaluation
- Caregiver assessment
- Requirements for periodic review
- Revision of the care plan (if applicable)
- Interaction and coordination with outside resources and practitioners

ACP Comments: ACP is pleased that CMS is considering adopting an add-on code for CCM services, which would allow clinicians to bill incrementally in order to reflect additional time resources. Additionally, the College supports proposals to create two new G codes to replace the single existing CPT code 99490 and replace the current CPT codes for complex CCM services (99487 and 99489) with two new G codes. The College believes these changes would not require substantial care plan revision and will improve payment accuracy and incentivize the use of CCM services, which will lead to improved patient care. Regarding the timing of implementing the new G codes, we feel the benefits of creating G codes for 2020 outweigh the downside of waiting for the new CPT codes. Additionally, we believe creating interim G codes will help to facilitate earlier implementation and will make transitioning to the CPT codes easier once they become available. The College appreciates CMS proposing to clarify what a CCM care plan typically includes, including what elements typically comprise a standard care plan.

ACP strongly recommends CMS create the proposed temporary G codes, which would allow clinicians to bill incrementally to reflect additional time resources, improve payment accuracy, and incentivize the use of CCM services, which will lead to improved patient care. The College strongly supports CCM services and is encouraged that the initial CCM code 99490 has already increased from 1 million in claims in 2015 to 4 million in claims in 2018. We recognize that additional changes to CCM may be warranted. Therefore, we encourage CMS to work with the CPT Editorial Panel to describe the services, create CPT codes, and consider data on appropriate valuation for 2021. Additionally, ACP recommends that CMS adopt the proposed changes to the CCM care plan that are in line with physician burden reduction and not require a substantial revision to the patient care plan for CCM services.

iii. Principal Care Management (PCM) Services

CMS Proposals: CMS proposes to create two new codes for PCM services that would pay physicians for providing care management to patients with a single, high-risk disease. The current CCM codes require patients to have two or more chronic conditions. CMS estimates an additional \$125 million in annual spending for these services, offset by reductions to the Medicare conversion factor. CMS proposes this new time-based code concurrently with a proposed new add-on code to each office visit code for similar patients. It is important that the service be appropriately described without overlap with other services.

ACP Comments: ACP believes there is a gap in coding and payment for care management services. The current CCM codes require patients to have two or more chronic conditions. We agree with CMS' proposal to establish separate coding and payment for PCM services, which describe care management services for one serious chronic condition. **Therefore, ACP recommends that CMS move forward with the proposal to create the two new codes for PCM services. ACP further recommends that CMS and specialty societies work together to transition away from G codes for this service to CPT codes as quickly as possible.** The February 2020 CPT meeting is a feasible target date for consideration and, if adopted, a survey for resource costs could be completed in time for the April 2020 RUC meeting. CMS should include these recommendations for comment in 2021 PFS rulemaking.

iv. Chronic Care Remote Physiologic Monitoring Services

CMS Proposals: In September 2018, the CPT Editorial Panel revised the code structure for CPT code 99457 effective beginning in 2020. The new code structure retains CPT code 99457 as a base code that describes the first 20 minutes of treatment management services, and uses a new add-on code to describe subsequent 20 minute intervals of the service. CMS previously valued the base code (99457) at 0.61 work RVUs and is proposing a work RVU of 0.50 for the proposed new add-on code. CMS further proposes the RUC-recommended direct PE inputs for CPT code 994X0 (the add-on code). Finally, CMS proposes that remote patient monitoring (RPM) services reported with CPT codes 99457 and 994X0 may be furnished under general supervision, rather than direct supervision, as is currently required. The changes to these codes are summarized in the table below.

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes	0.61	0.61

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
994X0	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)	0.50	0.61

ACP Comments: The physician work for 994X0 is the same as 99490 CCM services; at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional (QHP) per calendar month (work RVU = 0.61 and 23 minutes total time). Additionally, the typical patient receiving 994X0 has a chronic disease—for example, heart failure—and has a chronic heart failure management device at home to prevent hospitalization. Thus, **ACP recommends that CMS accept a work RVU of 0.61 for CPT code 994X0.**

C. Comment Solicitation on Opportunities for Bundled Payments under the PFS

CMS Proposals: CMS requests information on opportunities to expand the concept of bundling to improve payment for services under the RBRVS. Specifically, CMS seeks to explore options for establishing Medicare fee schedule payment rates or adjustments for services that are furnished together. CMS notes options could include a per-beneficiary payment for multiple services or condition-specific episodes of care.

ACP Comments: ACP generally supports the idea of exploring innovative payment arrangements within the traditional FFS architecture that reward the delivery of high-quality, cost effective care while smoothing the transition to participation in APMs. However, when selecting which conditions or services to include in the initial pilot bundles, CMS should carefully consider how payment will work in cases where conditions are co-managed by a patient’s primary care physician and a specialist, and how this might affect attribution. ACP strongly urges CMS to make such initiatives voluntary and underscores the importance that payment rates must be sufficient to cover the work, including face-to-face services as well as the range of services that goes on behind the scenes to better coordinate care and thus achieve better health outcomes.

Over ten years ago, the RUC, via the Relativity Assessment Workgroup, began identifying services that are inherently performed together by the same physician on the same date of service. Specialty societies are best able to determine if there are opportunities for development of new CPT codes to describe an episode of care. All stakeholders, including CMS, the CPT editorial panel, and specialty societies, must work collaboratively in order for these efforts to be successful.

D. Payment and Documentation Proposals for E/M Services

CMS Proposals: Effective January 1, 2021, CMS proposes to adopt the CPT Editorial Panel-recommended revisions to office/outpatient E/M code descriptors, prefatory language, and accompanying interpretive guidelines, which would govern what determines different levels of medical decision making (MDM) for office/outpatient E/M visits. CMS proposes to accept the RUC-recommended values for work, physician time, and practice costs for the stand-alone E/M office visits. CMS would retain five levels of coding for established patients, reduce to four levels for new patients (by deleting 99201), and revise code definitions and documentation guidelines. A new CPT code for extended office visit time would also be implemented.

Regarding the E/M documentation updates, CMS proposes to allow the choice of MDM or time to decide the level of office/outpatient E/M visit, along with updated CPT documentation guidelines for both options. These updates are based on the recommendations of the American Medical Association (AMA) Workgroup, of which ACP was an active participant. The MDM sub-components were not materially changed, but extensive edits were made to the elements for code selection along with numerous revisions and clarifications. For example, ambiguous terms and concepts such as “mild” were clarified (e.g. “acute or chronic illness with systemic symptoms”) and important terms like “independent historian” were formally defined. Data elements were also redefined to focus on tasks that affect patient management (e.g., independent interpretation of a test performed by another physician or clinician and/or discussion of test interpretation with an external physician/QHP). To minimize disruption, the current CMS Table of Risk was used as a foundation for the MDM requirements and current CMS contractor audit tools were consulted. The definition of time is minimum time, not typical time, and represents total physician/QHP time on the date of service. The use of date-of-service time builds on the movement over the last several years by Medicare to more accurately recognize the full scope of work involved in non-face-to-face services such as care coordination. These definitions would only apply when code selection is primarily based on time, not MDM.

ACP Comments: The College commends CMS for proposing to adopt RUC-recommended work, physician time, and practice cost values for the stand-alone E/M office visits. CMS states in the rule: “the RUC recommendations reflect a rigorous robust survey approach, including surveying over 50 specialty societies, demonstrate that office/outpatient E/M visits are generally more complex, for most clinicians.” One of the most consistent findings of the survey was that all specialty data indicated an increased complexity and time spent in providing office visits. **We urge the Agency to finalize acceptance of the E/M codes, CPT guidelines, and RUC recommended values exactly as implemented by the CPT Editorial Panel and submitted by the RUC. Moving forward, the College recommends CMS work with the medical community to urge Congress to implement positive updates to the Medicare conversion factor to offset the deserved increases to office visits.**

The College greatly appreciates CMS working to address the significant problems with documentation of E/M visits and proposing to allow the choice of medical decision making or time to decide the level of office/outpatient E/M visit, along with updated guidelines for

both. We strongly support the proposal to eliminate the use of history and/or physical exam for purposes of determining the level of E/M code. While the physician’s work in capturing the patient’s pertinent history and performing a relevant physical exam would contribute to both the time and MDM, we agree these elements alone should not determine the appropriate code level. The College has outlined these issues over the course of the past several years including in a 2015 paper entitled “*Clinical Documentation in the 21st Century*” published in the *Annals of Internal Medicine*¹ and in numerous comment letters and discussions with CMS and the Office of the National Coordinator for Health Information Technology (ONC). This has also been a core component of our *Patients Before Paperwork Initiative*,² as outlined in our 2017 policy paper, “*Putting Patients First by Reducing Administrative Tasks in Health Care.*”³

The College remains committed to working with CMS and other key stakeholders, including private payers, EHR vendors, clinician organizations, and patients, to improve clinical documentation and reduce burden. Since CMS’ initial proposals in the 2019 PFS proposed rule, ACP has formed a task force focused on developing resources to promote clinical documentation that tells the patient’s story in a meaningful manner while developing strategies for the effective dissemination and uptake of best practices in documentation. Another component of ACP’s work in this area, led by an ACP member advisory group, is to develop recommendations for modifications to electronic health records (EHRs) and health information technology (IT) that leverage the recent documentation proposals to improve the clarify and value of documentation while decreasing burden and furthering EHR usability and interoperability to facilitate better patient care.

CMS’ proposals present a unique opportunity to reexamine clinical documentation requirements to simultaneously lower the burden for physicians while improving its usefulness for clinicians and patients alike. The College applauds the Agency for its efforts to move the needle forward in this area. While these proposals are an important first step, the College a number of critical next steps are needed in order to fully operationalize and achieve the desired outcomes of these proposed updates. A key concept to consider when addressing documentation reform is that the guidelines themselves are burdensome, but there is also a great deal of burden associated with the lack of clarity and resulting differing interpretations around what is required. A recent article⁴ published in *the Journal of the American Medical Association* discussed the disconnect between the actual physician-patient encounters and what is documented in the note, concluding that payers should consider removing financial incentives that promote lengthy and verbose notes. Removing requirements for history and physical exam, as well as providing the option to document based on time or MDM will help to address these issues to a certain extent. However, there is still a lack of clarity and consistency around what will actually be accepted for these various options. The College fears that these

¹ <https://doi.org/10.7326/m14-2128>. <http://annals.org/aim/fullarticle/2089368/clinical-documentation-21st-century-executive-summary-policy-position-paper-from>

² <https://www.acponline.org/advocacy/where-we-stand/patients-before-paperwork>.

³ <https://doi.org/10.7326/m16-2697>. <http://annals.org/aim/fullarticle/2614079/putting-patients-first-reducing-administrative-tasks-health-care-position-paper>

⁴ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2751388>

updates will not be utilized due to fear of audits and financial penalty, resulting in little substantive change.

ACP recommends CMS provide additional clarity around what will be accepted for both time-based and MDM-based documentation, either in the final rule or through sub-regulatory guidance. Useful clarification should include a clear understanding of what is needed within the note to qualify to bill a certain level of code (and whether data stored within other areas of the EHR will qualify), as well as a baseline for what will be considered clinically appropriate. **Moreover, ACP recommends CMS work to ensure that the auditing guidelines and procedures are updated and aligned to focus on both time-based and MDM-based notes and that they are applied consistently by all auditing organizations.** With that additional clarity, the College and other medical professional societies can begin to provide resources to members on low-burden, valuable documentation practices and work with EHR vendors to build technology that supports and enhances the documentation process. To that end, ACP has included a number of clarifying questions as well as a documentation exemplar (for a 99214 level of service) for CMS’s consideration as it works to implement these proposals.

Clarifying Questions:

- For time-based documentation, must the note itself include the time audit or meta-data features from the EHR? Alternatively, could the time-based note that includes a physician attestation of time and describes the data that exists in other sections of the EHR (without replicating it in the note) suffice?
- For MDM-based documentation, what will CMS accept as information within other sections of the EHR that could substantiate an MDM-suggested code level (without the need for physicians to manually click a box)?
- Will CMS permit EHR vendors to develop and build functionalities that capture both time-based and MDM-based requirements simultaneously? For example, a clinician cares for a patient and writes their note based on what is clinically important. Ideally, an EHR could indicate: “Based on your use of the EHR during the visit, this visit would qualify for a 99213 based on time OR a 99214 based on MDM. Click to choose or modify a note or attestation.”

ACP Documentation Exemplars for a Note Based on Time and MDM – Level 99214:

99214 Time-based Note	99214 MDM-based Note
Patient returns for follow up of HTN and DM. Doing well, no new complaints. Taking medications regularly without side effects or concerns. Maintaining a simple diet of low sugar and low added salt.	Patient returns for follow up of HTN and DM. Doing well, no new complaints. Taking meds regularly without side effects or concerns. Maintaining a diet of low simple sugar and low added salt. Exercise by walking four times per week,

<p>Wt. 165 lbs. BP 122/70 P – 72, reg. RR 14</p> <p>PE: Unchanged from prior, except for tr ankle edema bilat.</p> <p>Assessment: Doing well, understands chronic conditions and managing appropriate diet, exercise, and medications.</p> <p>Spent additional time discussing how patient would not benefit from switching current healthy diet to a fad diet that was too high in saturated fats, including the risk of “yo-yo” weight loss.</p> <p>Plan – continue current regimens. Follow up in 4 months, sooner if need be. Discussed and updated patient goals. Spouse was present for entirety of discussion.</p>	<p>about 30 minutes per day. No emergency department visits or hospitalizations since last visit. Saw a cardiologist since last visit; no new diagnoses or medications.</p> <p>Wt. 165 lbs. BP 122/70 P – 72, reg. RR 14</p> <p>PE: Unchanged from prior, except for tr ankle edema bilat.</p> <p>Assessment: Doing well, understands chronic conditions and maintains appropriate diet, exercise, and medications including continued atenolol.</p> <p>Plan: Continue current regimens. Follow up for in 4 months, sooner if need be.</p>
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Billing Options for Time-based Note:

- **Option #1: Determined by a physician attestation.** (“I attest that I spent 32 minutes today on (include list of permitted activities) including face-to-face time with patient.”)
 - *Attestation time-based coding determination = 99214*
- **Option #2: Determined by EHR meta-data of 32 minutes.**
 - *EHR-calculated time-based coding determination = 99214*
- **Option #3: Determined by EHR meta-data of 27 minutes and physician attestation.** (“I attest that I spent an additional 5 minutes talking with the patient’s cardiologist discussing use, dosage of a beta-blocker.”)
 - *EHR-calculated time-based coding determination = 99213*
 - *EHR-calculated plus physician attestation time-based coding determination = 99214*

Billing Options for MDM-based Note:

- **Option #1:** Determined by two stable chronic illnesses and prescription drug management discussed in “Assessment.”
 - *MDM-based coding determination = 99214*

The College reiterates our support and appreciation for CMS' continued efforts to reduce administrative burden. We believe that the Agency's efforts to update clinical documentation requirements is a necessary step in the right direction. We look forward to future collaborations with CMS and all health care stakeholders on efforts to restore the patient and physician relationship and put high-value patient care first.

i. Proposed Add-On Code GPC1X

CMS Proposals: In addition to the CPT and RUC recommended changes, CMS proposes 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.

ACP Comments: ACP appreciates CMS proposing payment add-on codes for E/M services recognizing that the current E/M code structure does not adequately account for the intense cognitive nature of visits provided by these clinicians. ACP further appreciates positive changes to the code descriptions in that the codes can be billed with new patient visits in addition to established patient visits. We applaud CMS' overall responsiveness to stakeholder concerns that it is critical to make documenting this add-on code as minimally burdensome as possible.

