

September 10, 2018

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

Dear Administrator Verma:

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, Quality Payment Program, and other federal programs for Calendar Year 2019. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 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.

Throughout this letter, the College makes a significant number of specific recommendations to the Agency of ways we believe the proposed rule can be improved prior to implementation. We believe all of these recommendations are important for CMS to consider, but have summarized a subset of them that reflect our top priority areas (detailed explanations for each recommendation are included in the main text of the letter). This approach is intended to ensure that these key issues for ACP and internal medicine as a whole are not lost within the more detailed and thorough discussions that follow.

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I. Summary of Top Priority Recommendations:

- A. Evaluation and Management (E/M) Payment and Documentation Recommendations
 - ACP strongly believes that cognitive care of more complex patients must be appropriately recognized with higher allowed payment rates than less complex care patients. CMS' current proposal to pay a single flat fee for E/M levels 2-5, even when combined with proposed primary care and specialist add-on codes and payment for prolonged services, undervalues cognitive care for the more complex patients, potentially creating incentives for clinicians to spend less time with patients, to substitute more complex and time-consuming visits with lower level ones of shorter duration, schedule more shorter and lower-level visits, and potentially avoid taking care of older, frailer, sicker and more complex patients. It could also create a disincentive for physicians to practice in specialties, like geriatrics and palliative care, which involve care of more complex patients.
 Accordingly, the proposal to pay a single flat fee for E/M levels 2-5 must not be implemented.
 - ACP appreciates and supports the overall direction of CMS' proposals to reduce the burden of documentation for E/M services, yet strongly disagrees that such improvements should be contingent on acceptance of CMS' proposal to pay a single flat fee for E/M levels 2-5. While we understand CMS' concerns that changes in E/M documentation requirements, without changes in the underlying payment structure for E/M services, could create program integrity challenges, we believe that CMS should consider alternatives that would allow it to move forward on simplifying documentation, ensure program integrity, and preserve the overarching principle that more complex and time-consuming E/M services must be paid appropriately more than lower level and less time-intensive services. ACP strongly believes that CMS should work with the physician community, including ACP, to develop and pilot-test alternatives outlined in this letter in lieu of implementing the current proposals.
 - ACP urges CMS <u>not</u> to establish a regulatory deadline (e.g. January 1, 2019 or January 1, 2020) for finalizing and implementing its flat E/M fee proposals or possible alternatives that involve bundling or otherwise restructuring how such services are paid, and instead, to take the time to "get it right" in how to appropriately pay for cognitive care. Sufficient time must be allowed to engage the physician community to develop and pilot-test alternatives that preserve the principle that more complex and time-consuming E/M services must be paid appropriately more than lower level and less time-intensive services, while allowing CMS to move forward on simplifying E/M documentation and ensuring

program integrity. The stakes for patients, clinicians, and the Medicare program are too great for CMS to rush changes through that have not been thoroughly developed, evaluated, and pilot-tested. CMS should implement elements of the proposals to simplify E/M documentation requirements effective January 1, 2019, even as alternatives to the flat fee structure are being developed and pilot-tested. There are other components of the payment structure that have been proposed, including payment for prolonged services and for a number of technology-based and telehealth services, that ACP recommends CMS finalize for implementation in 2019.

B. Additional Physician Fee Schedule (PFS) Recommendations

- ACP supports CMS' decision to recognize of services outside of the telehealth
 restrictions that promote use of communication technology-based services on a
 broader scale. Reimbursement for appropriately structured telemedicine
 communications, whether synchronous or asynchronous and whether solely
 text-based or supplemented with voice, video, or device feeds in public and
 private health plans, may be a clinically appropriate service similar to a face-toface encounter.
- The College thanks CMS for accepting our previous requests that the Agency provide payment for e-consultations through adopting the existing interprofessional consultation codes as well as adding two new g-codes for these services. This proposal would more appropriately recognize the value of primary care physicians' knowledge and skills when consulting hospitalists and other specialists throughout the continuum of care.
- The College strongly supports lifting the originating site geographic restriction for the purposes of identifying and diagnosing strokes through telehealth. There is a strong evidence base behind the use of telestroke programs, as discussed in ACP's recent position paper in the *Annals of Internal Medicine* on telemedicine:¹
- The College strongly supports implementation of the BBA policies expanding
 access to home dialysis therapy services via telehealth. Removing the geographic
 and originating site restrictions to allow patients to receive monthly ESRDrelated clinical assessments is critical to patients who require home dialysis
 therapy.