We implore CMS to provide any specific assumptions regarding the projected utilization for this new add-on code. A comparison between CMS impact tables indicates that more than \$1.5 billion will be redistributed between specialties. We further encourage the Agency to explain the projected use of this code in more detail so that clinicians using the code can make the most informed decisions to protect the integrity of the Medicare program. It appears that CMS assumes the add-on code would be applied to nearly 50 percent of claims for 18 specialties. ACP agrees with CMS' intent to ensure that physicians are adequately paid for those patients that are outliers to the typical patient described in the valuation of office visits. Regardless of service performed, physicians should have a way to identify outlier patients where additional payment is warranted. **ACP recommends that CMS finalize the implementation of this add-on code, but notes additional clarification may be needed.** For example, what is the definition of "serious" in the code descriptor? **We encourage the Agency to work with medical specialties and the CPT Editorial Panel to better define the service to meet its intended purpose as we transition away from G codes to CPT codes.**

ii. Systematic Adjustments to Other Stand-Alone Codes

CMS Proposals: CMS seeks comments on whether it is necessary to make systematic adjustments to other services to maintain relativity between these services and E/M office visits, and whether it is necessary to make corresponding adjustments to E/M codes describing visits in other settings.

ACP Comments: ACP does not believe that CMS should make systematic adjustments to services without review by specialty societies and collaboration of the CPT Editorial Panel and

the RUC. Any valuing of other codes should first require a review of the coding structure to assure that it aligns with corresponding modifications to office visits. **ACP recommends that any requests to increase the valuation of other E/M services, or other services mentioned in this section of the proposed rule, be subject to additional survey and review in 2020 and beyond. A list of these identified services should be published in the final rule.**

iii. Surveyed Physician Time

CMS Proposals: Although CMS proposes to adopt the RUC-recommended times, it requests comment on how it which times it should use, specifically how it should resolve discrepancies between the component and total times when they conflict. The RUC approach sometimes results in two conflicting sets of times: the component times as surveyed and the total time as surveyed. For purposes of valuation of the E/M services, survey respondents were asked to consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a time frame of 3 days prior to the visit and 7 days after, respectively. This is different from the way codes are usually surveyed by the RUC for purposes of valuation, where pre-, intra-, and post-service times were surveyed, but not within a specific timeframe.

ACP Comments: **ACP strongly recommends CMS adopt the RUC recommended median total time for the office visits, as submitted.** The RUC recommendations were accepted and agreed upon by all specialty societies and a thorough explanation of these times were included in the RUC recommendations. The total median time for office visits should be placed within the “total time” field in the CMS time database. Through robust discussions at the RUC, the specialty societies indicated that the office visit codes currently include pre- and post-service time. The recent survey merely changed the way this time was captured. The pre-service time is described as three calendar days prior to the office visit, the intra-service time is described as the calendar day of the office visit, and the post-service time is described as within seven days following the office visit. Each individual survey respondent’s total time was used in determining the median total time. **Therefore, total time is the appropriate measurement of time for office visits.**

iv. Practice Expense Direct Inputs

CMS Proposals: CMS proposes to adopt nearly all the RUC recommendations for direct practice expense inputs for the office visit services. However, it declines to accept desktop computers (ED021, *computer, desktop, with monitor*) used in examination rooms as a direct medical expense.

ACP Comments: ACP appreciates that CMS has largely adopted the RUC’s recommendations regarding direct practice expense inputs. However, we respectfully disagree with the decision to not include the desktop computer as one of these inputs. **The computer is dedicated to each individual patient throughout the visit to collect history, share and discuss lab and test results, and document the visit. It is an essential tool in conducting today’s office visits and should be recognized as a direct medical equipment cost.**

v. Time Changes to E/M codes

CMS Proposals: The impact section of this proposed rule suggests that CMS may consider alternative relative values for CPT codes 99212 and 99214 by applying a formula based on a change in the time.

ACP Comments: The entire concept of the RBRVS is for one service to be paid relative to another service based on the resources typically utilized in providing the service. This is applied through magnitude estimation. In evaluating the office codes, the specialty societies and the RUC carefully reviewed not only the survey data, which CMS acknowledges to be robust, but also the relationship of the codes to other services. In addition, the specialty societies and the RUC made certain that the office visit codes were valued appropriately relative to each other. If CMS were to modify the values of 99212 or 99214, it would distort these important relationships. Importantly, 99212 and 99214 already have a modestly lower work per unit of time than the other office visit codes. Any reduction would create a misvaluation of 99212 and 99214 compared to the other office visit codes. **Therefore, ACP recommends that CMS finalize the proposal to accept the RUC recommendations for the E/M office visits as submitted.**

E. Review and Verification of Medical Record Documentation

CMS Proposals: The Agency proposes to amend existing regulations to specify that when furnishing their professional services, clinicians in all settings, not just teaching, may review and verify (sign/date) notes in a patient's medical record made by other physicians, residents, nurses, students, or other members of the medical team, rather than fully re-documenting the information. This proposal expands on previous burden reduction proposals focused on teaching physicians and is intended to apply more broadly to documentation requirements for professional services furnished by physicians, physician assistants (PAs), and advanced practice registered nurses (APRNs) in all settings, regardless of whether they are acting in a teaching capacity.

ACP Comments: The College strongly supported CMS' initial regulatory change allowing teaching physicians to sign-off on notes in a medical record made by other members of the clinical team, rather than having to re-document the entire note. **Therefore, we appreciate CMS' proposal to extend that regulation to allow clinicians in all settings to sign-off instead of re-document, and to extend this to other clinicians beyond teaching physicians.** These policies are taking steps to help reduce the regulatory burden associated with clinical note taking as well as the amount of unnecessary information contained within the clinical note, and will ideally lead to more meaningful, useful notes that will benefit patient care in the future.

F. Immunization Administration (CPT Code 90460)

CMS Proposals: CMS proposes to crosswalk PE RVUs from CPT code 96372 to codes 90471/90460, which will bring about a 60 percent reduction in PE RVUs, resulting in substantially lower payments. CPT code 90460 (immunization administration through 18 years

of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered) was reviewed by the RUC in October 2009. Rather than accepting the RUC recommendations, CMS crosswalked the PE RVUs for 90460 from CPT code 90471 *Immunization administration*, which is crosswalked from CPT code 96372 *Therapeutic, prophylactic, or diagnostic injection* (formerly CPT code 90772 and then 90782).

ACP Comments: ACP strongly recommends that CMS utilize the RUC recommended direct PE inputs to publish PE RVUs for CPT code 90460. The recent measles crisis highlights the importance of immunization administration (IA) being appropriately valued. One-third of pediatric visits include immunizations. Appropriate IA payment is essential to ensure access to vaccines provided in the medical home, where studies have shown immunization rates are higher. It should be noted that CMS has already validated the RUC-recommended values for CPT code 90460. CMS used the RUC-recommended values for CPT code 90460 to value the fast-tracked H1N1 IA code (90470) for 2010 – as both codes were reviewed during the same RUC meeting (October 2009).

Current administration codes already barely cover the cost of giving the vaccines. Reimbursement models for both the cost and administration of the vaccine have such narrow margins that the slightest reduction will make it impossible to provide vaccines to patients. This could potentially present a public health threat and fail to protect vulnerable patients. Vaccines are one of the most cost-effective interventions for patients. Influenza vaccinations for older adults have further been demonstrated to be a cost-savings in many scenarios. Conversely, reducing influenza vaccination could significantly increase costs for providing care to seniors. Since CPT code 90460 is reported more frequently in some practices than code 99213 (Level 3, established patient office visit), the impact to bottom line of a practice could be tremendous and can cause some practices to stop offering vaccines.

Stocking and ordering vaccines requires thoughtful planning and anticipation. Patients may have several overlapping conditions, medications, and treatments plans that must all be carefully considered when determining which vaccinations are appropriate, and when they should be administered. Because of these complexities, especially with more complex patients, **ACP further encourages CMS to explore vaccine administration codes and decouple them from the therapeutic injection codes.** Providing vaccines can prove to be a financial risk and strain for physicians who do not have any control over vaccine costs. CMS should instead advocate for lower vaccine costs directly with the manufactures.

G. Opioid Use Disorder Telehealth Services

CMS Proposals: CMS proposes to add the new payment codes for opioid treatment services to the Category 1 list of telehealth services, which entails services similar to professional consultations, office visits, and office psychiatry services on the list of currently covered telehealth services. The addition of the codes aims to expand the reach of opioid use disorder (OUD) treatment, particularly in rural areas experiencing high rates of opioid use or overdose.

The new codes are as follows:

- *HCPCS code GYYY1*: Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.
- *HCPCS code GYYY2*: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.
- *HCPCS code GYYY3*: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes.

ACP Comments: ACP appreciates CMS proposing to include these new additional codes to telehealth services and agrees that the Category 1 list of telehealth services is appropriate.

H. Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

CMS Proposals: The Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) directed CMS to establish a new Part B benefit category for OUD treatment services delivered by opioid treatment programs (OTP, also known as methadone clinics). Under this proposal, CMS would establish a bundled payment for OTPs for the delivery of medication assisted treatment (MAT) for OUD. The bundle would include FDA-approved medications for OUD (methadone, buprenorphine, naltrexone), dispensing and administration of such medication, substance use counseling, individual and group therapy, and toxicology testing, and other items and services that the Secretary determines are appropriate, which the Agency also seeks suggestions on (but specifically notes no meals or transportation). The Agency requests information on other OUD treatment medications in the development pipeline and how they could be incorporated into the benefit in the future. Certain services, specifically substance use counseling and therapy would be delivered via telecommunication. Under past regulations, telemedicine may not expand scope of practice or permit practice in a jurisdiction where the clinician is not licensed to practice. CMS would define a single episode of care as one week.

Under statute, OTPs must be: 1) accredited by a Substance Abuse and Mental Health Services Administration-approved (SAMHSA) accrediting body; 2) certified by SAMHSA; and 3) enrolled in Medicare. The rule establishes special requirements OTPs must meet in addition to standard Medicare enrollment requirements, including but not limited to: 1) maintaining and submitting a list of all eligible professionals legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP; 2) satisfying risk screening requirements (including site visits and background checks), and 3) not employing or contracting with any individual who within the preceding 10 years have been convicted of a related federal or state felony, been revoked from Medicare, are on the Medicare preclusions list, or have a current or prior adverse action imposed by a state oversight board. CMS intends to maintain program integrity and patient

safety through monitoring billing patterns and quality of care, performing audits, and revoking/terminating Medicare enrollment and clinician agreements for abusive or dangerous prescribing patterns or non-compliance with Medicare requirements. Enrollment revocations or terminations may be appealed.

ACP Comments: ACP supports provisions that would help to prevent opioid abuse and addiction, including increased access to treatment programs for opioid addiction and substance use disorders. More specifically, ACP supports lifting barriers to ensure patients receive access to medications to treat OUD and to reverse overdoses. MAT using buprenorphine and naloxone has an impressive success rate for treating patients with OUDs. According to SAMHSA, “when patients and physicians were surveyed about the effectiveness of buprenorphine, they reported an 80 percent reduction in illicit opioid use, along with significant increases in employment and other indices of recovery.” ACP supports expanding education opportunities for physicians who prescribe MAT to ensure this therapy is properly administered to patients. CMS should consider how these programs can further share patient information and data with a patient’s internal medicine specialist given the current constraints of the Health Insurance Portability and Accountability Act (HIPAA).

ACP understands the importance of ensuring patient safety in all clinician and supplier settings. **However, ACP believes it is excessively severe to revoke or deny a physician’s or eligible professional’s enrollment if he or she has been subject to any prior action from a state oversight board, federal or state health care program, IRO determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care.** Finalizing the policy as written would allow for automatic revocation of billing privileges or deny enrollment based on very modest sanctions, without careful consideration of the nature of the patient harm, clinician conduct, or sanctions or disciplinary actions imposed. **The College strongly encourages CMS to consult with the physician community prior to finalizing any policy that would establish broad criteria for revocation or denial of a clinician’s ability to participate in the Medicare program.**

I. Remote Patient Monitoring (RPM)

CMS Proposals: CMS proposes a new CPT code to report time spent beyond the initial 20 minutes for evaluating patient-generated health data (PGHD) obtained through RPM. For all RPM services, CMS also proposes to downgrade supervision requirements from direct to general supervision, which would allow clinical staff to monitor patient data and interact with patients remotely. CMS also proposes to create six new codes to reimburse for non-face-to-face patient-initiated digital communications that require a clinical decision, listed below.

- *CPT codes 98X00, 98X01, 98X02:* Qualified non-physician health care professional online digital evaluation and management service for an established patient, up to 7 days, cumulative time 5–10 minutes, 11-20 minutes, and 21+ minutes respectively.
- *HCPCS codes GNPP1, GNPP2, GNPP3:* Qualified non-physician health care professional online assessment for an established patient, up to 7 days, cumulative time 5–10

minutes, 11-20 minutes, and 21+ minutes respectively.

ACP Comments: ACP appreciates CMS' proposals to add these new additional codes to existing RPM services and downgrade supervision requirements to general supervision. These changes will help to relieve physician burden and allow physicians more time to treat the more complex patient issues that require more than remote monitoring.

J. Coinsurance for Colorectal Cancer Screening Tests

CMS Proposals: CMS seeks comment on whether the physician or staff should be required to notify patients of the cost-sharing implications and Medicare coverage rules prior to performing a screening colonoscopy. Specifically, whether physicians should be required to provide a verbal notice with a notation in the medical record, or whether CMS should consider a different approach to informing patients, such as a standard written notice. CMS also seeks comments on what mechanism, if any, should be used to monitor compliance.

ACP Comments: ACP understands the need for patients to be informed of cost-sharing implications regarding screening colonoscopies. However, due to the constraints of the availability of cost data, requiring physicians to provide verbal notice and a notation in the patient record would require excessive administrative burden for the physician practice. ACP believes this would be counter-productive to administrative burden reduction and request that CMS and stakeholders work to create a better solution to solving this issue.

K. Open Payments

CMS Proposals: Currently, applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) must annually submit information about payments or transfers to covered recipients, which includes physicians and teaching hospitals. Payments or transfers of value are defined as research, honoraria, gifts, travel expenses, meals, grants, and other compensation. These payments must be reported if they exceed \$10.79 in value, or \$107.91 in aggregate. Further, ownership or investment interest in covered entities held by physicians or physician's immediate family members must be reported, except when physicians are employed by the reporting manufacturer.

CMS proposes to expand the list of "covered recipients" as outlined in the SUPPORT Act to include PAs, nurse practitioners (NPs), clinical nurse specialists (CNSs), certified registered nurse anesthetists (CRNAs), and certified nurse midwives (CNMs) starting in 2021. This list would extend to the manufacturer-employment exception. CMS proposes to consolidate the categories for direct compensation for serving as faculty or as a speaker for medical educational programs and add new categories for debt forgiveness, long-term medical supply or device loans, and acquisitions. CMS also proposes to require applicable manufacturers to provide the device identifier for medical devices when reporting Open Payments data.

ACP Comments: The College recognizes the importance of prioritizing transparency in the relationships between the health care industry and physicians and teaching hospitals, as well as the need to minimize the adverse effects of conflicts of interest within health care. Physicians must be conscious of potential influences and always base their actions on the patient’s best interest and by principles of appropriate utilization. While collaboration among physicians, teaching hospitals, and industry is central to continued innovation and improvement within the system, we are also cognizant that payments made to physicians and teaching hospitals can introduce conflicts of interest that may diminish, or appear to others to diminish, the objectivity of professional judgment by influencing research, education, and clinical decision-making in ways that compromise clinical integrity and patient care and lead to increased costs.

ACP supports CMS’ proposal to consolidate the two continuing medical education categories that distinguish between accredited/certified and unaccredited non-certified programs, which would streamline the reporting process. We see no principled distinction that justifies different treatment of payments for speakers or faculty in different settings and believe that if the faculty member has knowledge of where the funding originated, there is a basis for a possible conflict of interest. ACP also agrees that requiring more precise device identifier data for medical devices would make the Open Payments data more useful for the public and would allow for the validation of submitted device information.

L. Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy

CMS Proposals: The 21st Century Cures Act created a Part B benefit to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment in the beneficiary’s home. The Act requires notification of the available options of infusion therapy to the patient, which could include verbal discussion with EHR annotation or in writing with written patient attestation. CMS seeks input on the appropriate form, manner, and frequency for physicians to satisfy the requirement of notifying beneficiaries with their infusion therapy options under Part B.

ACP Comments: In designing a mechanism to ensure Part B beneficiaries are informed of all the infusion therapy options available to them, CMS must strive to notify patients in a streamlined manner that minimizes burden for physicians and confusion for patients. As each practice varies in technical capabilities, the Agency should allow for flexibility in the form and manner physicians may notify and document the spectrum of available infusion therapy options. Specifically, verbally discussing options and documenting in the patient record whenever a new infusion therapy treatment is deemed necessary by the physician should qualify.

M. Advisory Opinions on the Application of the Physician Self-Referral “Stark” Law

CMS Proposals: CMS proposes several changes to the Stark Law advisory opinion (AO) process, including the logistics of requesting and receiving an AO, as well as updating their scope,

applicability, and permissible subject matter. Under current law, the Secretary is required, upon request and when requirements are met, to issue written AOs regarding whether an arrangement involving a designated health service referral is prohibited under Stark Law. These AOs are binding to the party or parties requesting the opinion and OIG is prohibited from opining on questions of interpretation, hypothetical situations, or those involving the activities of third parties. The proposed changes to the Stark Law AO process are outlined below:

- **Scope and Applicability:** CMS proposes that favorable AOs would prevent penalties from being assessed on parties specific to the arrangement described in the request, regardless of whether they were a requestor of the opinion. Further, the Agency proposes that it would not pursue penalties for those parties specific to an arrangement that CMS determines is indistinguishable to the specific arrangement of an existing favorable AO. Finally, CMS proposes codifying that individuals and entities may reasonably rely on AOs as non-binding guidance that illustrates the application of Stark Law to specific facts and circumstances.
- **Subject Matter:** CMS proposes relaxing existing restrictions that would allow the Agency to consider fulfilling requests in which they are aware of other investigations or proceedings that are substantially similar to the circumstances of the requestor. The Agency would also be permitted to deny a request that does not provide adequate information or does not respond to requests for additional information.
- **Timeline:** CMS proposes reducing the timeframe for fulfilling an AO request from 90 days to 60 days. The Agency is also considering offering an expedited option that would provide an AO within 30 days.
- **Fees:** CMS proposes replacing the current \$250 processing and issuing fee with a \$220 hourly fee, which would potentially be capped. Should the Agency pursue an expedited pathway, they are considering a \$440 hourly fee.

ACP Comments: The College commends CMS for its intent to make the Stark Law AO process more accessible and responsive to physicians and other entities. The Stark Law has helped to protect the integrity of the Medicare program by reducing fraud and abuse and ensuring the efficient and effective utilization of taxpayers' resources in the provision of necessary care. **While ACP supports the Stark Law's overall efforts in countering the adverse influence of financial incentives on medical decision making, we are also concerned that existing fraud and abuse laws and their enforcement are burdensome on practicing internists** and have created an environment where physicians feel almost all of their behavior is subject to scrutiny under these complex and confusing laws and inadvertent billing and coding errors made are being treated as fraud. **Preventing and punishing fraud in federal health care programs is a worthy and important goal, but it must be balanced with reducing unnecessary burdens for law-abiding, well-intentioned physicians.** Complying with the Stark Law and all of its intricacies is resource intensive and particularly burdensome for rural practices and others who provide care to underserved areas. Physicians and other entities must be able to reasonably request

and reliably depend on guidance provided in the form of AOs in order to navigate this complex law. **While these proposals are a step in the right direction, they are not bold enough to meaningfully improve access to and usefulness of AOs or reduce Stark Law's burden.**

ACP supports efforts to reduce the AO turnaround timeline and create an expedited pathway as a means to improve the AO process. The historically long AO wait times have left physicians with uncertainty over whether the arrangements they were engaged in or were planning to enter were unlawful. **However, to truly reduce compliance burden, CMS must allow for AOs to be issued in hypothetical situations.** It is unreasonable to expect a physician to plan to enter into an arrangement before obtaining guidance and assurance from CMS that their plans do not run afoul of Stark Law. While we appreciate the concern that lowering the standards to permit requests for hypothetical situations would burden CMS and result in an influx of new AO requests, mechanisms like the proposed altered fee requirements are already in place to serve as a barrier and filter only earnest and thoughtful inquiries. **Further, allowing parties in materially similar scenarios to rely on applicable previously issued AOs, as well as extending protection from penalties to non-requesting parties described in an AO request, would both provide much-needed clarification while drastically reducing the total number of requests.**

III. Updates to the Quality Payment Program:

A. MIPS Value Pathways (MVP)

CMS Proposals: CMS proposes to overhaul MIPS with a new, mandatory reporting pathway called the MVP. It aims to reduce burden on clinicians and increase alignment with APMs by featuring a set of measures and activities that would align around a certain condition and/or specialty, thereby streamlining reporting across the four performance categories while reducing the overall number of individual measures and activities reported. CMS seeks comment from stakeholders on a number of areas related to the design, development, and implementation of MVPs and anticipates a 2021 rollout.

ACP Comments: ACP appreciates CMS' receptiveness to longstanding calls from ACP to reduce burden in MIPS by creating more alignment across the performance categories and reducing the number of required metrics while providing more regular, actionable feedback. We support the goal of helping clinicians transition to applicable APM options and appreciate CMS' desire to solicit input from physicians and other stakeholders on a number of elements related to the design, feedback, and implementation of the MVP, which is critical for its eventual success. While we appreciate that CMS seeks feedback in many important areas, we do not feel 60 days is sufficient to fully consider and prepare detailed comments regarding this proposal in combination with the other sections of the rule. **Therefore, we ask that CMS offer further opportunity for ongoing, robust stakeholder feedback throughout the design and implementation of the MVP, including a separate opportunity to provide more detailed comments specific to these MVP proposals.** We also request that stakeholders are given an opportunity to comment on the detailed methodologies of a future MVP design and implementation plan as they become more fully developed.

ACP supports the development of an MVP MIPS reporting option because of its potential to make reporting more streamlined, clinically relevant, and therefore less burdensome on clinicians. However, we have major concerns that CMS' proposed implementation timeline, particularly its plan to mandate the MVP starting with the 2021 performance year, could result in massive disruptions, especially given the lack of details available at this point. ACP does not feel that this proposed timeline provides sufficient time for CMS to design this new pathway from the ground up in addition to designing the individual MVPs, much less allow for sufficient clinician education. **We encourage CMS to make the MVP optional for the foreseeable future until the Agency has data to assess how clinicians are adapting to this new pathway. At a minimum, CMS should institute a multiyear transition or pilot period.** Making the MVP an optional alternative to traditional MIPS, particularly in its initial years, would allow practices and clinicians who have an applicable MVP and are ready to transition can do so, while not forcing other practices who are not prepared or do not have an applicable MVP available to them to make that transition prematurely, which may be an issue particularly for certain specialists and subspecialists. CMS could establish a pilot period during which clinicians and groups opt into testing a limited number of MVPs in exchange for guaranteed MIPS credit equivalent to the MIPS performance threshold. This would help to encourage adoption of MVPs

without rushing implementation, particularly for subspecialists for which there may not be an applicable MVP at the onset. A pilot period would also allow CMS to start with a small set of MVPs—built off of the current specialty measures sets, for instance—while allowing for time to develop and review submissions of additional MVPs. The current quality measure set was developed over many years and is consistently evolving. Developing a new MIPS structure along with bundled MVPs will take more than eighteen months to responsibly develop and we urge CMS not to rush this process if it wants to ensure a smooth transition. Providing robust performance data and feedback to clinicians who participate in the MVP would be another added incentive that would boost participation, plus it would help to facilitate the transition to APMs, particularly risk-bearing APMs. If the MVP truly reduces burden and provides robust performance data for clinicians as intended, there is no question that clinicians will transition to this new reporting option without having to mandate it.

ACP greatly appreciates CMS' desire to reduce program complexity and reporting burden. However, we wish to draw the important distinction between maintaining key reporting flexibilities that are critical to accommodating a diverse range of practices and the unique patient populations they serve versus reducing the total number of metrics required to satisfy full program requirements. Requiring clinicians to monitor their performance on upwards of 19 distinct measures and report on at least 15 with no opportunity for streamlining credit for multiple categories and scoring methodologies that differ for each category is what causes complexity, confusion, and burden. **Giving clinicians some flexibility in which measures to report and how to report them does not add burden; it relieves it.** It also provides critical flexibilities that are necessary to accommodate a wide range of practices of varying specialties, sizes, and geographic locations, and the unique patient populations they serve.

Moreover, during a time of existing major transition, CMS should look to retain some element of consistency in reporting to minimize the level of disruption on clinicians and help to ensure a smoother transition. If clinicians are already preoccupied with attempting to wrap their heads around an entirely new reporting and scoring structure, the last thing they need is for the reporting option or measure that they have been relying on for multiple years to suddenly no longer be available to them.

Specifically, ACP urges CMS to: 1) allow practices and clinicians to self-select MVP(s) rather than assign them; 2) allow clinicians some choice in measure selection, rather than a pre-determined set of static measures; 3) not restrict collection types; and 4) allow sub-Tax Identification Number (TIN) reporting, while retaining a full-TIN reporting option. These flexibilities will help to ensure more clinicians are able to successfully comply with the MVP, particularly in its initial years of implementation. As clinicians will already be familiarizing themselves with the new requirements, it will be important to not overtly restrict the ways in which to participate and to maintain as much consistency as possible in the areas in which clinicians are familiar, including reporting data through the same method as under MIPS. Allowing at least some choice of measure selection helps to ensure clinicians are able to select measures that are more applicable to their unique patient population and allowing groups,

particularly multi-specialty practices, the option to report at the sub-TIN level will help ensure they meet data completeness criteria, including measure thresholds.

Performance measurement is only as useful as the accuracy of the individual metrics used. As elaborated on more fully in our comments specific to the Cost and Quality Performance Categories, it is paramount CMS establish transparent, independent standards for robust performance measurement. **Specifically, all measures must be statistically valid, clinically relevant, and subject to feedback and evaluation by independent third party reviewers with clinical expertise.** ACP maintains that a minimum reliability threshold of 0.75 should be instituted across all measures, and case minimums should be set accordingly. Additionally, 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 own Performance Measurement Committee (PMC), the Measures Application Partnership (MAP), or Core Quality Measures Collaborative. Stakeholder input throughout the development and implementation is paramount for accurate and effective performance measurement. ACP looks forward to providing more detailed feedback including which specialties and conditions MVPs should be designed around, which specific measures would be preferable, and potentially submitting MVPs of its own.

ACP agrees administrative claims-based measures have potential to reduce reporting burden. However, we have been concerned that many of the claims-based measures CMS has developed to date tend to take a one-size-fits-all approach to attributing broad-based costs to individual groups, or even individual clinicians, at which level it is difficult to establish a true cause and effect relationship. **If CMS does move forward with developing new administrative claims-based measures for the MVP, we encourage the Agency to ensure the measures are directly applicable to a well-defined set of services and attributed at a level that a clinician or practice has a reasonable ability to impact,** such as a cost-based measure specific to a set of services related to treating a particular condition. It is paramount these measures be developed and implemented in a transparent and predictable manner with stakeholder input throughout the process. Stakeholders should also be given an opportunity to submit their own proposals for administrative claims-based measures, which would help to facilitate the more expedient development of condition- or specialty-specific administrative claims-based cost measures.

Patients should always be assigned voluntarily and prospectively when possible. Knowing with more certainty for which patients they are responsible empowers clinicians to take more active responsibility for their overall care and downstream outcomes. **ACP reiterates its calls for CMS to expediently develop patient relationship codes,** which we believe could drastically improve patient assignment accuracy, and therefore performance measurement effectiveness.

To facilitate an easier transition for current specialty set reporters and enable CMS to expedite the rollout of MVPs, CMS should start by structuring initial MVP options around the existing specialty measure sets, provided the measures are valid, reliable, and clinically relevant. Meanwhile, ACP supports the idea of a call for MVPs, process similar to the current call for measures process, in which CMS would establish clear qualifying criteria and accept

submissions for new MVPs from specialty societies, Qualified Clinical Data Registry (QCDR) vendors, and other stakeholders. QCDRs have grown in popularity in recent years and offered a unique opportunity for vendors and stakeholders to develop and test a set of diverse, clinically relevant measures to accommodate a wide range of specialties. CMS should continue to support and encourage QCDRs and other vendors to develop new measures, particularly as it embarks on designing and implementing the MVP. **Offering incentives such as access to Medicare claims data to measure developers would help to offset the costs of developing new measures and MVPs and thus expedite the process, which would be particularly important in the initial years of implementation.** Ensuring that measures would be active for a certain number of years would also help to give measure developers confidence that their energy and investment would be worthwhile. Additional considerations for promoting the development of new measures are included in the third party intermediaries section.

ACP is disappointed that CMS did not leverage this opportunity to create more symmetry between the various performance categories to reduce burden on clinicians, particularly when it comes to the Promoting Interoperability Category. The College has continued to express our concern for this category (as discussed in more detail in a later section) and we feel that incorporating certain health IT activities into the MVP, or the use of CEHRT to conduct improvement activities or report measures, is a positive step towards appropriately recognizing physicians for leveraging health IT to deliver high-quality patient care. **Retaining the same four separate performance categories and siloed scoring will not achieve the meaningful reductions in reporting burden that CMS envisions with the MVP.**

For scoring, CMS should look to award credit in multiple performance categories for measures that are relevant to both. This will reduce the total number of metrics and therefore the burden of reporting. For example, for an opioids-based MVP, CMS could award credit toward the improvement activities category and PI category by leveraging their EHR to perform Improvement Activities, such as transferring care plans to specialty clinicians, reporting medication data to a state prescription drug monitoring programs (PDMPs), and evaluating patients for risk of opioid misuse. Practices could then receive credit toward the quality, cost, and PI categories for reporting related quality and cost outcomes. **Consistent with past ACP recommendations, CMS should award points corresponding to their weight for the overall MIPS composite score.** For example, transferring a summary of care record through an EHR could be worth five points toward the Improvement Activities Category score and five points toward the PI Category score and add ten points to their MIPS composite score. Scoring this way is significantly more intuitive and would allow clinicians to better understand the relative value of each activity or measure to their overall score.