¹ Daniel H, Sulmasy LS, for the Health and Public Policy Committee of the American College of Physicians. Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper. Ann Intern Med. 2015;163:787-789. doi:10.7326/M15-0498. http://annals.org/article.aspx?articleid=2434625.

- To address the flawed clinical laboratory fee schedule rates, ACP reiterates its
 call that CMS modify the existing PAMA regulations to conduct targeted market
 segment surveys (reference laboratories, physician office-based laboratories
 (POLs), independent laboratories, and hospital outreach laboratories) to validate
 and adjust the final fee schedule payments calculated based on the data
 collection to ensure Congressional intent—payment rates that accurately reflect
 private market payments across all market segments—is achieved. While the
 survey is being conducted and new rates are being established, CMS should
 revert back to the CLFS rates that were in place for 2017.
- We also reiterate our recommendation that the AUC consultation and reporting requirements be initially implemented as a pilot, with an evaluation of the AUC program occurring before moving to this complex and expensive system. As ACP and a number of other physician organizations noted in a recent letter,² we believe that requirements in MIPS make this program largely unnecessary. This is because MIPS is intended to move clinicians into a value-based payment system that is focused on tying quality and cost to performance, so clinicians will already be incentivized to ensure that the services they order and provide are appropriate and necessary.
- With regard to quality metrics in the Medicare Shared Savings Program, we urge
 the Agency to strongly consider the implications that removing so many at-risk
 population-based measures could have on current health disparities and to
 ensure that vulnerable patient populations would not be adversely impacted by
 the removal of these measures before proceeding.
- The College supports CMS' proposal to align statutory and regulatory language under physician self-referral law making it easier to satisfy writing and signature requirements for exceptions to billing and referral restrictions.

C. Quality Payment Program (QPP) Recommendations

- The College supports CMS' proposal to add a new criterion and an "opt-in" option to clinicians and groups that fall below the low-volume threshold because it will increase participation in MIPS while minimizing administrative burden on practices and encourages the Agency to finalize these policies as proposed.
- ACP wishes to express its strong opposition to CMS' proposal to maintain the current full-year minimum performance period for the Quality Category. We urge the Agency to instead apply a consistent 90-consecutive day minimum reporting period across all MIPS performance categories that require reporting

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² https://www.acponline.org/acp_policy/letters/auc_sign_on_letter_2018.pdf

to minimize burden on clinicians, reduce complexity in MIPS, and shorten the timeline between performance, reporting, feedback, and payment adjustments.

- The College appreciates proposals to simplify scoring for the Promoting Interoperability Category. However, we urge CMS to simplify MIPS scoring across all the performance categories to reduce complexity in MIPS, including awarding measures points based on their relative value in the MIPS total composite score, which is more intuitive. We also encourage the Agency to award cross-category credit where appropriate to align improvement objectives and yield more effective results while minimizing burden on clinicians.
- The College has major reservations about the low reliability standards for the episode-based Cost measures and urges CMS not to increase the weight of the Cost Category in the same year it proposes to add several new measures.
- The College strongly recommends that CMS reduce the number of required measures for full participation in the Quality Performance Category to three measures. We believe that reducing the number of quality measures that are required for full participation in MIPS is essential to allow CMS to have the space to truly overhaul the existing measures and measure development process to move toward better measures that are meaningful to clinicians and their patients. This will also help enable specialists and subspecialists select a full set of measures that are relevant to their specialty and scope of practice.
- ACP's Performance Measurement Committee (PMC) has assessed and provided detailed recommendations on many of the performance measures included in MIPS, with a focus on those that are particularly applicable to internal medicine.³ Based on this assessment, ACP's Performance Measurement Committee calls for improving the measure development process so that performance measures help physicians provide the best possible care to their patients without creating unintended adverse consequences. Therefore, ACP strongly recommends that CMS look to these recommendations first when considering what measures to use for reporting by internal medicine specialists. The College further recommends that any measures CMS proposes to use outside of the ACP recommendations and core sets identified by the Core Quality Measures Collaborative be those recommended by the Measure Application Partnership (MAP).
- The College supports the requirement for use of 2015 CEHRT in 2019 and agrees that moving to more up-to-date standards and functions is important; however we recommend that CMS allow for at least six months, if not a full year, for

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³ MacClean CH, Kerr EA, Qaseem, A. Time Out – Charting a Path for Improving Performance Measurement. N Engl J Med 2018; 378:1757-1761. https://www.nejm.org/doi/full/10.1056/NEJMp1802595

physicians to implement the upgrades once the 2015 CEHRT is ready and available from their vendor before they are graded on their use of the technology.