Designing MVPs around certain specialties or conditions is already a strong stepping stone toward participating in APMs, particularly bundled payment APMs such as BPCI Advanced. To further facilitate this transition, ACP urges CMS to provide detailed, frequent performance data so that practices can not only monitor their performance and target areas for improvement, but can also monitor trends and perform the necessary cost benefit analyses to determine if they are ready to enter into a risk bearing model. One of the most persistent pieces of feedback

we receive from members is the importance of data when making make or break decisions about whether to participate in a risk-bearing APM. Performance data should be provided at both a high-level overview, as well as a more granular breakdown of how well each clinician performed on each measure. Comparative data to other practices of similar sizes, locations, and specialties is also key to putting performance in perspective, particularly if performance evaluation and payment adjustments are contingent on the performance of other APM Entities within the model. Detailed financial data also is necessary for practices to make the necessary risk calculations to determine whether or not to participate in a given APM. **ACP has long advocated for performance feedback on a quarterly basis at a minimum, ideally working up to real time claims data. In addition to helping individual practices assess their performance, implement targeted interventions, and make risk calculations, it would also help to spur the development of private sector APMs.**

In terms of Physician Compare, ACP supports CMS' past policies to exclude newly used measures from public reporting for the first two years of use and encourages the Agency to continue this policy under the MVP. Doing so encourages physicians to test new measures, including MVPs, without fear of negative repercussion. For any publicly reported quality measures, ACP reiterates the importance of establishing a formal process to ensure the accuracy of measures before they are posted including adequate risk adjustment, statistical validity, and evidence base, as well as an opportunity for physicians to review measures in advance and potentially appeal for reconsideration if they suspect inaccuracies. Additionally, the College reiterates the importance of educating patients on the meaning and limitations of reported differences among physicians and clinicians and on how to effectively use this information to make informed health care decisions. These considerations will be especially important as CMS embarks on testing and implementing the new MVP pathway.

B. MIPS Category Weighting, Reweighting, and Scoring

CMS Proposals: CMS proposes to increase the weight of the Cost Category and reduce the weight of the Quality Category by five percent in 2020 and again in 2021. The Agency would also increase the MIPS performance threshold by 15 points and the MIPS exceptional performance threshold by five points each year. For weight redistribution in cases of category-level exclusions, weight would continue to be re-distributed to the PI and Quality Categories in most cases. However, CMS proposes to no longer weigh the Improvement Activities Category above 15 percent in any circumstance. Because of substantial changes to the Cost Category, CMS would avoid redistributing weight to the Cost Category in 2020, except when both the PI and Quality Categories are reweighted to zero, in which case Cost would be weighted 85 percent. CMS would begin re-distributing weight to the Cost Category starting in 2021.

ACP Comments: ACP strongly believes that the Cost Category should not increase in weight while it is undergoing a major overhaul. While we appreciate the Agency's interest in building up to the statutorily required 30 percent weight in 2022, increasing the weight by a proportionate amount each year does not outweigh the importance of ensuring the accuracy of individual measures before increasing the weight of the overall category. Moving forward

prematurely with increasing the weight of the category without due diligence of testing new measures that will largely determine the Cost score will majorly disservice clinicians. ACP urges CMS not to move forward with its proposal to increase the weight of the Cost Category for the 2020 performance year. **Instead, we urge the Agency to at a minimum maintain the current category weights, ideally lessen or even reweight to zero the Cost Category for one year until the Agency better understands the implications of the major changes to the measures that comprise this category before relying on them to impact physician payments.**

For these same reasons, ACP agrees with CMS' proposal to generally not redistribute weight to the Cost Category in 2020. While these situations would be rare, we strongly urge CMS to distribute additional weight to the Improvement Activities Category in cases where Cost is the only other category that would not be reweighted to zero. We have major concerns about the implications of Cost accounting for 85 percent of a clinician's or group's score, especially when that category is undergoing such substantive changes.

While ACP understands the need to gradually increase the performance and exceptional performance thresholds to meet statutorily required levels of the mean or median performance, **we maintain that the Agency first has a responsibility to address the deeply concerning gap for small practices, which based on the most recent performance data from 2017 scored on average 30 points lower than the average overall MIPS performance score. It is clear CMS must take a more comprehensive approach towards supporting small practices,** both within the MIPS pathway and when it comes to participating in APMs. ACP has suggested several possible solutions in the past, including evaluating small practices separately within MIPS, or establishing separate MIPS performance thresholds and Qualified Participant thresholds to recognize the unique challenges faced by small practices and compare them against peers that are on more of an even footing.

C. MIPS APMs Scoring Standard

CMS Proposals: CMS proposes to grant APM Entity groups participating in a MIPS APM half automatic credit toward the Quality Category, with additional limitations being considered, such as a possible limit on the number of years for which this automatic credit would apply, or limit the credit to two-sided risk models. CMS would look at individual and TIN-level data and would use the highest reported score for each clinician, then average these together to determine the APM Entity's final score. CMS would extend extreme and uncontrollable policies to clinicians under the APM scoring standard for the Quality Category, which includes possible reweighting to zero. However, if any quality data is submitted on behalf of the APM Entity, the Quality Category would not be reweighted to zero. While the TIN would not need to report data for clinicians that qualify for an exception, all clinicians in the TIN would count towards the TIN's weight when calculating the APM Entity score for the quality category.

ACP Comments: ACP supports the proposal that MIPS APM Entities would generally receive half credit toward the Quality Category. These clinicians and groups are taking meaningful steps toward transitioning to value and participating in an APM of any variety requires a substantial

amount of staff training, redesign of clinical processes and systems, and upfront and ongoing investment of limited practice resources. They should be recognized for these important efforts.

We urge CMS not to impose additional time or risk-based limits that would counter their goal of incentivizing clinicians and groups to move towards innovative payment arrangements, including risk-bearing models. ACP appreciates and supports CMS' proposal to calculate the NPI-level score for every clinician and use the higher of that or the TIN-level score in each case, as well as its proposal to extend the extreme and uncontrollable policies to clinicians under the APM scoring standard for the Quality Category. We encourage the Agency to extend these policies to other performance categories and while we appreciate that TINs technically would not need to report data for clinicians that qualify for an exception, we encourage the Agency to not count those clinicians toward the TIN's weight when calculating the APM Entity quality score, so that these excluded clinicians do not count against them.

D. Quality Category

CMS Proposals: CMS proposes to remove a total of 55 quality measures, modify several measures, and add four new measures for 2019, including a new Potential Opioid Overuse measure. CMS proposes CMS would delay implementing the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure until 2021 to allow for stakeholder input and consideration by the Measures Application Partnership (MAP). In addition, the Agency proposes a new criterion to be considered for removal: those that do not meet case minimum and reporting volumes required for benchmarking for two consecutive performance years.

CMS proposes increasing the data completeness requirements for all Part B claims, QCDR, clinical quality measures (CQMs), and electronic CQMs (eCQMs) from 60 percent to 70 percent and is separately considering increasing data completeness requirements specifically for topped out measures. The Agency proposes to extend certain scoring flexibilities and introduce a new policy to apply flat percentage benchmarks in cases where the standard benchmark could result in adverse treatment, patient harm, or other unintended consequences. Finally, CMS is considering several additions and changes to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey, including a new question on overall patient experience and satisfaction, open-ended narrative questions, collecting data at the clinician level, and collecting data via the web and email in addition to phone and paper surveys.

ACP Comments: ACP has called for and supports the removal of measures that are unreliable, of uncertain validity and clinical evidence-base based on findings by its PMC that only one third of 2019 MIPS measures relevant to internal medicine were found to be valid.⁵ Of the measures proposed for removal, ACP's PMC has reviewed three measures that were relevant to internal medicine. ACP supports the removal of measures QID #411 (Depression Remission at Six

⁵ [acponline.org/advocacy/acp-advocate/archive/december-7-2018/acp-analyzes-rates-performance-measures-in-2019-cms-mips](https://www.acponline.org/advocacy/acp-advocate/archive/december-7-2018/acp-analyzes-rates-performance-measures-in-2019-cms-mips)

Months) and QID #474 (Shingles Vaccination) in the current form, which ACP's PMC reviewed and found to be invalid. While both represent an important clinical concept, the committee raised numerous concerns with the methodologies for calculating both measures (see Appendix A). ACP urges CMS not to remove measure QID #442 (Persistence of Beta-Blocker Treatment after a Heart Attack), which was rated as valid by the PMC and is based on high-quality evidence from multiple specialty organizations and yet CMS proposes to remove with adequate replacement by another comparable evidence-based measure. **ACP supports CMS' proposal to delay the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure until 2021 to allow for stakeholder input and consideration by the MAP and urges CMS to use this time to address past concerns raised by the College.** ACP has repeatedly called for CMS to solicit stakeholder input throughout measure development and implementation and to not to move forward with measures unless approved by an independent third party, such as the MAP, and we commend the Agency for being responsive to these requests, which will help to promote transparency, accountability, and integrity of the program and improve the accuracy of performance measurement. We encourage you to read our previous letter,⁶ which goes over our concerns with the measure in more detail, including low reliability standards, inadequate risk adjustment, flawed attribution, and a general lack of actionability. ACP's PMC looks forward to reviewing the proposed new quality measures for 2020 and will report back on those relevant to internal medicine, as it has done in past years.

ACP is concerned by CMS' proposed removal of 55 performance measures while adding only four new measures, which represents a more than 20 percent decrease in the total number of available measures and would mean approximately one third of performance measures in the quality category would have been removed over the last two years. **While ACP supports the removal of invalid measures, we wish to clarify that reducing the number of available performance measures alone does not reduce complexity. Rather, it inhibits flexibility and potentially hinders clinicians' and practices' abilities to find enough relevant and valid measures to satisfy quality reporting requirements, particularly for certain specialties. CMS should instead work with stakeholders to improve the methodological shortcomings of invalid measures and only remove measures if it determined they are beyond repair or are inherently flawed in concept.** In its review of relevant internal medicine measures, ACP's PMC found that many measures aimed to capture outcomes that were extremely relevant to high quality patient care, but were flawed for a number of technical reasons that included insufficient numerator or denominator thresholds, inaccurate time intervals, a general lack of detail, or a number of other reasons. However, in many instances, ACP's PMC notes that the measure could benefit from modest technical changes, and if these change were tested and implemented the measure could become valid. In many cases, the PMC provides specific technical revisions that CMS should adopt to improve a particular measure. Rather than drastically reduce the inventory of available measures, CMS should work with ACP and other stakeholders to improve existing measures. This will help to ensure clinicians have a wide selection of statistically valid, clinically relevant measures to choose from that are applicable to

⁶ acponline.org/letters/acplettertocmsdevelopmentmipsoutcomemeasurehospitaladmissionrates2019.pdf

their unique patient population. When considering measures for removal, we urge CMS to give special consideration to how it may impact the ability of certain specialties or subspecialties to fully participate in MIPS, or if the measure captures useful information relevant to a particular patient segment or condition, even if it is relatively seldom reported. For these reasons, we urge CMS to reverse its proposal to automatically remove measures that do not meet case minimum and reporting volumes required for benchmarking for two consecutive years, and instead work with measure developers to improve and promote measures for more widespread use, rather than abandon a measure. Having a variety of measures to report is critical to ensuring full participation by a diverse range of practices and patients. In general, CMS should be looking to preserve areas of consistency where it can as it seeks to transition to the MVP, not create further disruption. ACP does appreciate CMS soliciting stakeholder concerns before removing measures due to low reporting levels.

CMS should adopt policies that encourage practices to report new measures, such as establishing a performance floor for new measures, awarding automatic credit up to full credit for at least one quality measure, or counting reporting a new quality measure as an improvement activity. The Agency should reconsider its policy for scoring measures with no benchmarks, which actively discourages reporting of new measures because practices may not receive more than three points, regardless of how well they perform. ACP strongly supports measures that have clear, transparent, and prospective benchmarks because these give practices a predictable, transparent target to aim for. CMS should consider adopting temporary, prospective benchmarks for new measures by relying on deciles from testing or establishing thresholds for high-quality care based on clinical evidence-base.

ACP strongly opposes CMS' proposal to increase data completeness requirements for Part B claims, QCDR, CQM, and eCQM measures from 60 percent to 70 percent. Data completeness requirements have a direct and significant impact on physician burden and pull directly from practice resources that could be used toward direct patient care. As CMS itself acknowledges in the proposed rule, this change would disproportionately negatively impact small practices and clinicians reporting individually, who average around 10 percentage points lower than medium and large practices reporting as a group. While ACP understands it is important to capture sufficient claims data to ensure an accurate indicator of performance for scoring purposes, 60 percent of all claims data over the course of a full year reporting period is already a substantial hurdle and provides more than sufficient data to capture an accurate snapshot of performance. **Rather than justify this increase given average reporting rate is higher than 70 percent, CMS should demonstrate why the data it receives at the 60 percent level is insufficient, how raising the minimum threshold would meaningfully improve the accuracy of quality data being captured, and how that positively impacts patient care.** Without this, it appears as though MIPS is more focused on collecting data than leveraging data to improve patient care. Maintaining the full reporting year while increasing the minimum data completeness threshold minimizes any room for flexibility to test new measures, or adopt new reporting technologies such as CEHRT or QCDRs. This hinders innovation and increases the likelihood that any temporary glitches in data collection or reporting due to a vendor issue (or other reasons outside the clinician's control) would cost the practice from having enough

measures to satisfy reporting requirements, thereby hindering their performance or causing them to seek a hardship request. Moreover, CMS should not propose this change at the same time it proposes to reduce the overall number of performance measures, increase the MIPS performance threshold substantially, and potentially overhaul MIPS reporting in its entirety by replacing it with the MVP. As for increasing data completeness rates specifically for topped out measures, CMS has already established a detailed plan for removing those measures and reducing their value in the interim to dissuade clinicians from reporting them. Increasing data completeness on top of that would only add unnecessary complexity to the program.

We support CMS' proposal to extend certain beneficial scoring exceptions, including the 3-point floor for measures that meet case minimum, data completeness, and benchmark scoring requirements, and the 1-point floor (3 points for small practices) for measures that meet data completeness requirements but do not have a benchmark or fail to meet case minimums. We believe that these policies offer practices a reasonable backstop for unpredictable performance and encourages program participation by offering practices some reward for making the effort to report measures and meet data completeness requirements. ACP appreciates CMS wanting to protect patient safety, which should always be the top priority. Therefore, we support the proposal to apply flat percentages in limited cases where the standard benchmark could incent adverse treatment or result in patient harm or other unintended consequences. Physicians' performance should not suffer because they do not meet strict numerator or denominator requirements that would be ideal under the standard measure methodology, but may not always be ideal or even safe for the individual patient given other comorbidities or unique circumstances. We also support CMS' proposal to propose any specific measures to which they would apply this methodology through formal rulemaking to allow for stakeholder input.

Regarding potential changes to the CAHPS for MIPS survey, ACP supports collecting data via the web and email in addition to phone and paper surveys, as we feel this will capture data from more beneficiaries and reduce the costs and burdens associated with data collection. **While we support collecting data about patient experience and satisfaction, we have some concerns with including open-ended narrative questions due to the length and burden this will add to the survey, which may result in fewer patients completing the surveys.** In addition to concerns over fracturing data to the point where it falls short of case minimums and cannot be used, we feel that collecting data at the individual clinician level runs counter to the team-based delivery system model that value-based initiatives like MIPS and APMs encourage. We wish to reiterate the importance of collecting information that is within the physician or practice's ability to influence. ACP supports collecting meaningful, accurate data about overall patient experience and satisfaction with their care. Accordingly, we support incorporating a measure that captures this, but as we do with all measures, we believe that the full impact of the measure, including any potential unintended consequences, should be fully realized before it is used to impact physician payment or educate the public. Therefore, we would support including this question on an informational basis without counting toward a physician's final score or being posted to Physician Compare until CMS can be confident that the measure is being accurately captured and evaluated and that it avoids negative, undeserved consequences on individual physicians.

Regarding the potential Opioid Overuse measure, ACP commends CMS for proactively seeking policy proposals in this rule and otherwise to combat the nationwide opioid epidemic. Physicians are obligated by the standards of medical ethics and professionalism to practice evidence-based, conscientious pain management that prevents illness, reduces patient risk, and promotes health. ACP strongly believes that physicians must familiarize themselves with and follow appropriate clinical guidelines related to pain management and controlled substances, including prescription opioids, as well as nonopioid pharmacologics and nonpharmacologic interventions. **However, as with any new measure, we urge the Agency to proceed cautiously with its development and implementation by ensuring proper risk adjustment; soliciting stakeholder input; subjecting the measure to rigorous reliable, valid, and clinical evidence base standards; and robustly testing the measure prior to using it to impact physician payments. CMS must be diligent in striking an appropriate balance between proactively monitoring for overuse while not overly restricting access to pain therapy for patients who need it.** We are concerned that setting strict dosage requirements may be too restrictive and support instead the establishment of evidence-based, more fluid guidelines that allow physicians to take into account the unique circumstances and tolerance of individual patients, which can vary widely. Certain patient populations, such as those with sickle-cell disease, may have special pain considerations that should be taken into account. Closely monitoring the combined prescription levels across clinicians and practices and checking for potentially unsafe drug interactions is critical, and this can only be accomplished if this type of data can be collected and meaningfully exchanged across EHRs, health information exchanges, QCDRs, and public health data registries. Part of ensuring this data is meaningfully exchanged means the most relevant, timely data rises to the top of a patient record and is available at the point of care. This is one of the most impactful areas where CMS should be directing its attention and resources. The Agency should also work to connect the valuable, but disjointed data currently being collected from statewide drug monitoring programs, possibly by establishing a national database, and promote alternative pain management services, including by covering them under Medicare.

E. Cost Category

CMS Proposals: CMS proposes ten new episode-based cost measures and, based on past concerns raised by ACP and other stakeholders, proposes to substantially revise the Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost (TPCC) measures. The new MSPB measure would distinguish between medical and surgical episodes and allow for attribution to multiple clinicians. Costs for certain services unlikely to be influenced by a clinician's care decision would be excluded. The TPCC measure would require at least two services for attribution, which would trigger a one-year "risk window" that would span multiple performance periods. Costs for the same beneficiary could be attributed to multiple clinicians under different TINs, but within a single TIN, costs would only be attributed to the clinician performing the highest number of qualifying services. Services performed by clinicians who frequently perform non-primary care services or are in certain non-primary care focused specialties would be excluded and beneficiary risk scores would be calculated on a rolling basis.

ACP Comments: ACP's PMC will review the new episode-based cost measures and looks forward to providing more detailed feedback. We wish to reiterate past concerns with the minimum reliability threshold for all MIPS cost measures, which at 0.4 is exceedingly low. **We encourage CMS to adopt a minimum reliability threshold of at least 0.75, which is considered the bare minimum for acceptable reliability by most statisticians.**⁷ Evaluating clinicians on unreliable measures is dangerous and could penalize physicians and practices with already limited resources caring for our nation's most at-risk patients. Setting robust case minimums is an impactful way to improve the reliability of all MIPS measures, particularly cost measures.

CMS must focus more resources toward improving risk adjustment and patient attribution methodologies for all measures, particularly cost measures. The inadequacy of HCC coding is well-documented.⁸ ACP reiterates the importance of accounting for social risk factors in risk adjustment, which have been proven to have a strong effect on patient outcomes.^{9,10} ACP is encouraged by CMS' thoughtful testing of the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure, including the addition of the Agency for Healthcare Research and Quality's SES index and specialist density. We hope the Agency will continue this trend of testing and introducing new social risk factors into all MIPS measures, including cost measures. ACP reiterates its strong support for the development of patient relationship codes and urges CMS to pursue developing and implementing these with all due expediency, while soliciting stakeholder input. We agree that these new codes would shed valuable insights into the relationships between clinicians and patients, specifically the interactions within and across multiple care teams as medicine becomes increasingly collaborative.

ACP appreciates CMS' ongoing commitment to responding to stakeholder concerns and improving the accuracy of MIPS performance measurement. While we note several positive changes to the redeveloped MSPB and TPCC measures, **ACP strongly opposes attributing broad-based downstream costs to upstream clinicians or practices, particularly at the clinician level.** Given the increased prevalence of value-based contracts and team-based care, attributing cost and quality measures at the TIN-level is more appropriate in most cases. As internal medicine specialists, our members have consistently underscored the lack of accuracy and actionability of these measures. **A more effective way to measure costs would be to look at those associated with a specific condition or specialty, which are more within a clinician's or practice's ability to influence.** The MVP can be leveraged to help to facilitate this transition.

In the event CMS does move forward with these measures, ACP has several concerns with the proposed detailed methodologies. To start, ACP strongly opposes CMS' proposal to attribute the same costs to multiple TINs for both measures, which would essentially double count costs. If CMS is to associate the same costs with multiple TINs, it should divide the costs, not count them twice. This leads to an inaccurate representation of costs. ACP favors a case minimum of

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4913118>

⁸ annals.org/aim/fullarticle/2678505/addressing-social-determinants-improve-patient-care-promote-health-equity

⁹ [who.int/social_determinants/en/](https://www.who.int/social_determinants/en/)

¹⁰ [kff.org/disparities-policy/issue-brief/testimony-the-status-of-health-and-health-care-disparities-in-the-US](https://www.kff.org/disparities-policy/issue-brief/testimony-the-status-of-health-and-health-care-disparities-in-the-US)

35 for both the TPCC and MSPB measures to improve reliability and promote consistency within the Cost Category. ACP supports excluding certain specialties and services, including those that occur prior to the triggering primary care service, those unlikely to be influenced by a clinician's decision (for the MSPB measure) and specialties who infrequently perform primary care services (for the TPCC measure). While these exclusions do not wholly solve the problem of attributing broad-based downstream costs to primary care practices and clinicians, they are an improvement on existing methodologies. ACP opposes dividing the one-year risk window into four week blocks for the TPCC measure, which adds unnecessary complexity and serves little practical purpose. CMS should initiate the one-year risk period with the triggering event and divide the costs between the relevant performance years using December 31st as a cutoff. ACP supports using more recent diagnostic data to calculate risk scores on a rolling basis, which will improve the accuracy of risk adjustment. Thus, clinicians would no longer be penalized if a patient's condition inherently worsens.

Finally, ACP supports requiring multiple services to establish a pattern of care for the TPCC measure. However, two services are insufficient to demonstrate an ongoing physician-patient relationship. Moreover, requiring an additional examination or test that is associated with primary care will only proliferate additional services or tests when they would otherwise not be performed, which runs counter to the goal of driving efficient care delivery. A two-service minimum would also capture a slew of services that are an initial service with follow up appointment, which again, is far from an ongoing, physician-patient relationship. ACP encourages CMS to adopt a higher threshold of at least four services to establish a true pattern of care for the TPCC measure, which would represent an average of one service every quarter. While this will result in less clinicians and practices being evaluated on this measure, it will greatly improve the accuracy of measure in clinicians that are measured.

F. Improvement Activities Category

CMS Proposals: CMS proposes to remove the specific accrediting organizations previously listed for Patient-Centered Medical Homes (PCMHs) and comparable specialty practice designations so as not to restrict to only these groups. The Agency proposes to increase the threshold from at least one clinician in the group to at least 50 percent of the group's NPIs who must perform the same activity for the same continuous 90-day period. In addition, CMS specifies criteria that would be used when considering removal of activities in the future, including whether a measure is outdated, duplicative, seldom reported, or does not align with current clinical guidelines or priority areas. Based on these new criteria, the Agency proposes to add two, modify seven, and remove 15 activities.

ACP Comments: ACP supports CMS' intent to allow a broader set of organizations to qualify as accrediting organizations for PCMHs and comparable specialty practice designations, provided they meet stringent, robust criteria for clinical practice transformation. The College supports the innovative delivery system reforms that PCMHs and comparable specialty practice designations promote and we support policies that encourage their growth, but we also want

to ensure that the integrity of the PCMH concept is preserved through rigorous criteria that holds all organizations to a high standard of care for the patients they serve.

ACP strongly opposes CMS' proposal to drastically increase the threshold from one clinician to at least 50 percent of the group's clinicians who must perform the same improvement activity in order to attest to completing that activity as a group. We understand CMS' intent behind this proposal to require meaningful system level change across an organization. However, improvement activities that are supported by one clinician can vastly improve the functioning of a practice. Instituting this broad rule could have unintended consequences on practices' abilities to attest to improvement activities when in fact they are genuinely improving the patient experience. For example, a practice may hire an additional full time physician to offer extended office hours. Though this function is technically only being performed by one physician, the practice as a whole invested in a new physician to increase its availability to its patients and should be recognized as such. We urge CMS to reject this proposal.

G. Promoting Interoperability Category

CMS Proposals: For the PI Category, CMS proposes to maintain the minimum 90-day (up to a full year) reporting period for 2021 performance year, aligning with the PI Program reporting requirements for hospitals and critical access hospitals (CAHs). The Agency proposes minimal updates from the 2019 to 2020 PI measure set and maintains the four overarching objectives from 2019, which include e-Prescribing, health information exchange, "provider" to patient exchange, and public health and clinical data exchange. Under the e-Prescribing objective, CMS proposes to keep the "Query of Prescription Drug Monitoring Program" (PDMP) measure optional and available for five bonus points in 2020, instead of requiring the measure as previously finalized. They also propose to change the structure of the measure from a numerator/denominator format to a "yes/no" attestation starting in 2019. Additional proposals include removing the "Verify Opioid Treatment Agreement" measure beginning in 2020, as well as updating exclusion criteria and point redistribution policies.

ACP Comments: ACP believes 90 days is a sufficient amount of time to capture the necessary information required for the PI performance category and allows flexibility for participating practices and physicians upgrading or replacing their health IT systems to be able to select the 90 days of data that reflects the highest utilization. **Therefore, the College remains supportive of the 90-day reporting period for the PI Program and further recommends CMS maintain the 90-day reporting period beyond 2021.** This PI reporting period allows for the opportunity to update or implement new and innovative technology throughout the course of the CY without the fear of negatively impacting performance data.

While we appreciate CMS' attempts to simplify and align the PI performance category, there is still much more that needs to be done to improve and evolve this performance category and program overall. The existing PI measures, which are the same measures (just a smaller number of them), have already been found to be cumbersome and inappropriate within the Meaningful Use era and do little to promote interoperability or help clinicians move forward

with health IT utilization. When considering the move to a value-based and learning health care system, and exploring ways to further advance the use of health IT, there is an opportunity to evolve the program to focus less on functional-use measures and more on innovation and leveraging health IT to support innovative, high-value patient care.

The College is disappointed that the PI measures still have a minimum threshold requirement of one or “yes” and that the category remains “all-or-nothing.” In other words, if participants do not report on or claim an exclusion for one of the six required measures, they would earn a zero for the entire category. This requirement is technically more than what was required under the base category in 2018 and the College does not support the fact that a single misstep by a participating clinician or practice could still eliminate any opportunity to score well with PI. In the rule, CMS promotes the concept of evaluating clinicians on their ability to truly leverage EHRs to collect meaningful data that allow clinicians to compare outcomes and patient satisfaction to inform decisions at the point of care and improve patient outcomes, rather than grading clinicians on the number of times they use the technology or the quantity of data they collect irrespective of the practical value to the clinician or practice. Unfortunately, in practice, these policies follow the same logic as the previous EHR reporting programs that we believe fundamentally misses the point. We refer you to our extensive comments on Meaningful Use Stage 3¹¹ and the former Advancing Care Information (ACI) performance category.^{12,13}

The PI performance category should not be limited to a small set of required measures or objectives. Instead, CMS should allow clinicians to select from a somewhat larger list of measures or activities in order to allow for some flexibility. Clinicians need specific, targeted new functionalities and tools within their health IT systems (e.g., clinical and administrative workflow support, data analytics, advanced data visualization, and anticipatory decision-support) in order to succeed in value-based care delivery and reform initiatives. The PI Category should be used as a vehicle to encourage vendors and clinicians to develop and put to use new, innovative ways of capturing, comparing, and leveraging targeted data to drive improvements in clinical decision making and workflows. CMS’ proposal to remove the separate performance category option under PI could result in even less flexibility in the PI category to achieve a high score based on what is actually relevant to the clinician’s specialty or patient population. Clinicians will be preoccupied with churning out numerators and denominators for the required measures to check boxes to avoid payment cuts instead of focusing on ways to really leverage their EHRs to the fullest to improve care for the patients they serve.

To provide more flexibility within the category, ACP recommends that the PI Category incorporate a list of optional, clearly defined, health IT-specific activities from which a clinician can choose from that are appropriate to their specialty, much like the IA Category. CMS should adopt this approach if they truly intend to move beyond the burdensome reporting elements of the legacy EHR reporting programs that have hindered health IT and EHR

¹¹ [acponline.org/acp_policy/letters/acp_mu_stage_3_comments_2015.pdf](https://www.acponline.org/acp_policy/letters/acp_mu_stage_3_comments_2015.pdf)

¹² [acponline.org/acp_policy/letters/comment_letter_macra_proposed_rule_2016.pdf](https://www.acponline.org/acp_policy/letters/comment_letter_macra_proposed_rule_2016.pdf)

¹³ [acponline.org/acp_policy/letters/cms_comment_letter_re_cy_2018_macra_qpp_proposed_rule_2017.pdf](https://www.acponline.org/acp_policy/letters/cms_comment_letter_re_cy_2018_macra_qpp_proposed_rule_2017.pdf)

innovation and left physicians dissatisfied with their EHR systems. Below is a list of specific health IT functionalities that could be incorporated into the PI category. These examples are relevant to CMS' request for information on additional health IT activities to consider in lieu of reporting on existing measures and objectives and are described in more detail in the next section of this letter.

Examples of health IT activities include:¹⁴

- EHR/Health IT educational activity developed/endorsed by medical specialty or professional societies;
- Precision medicine/learning health system (e.g., participation in practice-based research or other observational study efforts);
- Clinical informatics improvement (support iterative improvement in practical informatics via an "EHR feedback" application or participation in an EHR user group);
- Quality, safety, value improvement projects that leverage Health IT;
- Patient safety and near-miss reporting; and
- Development of eCQMs that support quality improvement (done within a QCDR).

ACP will continue to call for the PI performance category to be re-conceptualized in order for it to be a meaningful program that promotes the use of health IT to improve care and support practical interoperability. In the meantime, we have specific comments regarding the proposed 2020 PI measure set. **ACP supports the following PI measures provided there are no minimum threshold requirements or required performance measures. However, we have targeted concerns with each of the specific measures, as described more fully below.**

- ***E-Prescribing measure:*** Continued improvement of e-prescribing is necessary to make the process more efficient and effective. For example, the inclusion of a requirement to check a drug formulary becomes logistically challenging and burdensome in some instances, especially when some EHR systems do not have the functionality to query a Pharmacy Benefits Manager (PBM) or formulary within the EHR and therefore require clinicians to open a separate web browser. This is not only burdensome but it is also unclear that the clinician would receive credit for that query since it happened outside of the system.
- ***Query of Prescription Drug Monitoring Program (PDMP) Measure:*** ACP appreciates the proposal to keep this measure optional and allow for bonus points. The College supports CMS' focus on addressing the opioid crisis and agrees that PDMPs play an important role. However, 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.
- ***Support Electronic Referral Loops by Sending Health Information Measure:*** The College does not believe that measuring and promoting interoperability should focus on sending

¹⁴ [acponline.org/acp_policy/letters/comment_letter_macra_proposed_rule_2016.pdf](https://www.acponline.org/acp_policy/letters/comment_letter_macra_proposed_rule_2016.pdf)

continuity of care documents back and forth. This measure does not address the key issue of clinicians having access and sharing useful, actionable clinical data at the point of care.