- The College recommends that the PI performance category not be limited to a small set of required measures or objectives but instead allow for some flexibility and for clinicians to select from a somewhat larger list of measures or activities. As a way to provide more flexibility within the category, ACP recommends that the PI performance category incorporate, much like the IA performance category, a list of optional, but clearly defined, health IT-specific activities from which a clinician can choose from that are appropriate to their specialty.
- The College generally supports CMS' proposal to add a facility-based scoring option, but cautions the Agency to closely monitor the perverse impact this could potentially have on average and median MIPS performance scores in terms of disadvantaging non-facility-based clinicians and practices.
- ACP appreciates CMS' proposal to extend the current 8 percent nominal amount (risk) threshold through the 2024 performance period for both the Medicare and All Payer Combination Options. This will create stability and predictability for APM participants and developers and will help APMs to grow and thrive. We urge CMS to consider establishing a separate, lower threshold for small and/or rural practices, which often struggle with unique challenges and barriers to participation in APMs.
- We call on CMS to drastically expand opportunities for participation in Advanced APMs, including but not limited to: implementing physician-focused payment models (PFPMs) recommended by the PFPM Technical Advisory Committee, implementing several Medicare payment models under development, counting participation in Medicare Advantage APMs toward Advanced APM participation under the Medicare Option, expediting the process to approve Other Payer Advanced APMs determinations and begin counting them toward the All Payer Combination Option in the 2019 performance period, and alleviating barriers to APM development caused by the Stark and anti-kickback laws and other fraud and abuse restrictions. With only four performance years remaining to earn the 5 percent lump sum bonus for Advanced APM participation, time is running out.

II. PFS Detailed Recommendations:

A. Determination of Proposed Practice Expense RVUs

CMS Proposal: Practice expense (PE) is the portion of the resources used by a clinician when providing clinical services such as office rent and personnel wages. CMS uses a resource-based system for determining PE Relative Value Units (RVUs) for each specific physician service and develops PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expense categories include administrative labor, office expense, and all other expenses.

ACP Comments: ACP recommends that CMS improve the accuracy and reliability of the resource inputs for derivation of the PE RVUs by:

- More accurately pricing expensive equipment items and disposable supplies and;
- Performing another physician practice expense survey.

i.More Accurate Pricing of Expensive Equipment and Disposable Supplies

CMS Proposal: Current pricing of expensive equipment items and disposable supplies depends upon submission of paid invoices from specialty societies. The small number of submitted invoices and the potential for highly biased, non-representative invoices make these cost inputs relatively unreliable and possibly highly inaccurate. Prior review of governmental pricing (e.g., from the Government Accountability Office or Department of Veterans Affairs), hospital acquisition costs (from Medicare cost reports), and commercially available proprietary databases (e.g., Veterans Health Administration and others) suggests that the invoice submission process for these expensive equipment items and disposable supplies in fact overestimates the costs used for derivation of the PE RVUs. This overestimation augments the reimbursement disparities between proceduralists and primary care physicians and other physicians providing cognitive services, inappropriately rewards procedural physicians, and provides an improper incentive for overuse of these services.

ACP Comments: ACP recognizes the critical need for transparency in all CMS processes. The College also understands the difficulty of using 1) governmental pricing, 2) hospital acquisition costs, or 3) commercially available databases. Each of these sources of more accurate cost data has unique limitations. In aggregate, all three of these sources of more accurate cost data may not be completely applicable to the more limited purchasing power of physician practices; however, these data sources do underscore the existence of an inequity in the current PE RVU calculation methodology.

ACP recommends that CMS correct this inequity in the current PE RVU calculation methodology, demonstrated by the three sources of more accurate cost data discussed above. Expensive equipment items and disposable supplies beyond a specific threshold (e.g., \$250,000 for equipment, \$250 for disposable supplies) could be subject to a fixed discounting of the costs inaccurately estimated by the current, submitted invoice process. This fixed discounting would be in addition to the direct adjustment of the aggregated pool of direct PE costs, and follows logically with the same rationale of more accurately scaling the direct to the indirect practice expenses. The fixed discounting would be an arbitrary percentage (e.g., 8 percent), created from review of the three sources of more accurate cost data (governmental pricing, hospital acquisition costs, and commercially available databases). ACP notes that CMS already implements unique rules for expensive items of equipment in the derivation of PE RVUs, such as a) the location of certain clinical staff activities outside of expensive imaging rooms; and b) the assumed utilization rates for expensive equipment.

ii. Need for a New Physician Practice Expense Survey

ACP Comments: Maintaining the relationship between direct and indirect practice expenses is entirely dependent upon the relationship between these expenses in the Physician Practice Information Survey (PPIS) survey. The PPIS survey was conducted more than a decade ago. In addition to simply being outdated, the practice of medicine has significantly and substantially evolved in this past decade including advances in health IT and incorporation of EHRs in the majority of physician practices. Immense numbers of advanced practitioners now provide a large range of services, previously performed by physicians or clinical practice staff. Clinical staff performs a wide array of non-face-to-face services, and only a small number of these services are reportable with existing CPT codes, representing an unreimbursed and unmeasured expense borne by physician practices (e.g., expenses associated with expanding staff to provide CCM services, maintaining time logs for providing CCM services, updating EHR modules, etc.). Many specialties (e.g., cardiology) have had extensive changes in physician employment models, such that the physicians currently in private practice and reimbursed for their technical services represent a different group of physicians experiencing different direct and indirect costs than actually surveyed more than a decade ago. Finally, participation of practices in a wide variety of new, advanced payment models (including Comprehensive Primary Care [CPC] initiative and CPC+, as well as Accountable Care Organizations [ACOs], Advanced Alternative Payment Models [AAPMs], and gain-sharing arrangements) have required new forms of practice support and operational implementation that result in higher indirect practice expenses; none of these indirect expenses were captured in the decade-old PPIS.

Therefore, ACP believes that continued use of the outdated PPIS survey leads to an inappropriate and inaccurate distortion of the PE RVUs for current, modern practice. ACP strongly recommends that CMS proceed with another physician practice expense survey, utilizing available funds dedicated to improving the relativity and allocation within the Resource-based Relative Value Scale (RBRVS).

B. Evaluation and Management (E/M) Visits

i.<u>Implementation Timing</u>

CMS Proposal: The proposed implementation date of proposed changes to the E/M payment structure and documentation requirements is January 1, 2019. CMS is seeking comment on whether the implementation should be delayed to January 1, 2020.

ACP Comments: The College strongly recommends that CMS not finalize the new E/M payment structure proposal—including the blended payment rates for officebased/outpatient E/M visit levels 2 through 5, the add on codes, and the multiple procedure payment reduction—in 2019 or in a subsequent calendar year. ACP urges CMS not to establish a regulatory deadline (e.g., January 1, 2019 or January 1, 2020) for finalizing and implementing its flat E/M fee proposals or other any other alternatives that devalue complex cognitive care, and instead, to take the time to "get it right" by engaging with the physician community to develop and pilot-test alternatives. Any fee schedule E/M payment changes must give consideration to downstream implications that could have massive implications for the APMs that are already underway as well as benchmarks for the ACOs. For example, in CPC+ Track 2, there is partial capitation based on an assumed amount of patient visits tied to prospective payment and the remainder of the visit fee paid is if the patient requires an E/M visit. How would a shift to a collapsed E/M payment rate be taken into account? Such alternatives for testing must preserve the principle that complex and time-consuming E/M services must be paid appropriately more than lower level and less time-intensive services. As is outlined in greater detail below, ACP opposes these components of the proposal that devalue complex cognitive care and recommends testing of alternative pathways for achieving the same goals of updating and simplifying the payment for cognitive services while reducing E/M documentation requirements.