- ***Provide Patients Electronic Access to Their Health Information Measure:*** All patients should be offered timely access to their own health information.
- ***Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting Measures (report two):*** The College understands the value of data reported to Public Health and Clinical Data registries but highlights the fact that these registries may not always be prepared to receive electronic reports using preferred data standards. ACP appreciates the flexibility in choosing any of the two types of public health and clinical data exchange options but recommends that bonus points be available for reporting to additional entities, whether they are quality measurement organizations, clinical data registries, public health organizations, health information exchanges, or research organizations.
- ***Verify Opioid Treatment Agreement Measure:*** ACP supports removal of this measure and appreciates CMS considering ACP's concerns regarding burden and lack of evidence as to whether this type of measurement would be useful.
- ***Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure:*** ACP does not support this measure and recommends CMS not implement. The College remains skeptical as to whether this measure will actually improve interoperability. It is not clear that clinical reconciliation is an activity that adds value to care transfers from any clinician to any other clinician. Experience has shown that duplicative information is being sent back and forth causing information overload when just a small amount of information has actually changed. Moreover, mandatory clinical list reconciliation without a shared convention of how the lists are used, which is the current state of practice, is likely to cause more problems than it resolves.

H. Promoting Interoperability Performance Category Requests for Information

CMS Proposals: The Agency seeks comment and information on a number of topics for the future of the PI Category including new opioid-related measures, incorporating physician efficiency metrics, specific requirements regarding how and when patients can access their health data, patient matching, integrating patient-generated health data in EHRs, and promoting EHR safety.

i. Developing a Metric to Improve Efficiency of "Providers" within EHRs

ACP Comments: ACP believes that measuring resource use linked to health IT-enabled processes is problematic and not feasible at this point. As it stands, there is no way to accurately measure the data that all physicians have access to at the point of care when they are deciding whether or not to order certain labs, tests, or services. It is also difficult to

measure the burden of obtaining non-integrated outside records to avoid duplicate testing. Rather than focusing on the number of seconds it takes to log onto a system (via authentication apps, etc.), measurement should focus on the EHR metadata regarding the time of day that physicians or others are using their EHR outside of scheduled working hours. The College reiterates that any new measure added to the PI Category should not add unnecessary administrative burden for participating physicians. To our earlier point about burdensome and cumbersome PI measures, any type of new measurement (including numerator, denominator, exclusions, and exceptions) needs to be automatically calculated from the EHR to minimize manual documentation required of the clinician and should have no minimum performance threshold requirement. If one of CMS' primary goals is to reduce unnecessary administrative burden and put patients first, the metric of "pajama time," while imperfect, could acknowledge the burden of this work and its contribution to clinician burnout.

- ii. *Establishing an alternative measure under the "Provider to Patient Exchange" Objective requiring clinicians to give patients their complete data contained within their EHR*

ACP Comments: The questions posed by CMS regarding requirements for clinicians to give patients all of their data contained within the EHR are based on the application programming interface (API) proposals outlined in rulemaking from both CMS and ONC earlier in 2019. The College agrees that APIs are an important component in health information exchange and have the potential to greatly advance patients' access to their data and the exchange of information. We support the concept of patients having seamless access to their health information and have long advocated for the use of standards-based APIs to help promote electronic health information (EHI) exchange. However, we have concerns related to privacy, security, and cost.

Specifically, the College is concerned that a number of patient privacy issues will arise when allowing third-party app developers to access EHI on behalf of the patient when the patient is unaware of to whom they are actually allowing to access their data. As proposed, there is no requirement for API technology to include privacy controls even though the technological capability exists to do so. Recent reports¹⁵ discuss how application developers sell data to third parties and how most do not share privacy policies with the patient or, when they do, do not adhere to those policies. Personal health information is some of the most sensitive and private information for an individual. While it is absolutely a patient's right to have access to that information, allowing and promoting access without requiring necessary privacy and security controls presents a very real risk and will ultimately affect the patient's willingness to disclose information to his or her clinician.

As the health IT app ecosystem continues to evolve, patients need to be properly educated and provided clear guidance around what they are agreeing to when signing into an app and that their personal EHI could be at risk. There must be a uniform and plain language description to the patient about how the information is sold so that both the app developer and the clinician

¹⁵ jamanetwork.com/journals/jamanetworkopen/fullarticle/2730782

can accurately reflect what is being shared while decreasing the burden on clinicians who will have to navigate differing privacy practices across the application industry. Additionally, there needs to be some mechanism to report bad actors or app developers that consistently share data inappropriately. From the physician perspective, ACP has significant concerns that clinicians will be required to allow apps to query their systems without certainty that the apps are behaving appropriately. Physicians feel a fundamental responsibility to protect their patients and their information. API access coupled with ONC's information blocking regulations should not absolve physicians or require them to ignore deeply felt professional responsibilities to their patients. We also are concerned about the costs associated with installation and the ongoing operation of APIs. While the College supports ONC's proposals to limit the fees a vendor can charge a physician and provide patients access to data free of charge, we are concerned that physicians would be expected to provide data exchange services without being permitted to charge for these services. We would also like to highlight that use of APIs cannot be relied upon as the only solution to issues with interoperability. The fact that there is no standard API and that a clinician interacting with multiple EHR systems is dealing with multiple APIs can lead to numerous versions of clinical data outputs – with clinical data presented in varying forms leading to the information overload. There is also a considerable amount of work required to appropriately map data elements outside of a standard data set.

Given these concerns, ACP recommends CMS not shorten any timeframe requirements for providing patient data until these privacy, security, cost, and technical concerns are addressed. We support making bonus points available within the PI category for adoption of Fast Healthcare Interoperability Resources (FHIR)-based APIs provided this API technology is accompanied with appropriate privacy and security agreements and controls. The College recommends CMS not add measures that require clinicians to use technology certified to the EHI criterion to provide patients' their complete electronic health data until the EHI export functionality has been shown to be valuable and produce meaningful and useful data.

iii. *Additional Health IT Activities to Consider in lieu of Reporting on Existing Measures and Objectives that would Most Effectively Advance Priorities for Nationwide Interoperability and Spur Innovation*

ACP believes the following types of health IT-related activities would be beneficial in lieu of existing PI measures and objectives:

- 1) *EHR/Health IT educational activity developed/endorsed by medical specialty or professional societies:*** Clinicians face a steep learning curve when it comes to implementing new health IT in their practices. Providing an incentive to participate in educational courses and continuing medical education in basic use of health IT (particularly when it comes to supporting patient engagement, safety, quality, and cost) would be beneficial to the clinician, the health IT community, and most importantly, the patient. ACP continues to support such programs where CMS and ONC partner with medical specialty and professional societies who could create or endorse such educational programs for their memberships.

- 2) **Participation in precision medicine/learning health system (e.g., participation in practice-based research or other observational study efforts):** Precision medicine and the learning health system is the future of meaningful use of health IT. No matter what their specialty, clinicians may find value in getting involved with an observational study or any other activity that might be considered as evidence-generating medicine. Clinicians could run phenotyping algorithms on their data and contribute the results or use existing data collections to identify appropriate treatment patterns for specific patients based on social determinants they have collected.
- 3) **Clinical informatics improvement (e.g., support of iterative improvement in practical informatics via use of an “EHR feedback” application or participation in an EHR user group):** Certified EHR systems should have a “feedback” mechanism available so that EHR users can quickly and easily collect context sensitive thoughts for submission to a vendor-managed improvement process or user group, or for later consideration and elaboration. Having this type of bottom-up approach to health IT design allows for clinicians to have the opportunity to contribute to the software personalization in a way that helps them consistently deliver better care.
- 4) **Quality, safety, value improvement projects that leverage Health IT:** CMS should create a measure for reporting on an innovation involving health IT that clinicians could report each year using a specified format. A simple example might be a data quality improvement project aimed at addressing variation in how a particular data element is collected at the point of care.
- 5) **Patient safety and “near-miss” reporting:** Clinicians should have the ability to easily report patient safety, adverse events, and near-miss reports directly from the EHR system. While the point value would be expected to be low for a single completed report, the value to improving patient care warrants making this a PI measure. Safety reporting levels are unacceptably low, and the PI program can help to resolve this problem.
- 6) **Development of eCQMs that support quality improvement (done within a QCDR):** The current set of eCQMs is not sufficiently diverse to support an array of specialties and patient populations. Moreover, many existing measures are of such poor quality that they should not be used. Attempts to create new electronic measures have resulted in an entirely new set of data quality problems. Clinicians should get credit for proposing measures that conform to the constraints of a defined template while using existing EHR data. These “e-measures” should measure implementation of evidence-based care. Registry technologies, such as QCDRs, offer a way for clinicians and practices to collect encounter data and analyze them for opportunities to measure and improve quality. Such a platform could allow practices to focus on areas that truly matter at the individual- and practice-level.

iv. Facilitate Private Sector Efforts on a Workable, Scalable Patient Matching Strategy

ACP Comments: Absent a national patient identifier, ACP supports a national initiative that explores the use of a common set of data elements to match a patient to his/her individual EHI. However, ACP is concerned that this may require the use of a relatively large set of identifiable patient demographic data to support matching. We believe this dependence on so many data elements may present another privacy risk for patients. Accordingly, ACP believes that use of a voluntary universal unique healthcare identifier that patients would opt into could help to protect privacy and should be studied and explored. A voluntary universal unique identifier for patients that has no other use beyond associating them with their health records might be less risky than using a set of demographic information that could have value beyond identification for health care purposes. These privacy concerns should not be dismissed without thorough evaluation of the potential risks and benefits. **The College strongly recommends that CMS and ONC initiate a thorough study of the risks and benefits of a voluntary universal unique patient identifier.** As both CMS and ONC begin to address some of the complexities of patient identification and matching, they should consider the policies discussed in the second draft of the Trusted Exchange Framework and Common Agreement (TEFCA) and recommendations for qualified health information networks (QHINs).

v. Integrating Patient-Generated Health Data (PGHD) into EHRs using CEHRT

ACP Comments: ACP believes that PGHD is valuable and has the potential to provide additional insights into improving patient health, provided the data is collected and displayed in reliable and meaningful ways. It is important that efforts to incorporate this data within the EHR are focused on high-yield clinical use cases that present valuable data captured in a way that aligns with its clinical use. For example, meaningful PGHD should be easily summarized and digestible, and not provide 120 blood pressure measurements from the last 60 days without summary, context, or appropriate flags for results that fall outside of normal limits, as is currently the case. Another example- receiving an output of glucose readings performed three times per day without a summary, ranges, outliers, or other relevant contextual information. How the source of the data is labeled and maintained should also be an important consideration (laboratory systems will likely require this type of labeling due to Clinical Lab Improvements Amendments (CLIA) regulations). As CMS explores in this area, it should concurrently be working to create powerful and specialty-specific informational displays that unlock the power of this type of information. Any data can only be as valuable as its ability to be readily interpreted.

I. Third Party Intermediaries

CMS Proposals: CMS proposes to align the MIPS quality measure update cycle with the eCQM annual update cycle and introduces several new stipulations on measure developers, including that they must: 1) agree to provide services for the duration of the entire performance period and applicable data submission period as a precondition of their approval and must aid in transitioning clients to an alternative vendor if this does not occur; 2) submit data for all three

MIPS performance categories that require active reporting (with limited exceptions); 3) engage in activities that foster quality improvement and enhanced performance feedback; and 4) only submit measures that have already been fully developed with complete testing results at the time of nomination. The Agency also proposes to reject any measures that are not available for reporting through other QCDRs, following a policy finalized last year that vendors must agree to enter into licensing agreements with CMS permitting any approved QCDR to submit data on the measure for purposes of MIPS. The Agency also proposes a new two-year process for removing QCDR measures that largely aligns with the process for removing other measures and lists several criteria to be considered when approving new measures and removing measures.

ACP Comments: ACP supports CMS' proposal to align the MIPS quality measure update cycle with the eCQM annual update cycle. We agree that this will help to reduce burden on measure developers and encourage the Agency to finalize this provision as proposed. We also support efforts to prioritize high-priority measures such as those that are outcome-based and the removal of low-value measures, provided they do not limit a particular specialty's ability to succeed in the program. We support a two-year removal process that would allow time for stakeholder input prior to a measure's removal and in addition to seeking stakeholder input through the comment process, we encourage CMS to actively seek out input by reaching out to potentially affected specialties and subspecialties.

ACP supports certain criteria CMS proposes for measure developers that would provide clinicians with more assurance and predictability, including that vendors must agree to provide services for the duration of the entire performance period and applicable data submission period or aid in transitioning clients to an alternative vendor if this does not occur, as well as engage in activities that foster quality improvement and enhanced performance feedback.

That said, we have some concerns over some adverse unintended consequences that may result from some of the specific proposed criteria. For instance, while ACP has long underscored the importance of regular feedback to drive performance improvement and **we support CMS requiring quarterly feedback reports (at a minimum) from QCDRs and other vendors, provided clinicians provide the necessary data, we encourage CMS to mandate implementation no earlier than the 2021 performance year** to provide vendors with adequate time to perform any necessary system upgrades to prevent possible data reporting disruptions for clinicians who rely on those products. ACP is also an ardent supporter of tightening the timeframe between performance, data reporting, feedback, and payment adjustments and we believe supporting clinicians in their ability to report data throughout the performance period is a noble goal to work toward. **However, mandating this change in the near term would require many practices to substantially alter their practice workflows, including training staff and implementing system upgrades, which would drastically increase reporting burden and impose added expense.** Additionally, an overhaul to MIPS data reporting of this extent would require substantive lead time to responsibly implement and should not be imposed at the same time CMS is considering transitioning to the MVP. If CMS does consider such a policy in the future, it should closely monitor and provide transparent data on how many practices already

have this ability to report data on an ongoing basis to assess how prepared the industry is for this type of transition and the level of disruption it would cause.

While we see the merit in requiring vendors to report for all three performance categories that require active reporting, we are concerned that technologies that are specially designed may not be able to meet this requirement, particularly in the timeframe between the finalization of the rule and the start of the 2020 performance period. While we agree it benefits clinicians to streamline reporting across categories and to be made aware of any product limitations up front, it also benefits clinicians to have an array of reporting options. Certain categories, such as Improvement Activities, can be easily reported through the CMS MIPS portal at no cost, so there is not as strong of a market demand to spend the money to build this into QCDRs. Requiring this may lead them to raise prices for the products, which would negatively impact practices, particularly smaller practices that can struggle to afford these technologies. **Instead of forcing QCDRs to close if they do not support reporting for these three performance categories, thereby potentially limiting reporting options for clinicians, ACP encourages CMS to implement strong transparency requirements so that QCDR vendors are required to clearly inform clinicians prior to purchase if a particular product does not support reporting for a particular MIPS performance category/categories.** At a minimum, if CMS does decide to move forward with mandating this requirement, we urge the Agency to delay required compliance by one year to give vendors more time to make the necessary system upgrades to prevent an abrupt decline in the number of available QCDR options for the 2020 performance year.

ACP has major concerns about the potential negative impact that rejecting measures from QCDR measure developers that do not sign a licensing agreement with CMS would have on future measure development. QCDR measure owners invest significant resources into measure development, data collection, and validation and often develop these measures for use beyond MIPS reporting (e.g., research, guideline development, quality improvement, etc.). They might not be willing to make the same investments in the future if CMS removes this important incentive. Moreover, allowing other QCDR developers to use the same measure does not guarantee that it will perform oversight responsibilities in the same way, which could lead to key data inconsistencies across vendors. A more effective approach would be taking a more active role in facilitating multi-stakeholder collaborations on development of future measures. Not only would CMS be able to more proactively drive the development of measures in key strategic priority areas, it would also accomplish the end goal of achieving consistency of measures across vendor platforms without dissuading development of future measures, and likely facilitating the more timely development of additional measures because vendors would be able to pool resources. In addition, the measure developers would continue to collaborate in monitoring and updating the measure, averting data inconsistencies down the road.

While ACP appreciates the importance of ensuring measures are valid and reliable, we have some concern that requiring all measures to be fully tested with any concerns over validity, reliability, and feasibility already resolved prior to nomination may slow the development of new measures. Responsible measure development takes time. ACP has long supported the concept of testing measures during a trial period during which performance would not be

counted against clinicians, and they may be offered some small incentive to report on the measures so that the developer can continue to refine them. Adopting new measures on a trial basis would facilitate and expedite the testing of new measures on a large scale without negatively impacting clinicians' performance if refinements need to be made to improve the reliability, validity, or feasibility and we strongly urge CMS to adopt this approach instead.

J. Targeted Review and Data Validation and Auditing

CMS Proposals: CMS proposes to allow third party intermediaries to submit a request for a targeted review on behalf of a clinician or group (or multiple). CMS proposes to limit the targeted review period to 60 days, which would begin on the day CMS makes available the MIPS payment adjustment factors and extend to a date specified by CMS, which may be extended. Requests for targeted reviews may be denied if: 1) they are duplicative of another request; 2) they are not submitted within the submission period; 3) they are outside the scope of targeted reviews, which is limited to MIPS payment adjustment calculations; or 4) requested supporting documentation is not provided within 30 days. CMS will notify all submitters of the final decision and reiterates in the rule that targeted review decisions are final and not subject to review or appeal.

ACP Comments: ACP supports CMS' proposal to allow third party intermediaries to submit requests for targeted reviews on behalf of multiple clinicians and groups, which will greatly streamline the number of review requests for CMS and therefore expedite their review and approval, as well as reduce administrative burden on physician practices. However, ACP has concerns over placing such a restrictive time limit on clinician's abilities to review process, and maintains that clinicians who are wrongly assessed with an inaccurate payment adjustment (through no fault of their own) should be able to review a request at any time up until the end of data submission period. At a minimum, clinicians should be given an opportunity to request review requests following the first impacted payment. We additionally reiterate that CMS should institute a reviews process for denied requests, which would help to promote integrity within the MIPS Program.

K. Physician Compare

CMS Proposals: CMS proposes to publicly post individual MIPS performance data, including final MIPS scores and individual performance category scores, in addition to aggregate MIPS data with minimum, average, and maximum scores, starting with 2018 performance data. It would post this information as soon as feasible. Clinicians would be indicated if scored using facility-based scoring with a link to facility-based measure-level information and Advanced APMs would have clinicians listed and link to information about that APM, including relevant performance information, as feasible. In a separate rule, CMS proposes to indicate whether clinicians successfully completed CEHRT compatibility/interoperability attestations. CMS seeks comment on adding additional data to Physician Compare in the future, including patient narratives, patient reported outcomes measures, and a single "value indicator" that would aggregate cost, quality, patient experience, and patient satisfaction data.

ACP Comments: ACP supports the important work of Physician Compare to promote transparency of reliable, valid cost and quality indicators. We reiterate the importance of ensuring that data on the website is up to date, accurate, and provided with appropriate context and emphasize the importance of ensuring measures have been thoroughly tested and vetted for evidence-base and statistical reliability before being added to Physician Compare. This which be particularly important to patient-reported and administrative claims based measures, both of which are calculated independently of any data reported by the clinician. Dispensing misleading or inaccurate information can do more damage when it comes to educating patients than no information at all.

ACP has repeatedly noted the impact that social determinants can have on patient health outcomes, along with the fact that these are not adequately accounted for in current risk adjustment methodologies. That means physicians who are treating more vulnerable patient populations could have worse quality outcomes, though much of this may be associated more with the patient populations they are treating than their skills as a physician. ACP urges CMS to consider these important ramifications and reiterates the importance of continuing to provide physicians with an opportunity to review measures in advance and appeal for reconsideration if they suspect inaccuracies, and ensuring data corrections are made as expediently as possible. ACP members report that many months can pass between when CMS is notified of a potential inaccuracy and when the correction is posted. In that time, the physician or practice could have already experienced substantial, undeserved damage to their reputation. ACP supports markers to indicate information such as if a practice was measured using facility-based scoring or under the MIPS APM scoring standard with links to relevant information but reiterates that all metrics and indicators should be provided in appropriate context. For example, if a particular measure was not available to a practice because they did not qualify, this should be indicated differently than for practices who simply did not report on the measure. These considerations will be especially important as CMS embarks on testing and implementing the new MVP.

L. Medicare Shared Savings Program (MSSP) Quality Changes

CMS Proposals: CMS proposes a few changes to the MSSP quality measures set summarized in Table 32 of the rule and seeks comment on replacing the MSSP quality score with the MIPS quality performance score. The Agency also proposes to raise the minimum quality threshold so that every MIPS quality measure must meet or exceed the fourth decile, and raises the possibility of further raising this threshold in the future to either the median or mean quality score. Finally, CMS explores removing the exemption from minimum quality reporting requirements for ACOs in their first performance year.

ACP Comments: ACP generally supports alignment between Medicare programs, including the MSSP and MIPS, in the interest of reducing program complexity and reporting burden. We are supportive of certain changes in the rule that would come with that, such as adjusting for social risk factors for the multiple chronic conditions measure and awarding a score of zero for a non-reported measure, rather than designating an ACO as an “incomplete reporter” and therefore ineligible for shared savings. However, ACOs are already navigating a complete overhaul of the

program under the new rules established by the Pathways to Success final rule, which just took effect July 1. Quality reporting and scoring is one of the few elements of consistency; this is not the time to overhaul it amidst all of the other changes MSSP ACOs are grappling with. This uncertainty is exacerbated by proposals in this rule to overhaul MIPS quality scoring itself by introducing the MVP as soon as 2021. CMS notes in those sections of the rule that one of the goals is to eventually facilitate an easier transition to APMs, which ACP supports. **However, rather than force ACOs to grapple with another entirely new set of requirements that could themselves change one year later, ACP urges CMS to hold off on this proposal, and to instead focus on developing the structure of MVPs in collaboration with stakeholders, with an eye toward aligning MIPS and MSSP quality reporting in the future.**

ACP opposes raising the minimum quality threshold used to determine if an ACO is eligible to share in savings, which would create a substantial increase in reporting burden. As we look to transition to the MVP, this is not the time to also increase reporting burden for ACOs. Moreover, while many ACOs may be successfully meeting quality targets now, this may not always be the case as new ACO quality measures are introduced in the future. As demonstrated with ACO #17, even small tweaks to an existing measure's methodology can have a detrimental impact on performance,¹⁶ much less introducing new measures altogether. Raising permanent thresholds that would last through unforeseen changes to the quality measure set based on performance of a current set of measures that ACOs have spent years gaining familiarity with is unwise and risks setting ACOs up for future failure.

ACP also has major reservations concerning CMS' proposal to no longer exempt ACOs in their first performance year from minimum quality requirements. Starting or joining an ACO requires a substantial amount of resources and time getting the necessary infrastructure in place and in many cases, adjusting to new clinical workflow process and familiarizing staff with new reporting technologies. Before joining an MSSP ACO, it is likely that a clinician or practice reported through another collection type such as CEHRT or QCDR and therefore has no experience with Web Interface reporting. This first year of flexibility is critical to giving ACOs the necessary time to build the required infrastructure, train staff, and get comfortable submitting data through the Web Interface. **We urge CMS to rescind its proposal to eliminate the one year exemption from quality reporting requirements, which comes at a particularly challenging time as ACOs are already grappling with a major overhaul of the program.**

Regarding specific changes proposed to the MSSP quality measures set, ACP does not support CMS' proposal to replace *ACO #14 (MIPS #140) Preventive Care and Screening Influenza Immunization* with *ACO #47 Adult Immunization Status* because it would incorporate new vaccinations not covered by Medicare that patients could therefore have to pay for out of pocket. ACP supports CMS' proposal to make *ACO #17 Preventive Care and Screening: Tobacco Use* pay for reporting for the 2018 performance year. Based on preexisting policy to make measures that undergo substantial changes pay for performance for two years, we urge the Agency to retain the measure as pay for reporting in 2019 as well. Giving clinicians adequate

¹⁶ naacos.com/naacos-letter-to-cms-on-aco-qualitymeasure-17

notice of measure methodology changes is critically important to their ability to successfully prepare for changes and retain confidence in the program.

M. Advanced APMs: Qualifying Payment Arrangements

CMS Proposals: The Agency proposes to make several changes to the definition of risk that would impact which models qualify as Advanced APMs. First, CMS would modify the definition of marginal risk so that any expected expenditures under the APM that exceed what an APM Entity would expect to incur in the absence of that APM would not count toward the benchmark for purposes of evaluating financial risk, though risk adjustment expenditures would still count regardless. This is to avoid payers inflating benchmarks so that the risk of actual expenditures reasonably exceeding it is artificially low. CMS also proposes that for models in which marginal risk varies based on the level of losses, the average marginal risk rate would be used, with exceptions for small and large losses. CMS proposes to establish the term “Aligned Other Payer Medical Home Model” (MHM) and would require all private sector medical homes to formally partner with CMS in a multi-payer model in order to qualify under the medical home standard for the All-Payer Combination Option. Criteria would mirror that for Medicare and Medicaid medical home model standard, including the 50 eligible clinician limit.

ACP Comments: **ACP strongly opposes CMS’ proposal to preemptively establish a broad restriction on private sector models that may qualify as Advanced APMs, which sends the wrong message and could severely inhibit future model development at a time when CMMI should be looking to significantly expand its portfolio of Advanced APMs.** ACP has consistently emphasized the importance of providing stakeholders with transparent, advance notice of changes to program requirements, particularly when those changes would have a substantial impact on a clinician’s QPP status, as these would. APMs take years to design, test, implement, and refine and tens or hundreds of thousands, if not millions of dollars, to develop. Model developers have already submitted models for consideration for the 2020 performance year. Physicians, specialty societies, vendors, and other stakeholders are willing and eager to partner with CMS to transition to a value-based health care delivery and reimbursement system, but when CMS makes massive changes like this with virtually no warning, it makes it nearly impossible to plan for the future and erodes trust and willingness to invest in future model development, which would be detrimental to transitioning more physicians to APMs. Moreover, while we appreciate CMS’ interest to maintain robust standards for a model to be designated as an Advanced APM, CMS already has the ability to monitor this on a case-by-case basis through its Other Payer Advanced APM Determination Process. **Therefore, we encourage CMS to leverage this existing process to monitor that private sector APMs meet robust risk requirements on a case by case basis and gain a better understanding of how much of an issue this would actually be over a few years of experience before preemptively instating this highly impactful, generalized new criteria.** CMS also fails to sufficiently explain how it would determine which expected expenditures under an APM “exceed what an APM Entity would expect to incur in the absence of that APM,” which is alarming.

ACP supports CMS' proposal to exclude lower marginal loss rates at higher levels of losses to protect APM Entities against potentially catastrophic losses. **However, we have reservations about the Agency's proposal to disregard "small losses," which could hinder a model's ability to meet the 30 percent marginal risk threshold.** CMS defines this limited exception for small losses as any case in which actual expenditures exceed expected expenditures by less than four percent of expected expenditures. Four percent of expected expenditures can represent a substantial amount of an APM Entity's profit margin. Additionally, experience with Advanced APMs to date shows that the vast majority of APM Entities tend to fall within this margin of small savings or losses. Consequently, many more APM Entities will be subject to this higher marginal risk rate than those exposed to the marginal risk rate for exceptionally high losses, so to not include them toward the calculation of marginal risk would be misleading.

While ACP supports the proliferation of multi-payer models, we strongly oppose CMS' proposal to defy Congressional intent by restricting the definition of a private sector models that qualify under the medical home standard for the All Payer Combination Option to only those that formally align with Medicare. The Medicare Access and Children's Health Insurance Program Reauthorization Act (MACRA) established a medical home standard specifically under the All-Payer Combination Threshold Option that allowed other payment arrangements to qualify "regardless of payer," provided they are a medical home that meets criteria comparable to medical homes expanded under section 1115A(c) of the Social Security Act. If an Other Payer arrangement meets this criteria, along with the use of CEHRT and quality measures that are comparable to MIPS, there is no question that it should qualify under the medical home standard toward the All-Payer Combination Threshold Option.

Today, medical homes are one of the most pervasive and successful types of innovative payment arrangements in the private sector with hundreds of participating private payers and are expected to be one of the key pathways for private sector models to qualify as an Other Payer Advanced APMs. ACP was responsible for helping to popularize the medical home concept in the early 2000s with its advanced medical home criteria,¹⁷ followed by defining principles for patient-centered medical homes developed in partnership with the American Academy of Pediatrics, American Academy of Family Physicians, and American Osteopathic Association.¹⁸ Today, there are thousands of private sector medical homes with promising results on patient quality outcomes and costs.^{19,20} To not count these models toward the All-Payer Combination Option would be pulling the rug out from thousands of practices that for years have invested in value-based clinical transformations, have shown positive results, and up until now, were expecting to have these efforts recognized by qualifying as an Other Payer Advanced APM under the medical home standard. **This type of unexpected and major change, the sole purpose of which appears to be to restrict the number of private sector models that qualify as Advanced APMs, would undermine physicians' confidence in the QPP and could**

¹⁷ [acponline.org/acppolicy/policies/advmedicalhomepatientcenteredmodelhealthcare2006.pdf](https://www.acponline.org/acppolicy/policies/advmedicalhomepatientcenteredmodelhealthcare2006.pdf)

¹⁸ [acponline.org/acp_policy/policies/joint_principles_pcmh_2007.pdf](https://www.acponline.org/acp_policy/policies/joint_principles_pcmh_2007.pdf)

¹⁹ [pcpcc.org/2016/07/14/patient-centered-medical-homes-save-money](https://www.pcpcc.org/2016/07/14/patient-centered-medical-homes-save-money)

²⁰ [healthcarediver.com/news/acos-using-medical-home-physicians-save-money-yield-higher-quality-report/](https://www.healthcarediver.com/news/acos-using-medical-home-physicians-save-money-yield-higher-quality-report/)

potentially have a devastating and long-lasting impact on their willingness to invest in future APMs. We urge CMS in the strongest possible terms to reverse this proposal and to count strictly private sector medical homes toward the All-Payer Combination Option under the medical home standard, as Congress intended when it wrote MACRA. We also reiterate past calls for CMS to remove the arbitrary and restrictive 50-clinician limit for both Medicare and multi-payer MHMs.

N. Exclusions under Full Capitation Arrangements

CMS Proposals: CMS seeks comment on categories of items and services that should be excluded from a capitation arrangement and what percentage of total cost should constitute a “full capitation” arrangement.

ACP Comments: ACP appreciates CMS’ interest in exploring full and partial capitation models, which we fully support. **We feel capitation models are an important component of a modern health care delivery and payment system that is focused on value, particularly for internal medicine physicians who provide primary care and other cognitive services.**

For capitation models to work, payments must be sufficient to cover the costs and practice expenses associated with the daily functioning of an internal medicine practice. We expect the proposed reevaluation of E/M changes to help in this area and to provide a more suitable foundation for the calculation of future capitated payments based on underlying services. Payments must be sufficient to support the types of advanced clinical supports and infrastructure inherent to a high efficiency-based model, including additional support staff, health IT to facilitate the capturing and sharing of critical quality and cost data, and additional patient supports. Existing research places this at around 10-15 percent of physician compensation.²¹

Capitation-based models also present a unique opportunity to drastically reduce administrative burden, particularly billing requirements for non-face-to-face or other supplemental services because practices are inherently responsible for total costs. That said, CMS must monitor service patterns for any unusual downturns in service billing to ensure that services are not being inappropriately rationed to control costs. Equally important, CMS must carefully consider and monitor the impact on access to care, particularly for high-risk patient populations. This would be particularly important for direct primary care models in which physicians directly contract with patients. As with any model, but particularly in capitation-based models, accurate risk adjustment is critical, including adjusting for natural downturns in health status and social risk factors.

That said, as CMS explores capitation models, it is important to keep in mind that while full capitation models may certainly be an effective way to hold practices accountable for cost while minimizing burden and improving patient outcomes, these inherently high-risk models

²¹ www2.deloitte.com/insights/us/en/industry/health-care/volume-to-value-based-care.html

may not be appropriate or sustainable for practices of all specialties or sizes, particularly those in rural areas or treating at-risk patient populations, which tend to require additional support. Accordingly, ACP encourages CMS to explore and test a wide range of capitation-based designs, including physician salaries, direct contracting, and a variety of hybrid, or partial capitation models based around a particular condition or set of related services, similar to the Bundled Payments for Care Improvement Model. Offering practices opportunities to scale up financial risk and build confidence with higher levels of risk over time is critical to successfully transitioning practices of all varieties and sizes to APMs, particularly risk-bearing APMs.

CMS should seek feedback from other payers for lessons learned from their experiences with existing capitation-based models, particularly Medicare Advantage (MA), which has a strong hold in population-based payment models including global budgets.²² ACP also strongly encourages CMS to collaborate with MA plans, Medicaid managed care organizations, and private sector developers in the development of multi-payer capitation models. Practices are better equipped to succeed when they have aligned incentives, rather than one foot in the fee for service world and one in the value-based payment world. As CMS continues to explore capitation models, ACP wishes to underscore the importance of stakeholder feedback throughout both the design and implementation process, and offers our willing assistance to solicit more detailed feedback in response to specific model designs.

O. Advanced APMs - Qualified Advanced APM Participant (QP) Status

CMS Proposals: CMS proposes several changes to the way Partial QP thresholds would be calculated moving forward. Currently, elections to participate or not participate in MIPS based on Partial QP status are often made at the APM Entity level. Partial QP elections are then applied at the National Provider Identifier (NPI) level, across all TIN/NPI combinations. Moving forward, CMS proposes to only apply Partial QP status to the TINs through which a clinician achieves partial QP status, allowing individual clinicians to participate in MIPS and be eligible for a payment adjustment under other TINs even if an APM Entity in which they participate elects to opt out. However, this would also mean clinicians would still be expected to participate in MIPS or face a penalty for any non-APM TINs. In addition, CMS proposes to not count Advanced APM Entities towards a clinician's QP status if they terminate (voluntarily or involuntarily) before: 1) the end of a performance period; or 2) prior to bearing responsibility for financial risk under the terms of the APM.

ACP Comments: ACP appreciates CMS' concern that some eligible clinicians may miss out on a MIPS bonus as a result of its current policy in which APM Entity's make a decision to participate or not participate in MIPS on behalf of the eligible clinician, so clinicians who would have qualified for a MIPS bonus through another TIN would miss out. On the other hand, we fear this proposed policy change would result in unintended consequences that would also negatively impact clinicians. Specifically, even those clinicians who substantially participated in Advanced APMs enough to achieve Partial QP status would still be expected to simultaneously participate

²² <http://hcp-lan.org/workproducts/apm-discussion-2018.pdf>

in MIPS, or face a possible penalty under any TIN that is not an Advanced APM Entity. Clinicians participate in Advanced APMs with the goal and expectation of becoming Qualified Participants. While meeting the rigorous demands of the Advanced APM, they likely will not simultaneously prepare a backup plan for MIPS reporting in the event they do not qualify. Missing the QP threshold is disappointing, the primary advantage to earning Partial QP status is the option to be exempt from MIPS which was intended to recognize the hard work and investment that goes toward participating in an Advanced APM. To take this away from clinicians would be a major setback to those clinicians and undermine their confidence in the QPP and willingness to invest in Advanced APMs, particularly as the QP and Partial QP thresholds rise in the future. **We urge CMS to instead calculate the individual scores for all MIPS eligible clinicians that are Partial QPs and, similar to its policy for facility-based scoring, apply the score that yields the advantageous outcome to the clinician.** In other words, clinicians who would earn a MIPS bonus would be assessed that bonus, while those that would earn a penalty would be exempt from MIPS. This would mirror other MIPS policies including facility based scoring and the proposed new policy for the MIPS APM scoring standard in which CMS would calculate and use the highest reported score for each clinician. We urge CMS to adopt this revised alternative proposal, which aligns with CMS' intent behind the proposal to eliminate unintended consequences while creating consistency with other MIPS policies, incenting APM participation, and minimizing burden both on clinicians and CMS.

Concerning CMS' proposed policy to not count APM Entities toward a clinician's QP status if they terminate before the end of a performance period or prior to bearing responsibility for financial risk, individual clinicians have virtually no control over whether their APM Entity folds prior to either of these points, despite their best efforts to participate in and support the Advanced APM Entity and would have little recourse to participate in MIPS if the APM Entity terminates and fails to report on their behalf during, or even potentially after the performance year under this proposal. Data that was reported to the APM Entity could be lost in many cases, giving clinicians no resource for reporting data to MIPS since they could already be well into, or even completed the performance year. As CMS hopes to shift more clinicians to risk-bearing APMs, it is critical that they incentivize, not penalize, clinicians for doing so. Combined, these two proposed changes to the QP threshold could significantly deter clinicians from making the substantial upfront investment to participate in an Advanced APM. Therefore, **we urge CMS to instead offer these clinicians who participate in Advanced APMs a one-year exemption from MIPS if the APM Entity in which they participate terminates prior to the end of the performance year or bearing responsibility for financial risk.** This would protect clinicians who take the risk of participating in Advanced APM and provide them time to secure participation in another Advanced APM or MIPS reporting method. Clinicians would still be incentivized to report MIPS data to be eligible for a positive MIPS bonus if they are able, but would importantly be protected against a penalty in exchange for their willingness to support the transition to risk-bearing APMs.

It has come to ACP's attention that physicians and other clinicians who have qualified for an Advanced APM bonus in 2019 based on their participation in 2017 have yet to receive their bonuses as of September 26, despite the fact that those participating in MIPS began receiving

adjustments January 1. These clinicians took the necessary steps and made significant upfront investments to prepare for participation in Advanced APMs, including hiring additional staff to improve care coordination within and across clinical care teams and investing in new technologies to support advanced care processes and performance data submission. In many if not all cases, the prospect of the additional five percent bonus impacted their decision and ability to weather this investment. Waiting two years is already a significant amount of time to wait to recoup these up front investments, if these payments are not made soon, we fear clinicians could be dissuaded from participating in Advanced APMs in the future, or worse, be forced to make difficult budgetary choices in the short-term that could hinder patient care or inhibit their ability to succeed in APMs, such as letting go of additional staff hired to support enhanced care coordination and other essential functions. **We urge CMS to expeditiously pay the 2019 Advanced APM bonuses and in future years commit to pay these bonuses no later than June 30th of each year.** We refer you to a September 16 [letter](#) that was signed by ACP along with eight other major medical trade organizations calling for the expedient payment of these bonuses.

P. Small Practices

CMS Proposals: CMS proposes to carry over many of the same policies to benefit small practices, including the indefinite three-point floor for measures that meet data completeness requirements, claims-based reporting, and technical support. The Agency proposes no new policies specifically geared towards small and/or rural practices.

ACP Comments: Based on the 30-point differential between the average MIPS score for small practices versus the overall MIPS score and the lower participation rates by small practices in Advanced APMs, **it has become abundantly clear that more wide scale changes to the QPP are needed in order to better accommodate small and rural practices and give them a chance to succeed.** ACP reiterates its past suggestions to establish MIPS performance, exceptional performance, and QP thresholds for small practices, which CMS solicited comment on in previous rulemaking but never finalized. This would ensure small practices are still held to a robust standard for transitioning to value without pitting them in a tournament style program against much larger practices with much greater resources at their disposal, particularly in the case of MIPS where payment adjustments are directly attributed to your performance relative to other practices. In addition, CMS should offer small practices increased sharing rates or an additional extension of the five percent bonus for participating in Advanced APMs beyond that offered to medium and large practices to offer them enhanced incentives to participate in Advanced APMs, or offer reduced risk options for small practices who tend to have tighter margins making the same levels of financial risk potentially catastrophic. Offering models with graduated levels of risk and opportunities for advance payments in general is critical to helping all practices transition to and build confidence with risk-bearing models. However, it would particularly benefit smaller, independent, and more rural practices, who often have the desire to participate in APMs and patient populations that could potentially benefit the most from this type of intervention, but are unable to do so because of substantial entry barriers including significant startup costs.


IV. Conclusion

The College appreciates the opportunity to offer our comment's on CMS' proposed rule on PFS, QPP, and other federal programs for CY 2020. In finalizing its proposed rule, we urge the Agency to consider several key recommendations outlined in this letter, including:

- Finalize E/M codes, CPT guidelines, and RUC recommended values exactly as implemented by the CPT Editorial Panel and submitted by the RUC;
- Reduce documentation burden for E/M services by allowing choice of MDM or time;
- Count examination room desktop computers as a direct medical equipment cost;
- Promote care management by utilizing cost savings to offset PCM codes;
- Require additional survey and review for any requests to increase non-outpatient E/M or other services;
- Work with the physician community prior to finalizing any policy affecting eligibility to participate in the Medicare program;
- Keep MVP participation optional, especially in 2021;
- Work with stakeholders to improve the validity and reliability of MIPS measures prior to removing them;
- Improve risk adjustment and patient attribution methodologies;
- Eliminate the MSPB and TPCC measures and refraining from increasing the weight of the Cost Category amid largescale changes to the category;
- Reverse proposals that would alter the calculation of total and marginal risk to make it more difficult for a payment arrangement to qualify as an Advanced APM;
- Allow non-Medicare aligned private sector medical homes payment arrangements to qualify under the medical home standard towards the All Payer Combination Option;
- Continue applying Partial QP status designations to all of a clinician's TINs;
- Offer clinicians whose QP status would be impacted by an APM Entity that terminates prematurely a one-year exemption from MIPS; and
- Empower small practices to succeed in the QPP by reducing barriers to APM participation and reducing the 30-point MIPS performance gap.

Thank you for considering our comments. ACP looks forward to continuing to work with CMS to strengthen our health care system and continue the transformation towards improved patient access and higher quality of care at reduced costs. Please contact Brian Outland, PhD, Director, Regulatory Affairs, by phone at 202-261-4544 or e-mail at boutland@acponline.org if you have questions or need additional information.

Sincerely,



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

Appendix A: ACP Performance Measurement Committee (PMC) Quality Measure Recommendations in Response to TABLE C*: *Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years*

**Note: ACP only comments on performance measures that are relevant to the practice of Internal Medicine*

QID	Measure Title	ACP Recommendation	Rationale for Recommendation
411	Depression Remission at Six Months	<p>ACP supports the removal of this measure from the measure list.</p> <p>ACP cannot comment on whether to maintain this measure with the substantive changes proposed by the measure steward until the measure has been fully specified and tested to reflect these changes and the PMC has had an opportunity to review the complete measure information (including any data on a performance gap, evidence, and testing results) supporting these changes and the development and implementation of the measure.</p> <p>ACP does not support the inclusion of measure Q370 for the same reasons that we do not support measure Q411.</p>	<p>While this measure represents an important clinical concept and we support the development of patient reported outcome-based performance measures, there is a lack of high-quality evidence to support the 6 month (+/- 30 days) time interval included in the numerator specifications and the threshold of reaching a specific PHQ-9 score (<5) is arbitrary and does not take into account the individual starting points for each patient. For example, a reduction from 10 to 5 can be considered as less progress than a reduction from a 25 to 6; however, this measure would reward the former and penalize the latter. Clinical trials demonstrate that even with effective medical management of major depressive disorder, many patients are unable to achieve a PHQ-9 score of <5. The measure may penalize clinicians caring for severely depressed patients for their inability to satisfy measure requirements and as such, this measure may encourage clinicians to over treat patients for major depressive disorder. The developers should consider revising specifications to include risk adjustment to account for individual starting points for each patient. Furthermore, the PHQ-9 is not necessarily the best tool to track patient remission. Developers should consider revising denominator specifications to include additional depression remission tracking tools. Lastly, we suggest the measure specifications exclude patients with dementia or severe cognitive impairments and patients permanently residing in nursing homes.</p>
442	Persistence of Beta-blocker Treatment After a Heart Attack	<p>ACP supports the inclusion of the measure as currently specified.</p> <p>ACP cannot comment on whether to maintain this measure with the substantive changes</p>	<p>The exclusion criterion is broad and it is appropriate to attribute the measure outcomes to the individual clinician. Additionally, the measure is based on high-quality evidence from the most recent recommendations of various organizations (*ACP, ACC, ACCF/AHA, ESC). While we support this measure, we note the measure is close to being</p>

		<p>proposed by the measure steward until the measure has been fully specified and tested to reflect these changes and the PMC has had an opportunity to review the complete measure information (including any data on a performance gap, evidence, testing results) supporting these changes and the development and implementation of the measure.</p> <p>ACP supports the inclusion of Q007 in addition to this measure as currently specified.</p>	<p>topped out. Data from the 2014 HEDIS reporting period demonstrates an 84% compliance rate.</p>
474	Zoster (Shingles) Vaccination	<p>ACP supports the removal of this measure from the measure list.</p> <p>ACP cannot comment on the inclusion of measure A.3: Adult Immunization Status which CMS proposes as a substitution for measure 474 until after the ACP PMC has had an opportunity to review the complete measure information (including any data on a performance gap, evidence, and testing results) supporting the development and implementation of this measure.</p>	<p>While this measure represents an important clinical concept, the measure steward does not present detailed information on the measure specifications, opportunity for improvement, testing results, or evidence reviewed by the developers to form the basis of the measure, therefore; we cannot meaningfully assess the validity of this measure. That said, we do note some concerns for the developers to consider prior to submitting this measure to payment, accountability, and reporting programs for adoption. First, specifying the age parameter as >50 years could be problematic as vaccine availability rates across the country are low. Second, the fact that the specifications do not include any exclusion criteria is challenging. Developers should consider revising specifications to include exclusion criteria for socio-economic and environmental factors affecting accessibility; patients with limited life-expectancy; and patient refusal. Third, developers should identify vaccines that meet the reporting requirements in the numerator details. Many patients refuse vaccination because they cannot afford treatment or, they cannot withstand the side effects of treatment or the pain associated with the injection. Finally, poor interoperability across electronic systems poses some burden on clinicians who report this measure.</p>