There are other components of the payment structure that have been proposed, including payment for prolonged services and for a number of technology-based and telehealth services, that ACP recommends CMS finalize for implementation in 2019. The proposed prolonged services code will help address a long recognized challenge with the existing prolonged services CPT code due to the time thresholds that code requires. Further, the technology-based and other telehealth services were proposed as separate components of the rule from the E/M payment structure, and are clearly important services that should be compensated, so can be implemented immediately.

ACP also recommends that CMS finalize for implementation on January 1, 2019 the proposals related to simplified documentation, including providing choice in documentation options with some improvements, reducing redundant documentation, and eliminating extra documentation for home visits. As outlined in greater detail below, the College does not believe that the documentation options are intrinsically tied to the payment structure that has been proposed, and thus can be implemented independently.

ii.Documentation

CMS Proposal: CMS proposes to allow additional options for documenting an office visit or outpatient E/M visit. Under the proposal, in order to report an office/outpatient visit to Medicare, physicians would need to document medical necessity and then one of the following:

- (1) 1995 or 1997 documentation guidelines: Two of the three components: (1) problem-focused history that does not include a review of systems or a past, family or social history; (2) a limited examination of the affected body area or organ system; and (3) straightforward medical decision making measured by minimal problems, data review and risk (two of these three); or
- (2) *Medical Decision-making (MDM):* Straightforward medical decision making measured by minimal problems, data review and risk (two of these three); or
- (3) Time-based Standard: Time personally spent by billing clinician face-to-face with the patient. Clinicians would be required to document the medical necessity of the visit and show the total amount of time spent by the billing clinician face-to-face with the patient. CMS is soliciting comment on what time should be required if this is the documentation selection (two options mentioned, typical time for the CPT code that is reported (CPT defined typical times for E/M codes, e.g., a clinician reporting a level 4 established patient visit would be required to document having spent a minimum of 25 minutes) or 16 minutes, using the CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed (midpoint of the weighted average of all established office visits).

ACP Comments: ACP appreciates CMS working to address the significant problems with documentation of E/M visits via this proposal. The College has outlined these issues over the course of the past several years, including in a 2015 paper, "Clinical Documentation in the 21st Century" published in *Annals of Internal Medicine*⁴ and in numerous comment letters to and discussions with both CMS and the Office of the National Coordinator. It also has been a core issue within our own Patients Before Paperwork⁵ initiative, as outlined in our 2017 policy paper, "Putting Patients First by Reducing Administrative Tasks in Health Care." ⁶

Along these lines, ACP has consistently recommended that any revisions made to the E/M documentation guidelines should not result in a revaluation of the entire E/M code set.⁷ The effort to reform the documentation guidelines to make them consistent with current medical practice does not need to be coupled with changes to the established values of the E/M services. Therefore, the College strongly recommends that the documentation options

⁴ http://annals.org/aim/fullarticle/2089368/clinical-documentation-21st-century-executive-summary-policy-position-paper-from?resultClick=3

⁵ https://www.acponline.org/advocacy/where-we-stand/patients-before-paperwork

⁶ http://annals.org/aim/fullarticle/2614079/putting-patients-first-reducing-administrative-tasks-health-care-position-paper

⁷https://www.acponline.org/acp_policy/letters/letter_to_cms_recommendations_for_patients_over_paperwork_i nitiative_2018.pdf

outlined above, with some improvements, be implemented in 2019 without any changes to the valuation of the E/M code set. There is simply no need for these two proposals to be coupled together. It is possible for CMS to move forward on simplifying E/M documentation while still ensuring program integrity. Further comments on how CMS could address the issues related to updating and improving the E/M code set are provided later in this letter.

The College agrees that maintaining the option of the 1995 and 1997 documentation guidelines over the short term will assist with the transition for many physicians to the other proposed options of medical decision making and time based standards. ACP also agrees that a more appropriate approach to documentation should focus on the level of medical decision making that is necessary based on the unique needs of individual patients. However, we do not agree with CMS' approach that these documentation options must be tied to a single, bundled payment amount for levels 2 through 5. While we recognize the Agency's thought process in this area, the College strongly believes there is a revised approach to the documentation proposal that allows it to be fully decoupled from the proposed payment structure and preserve program integrity.

This alternative approach involves both short-term (for implementation in 2019) and longer term steps. Our short-term recommendation would essentially be a blending of CMS' first two proposed options—using the current 1995 and 1997 guidelines and medical decision making. ACP recommends that CMS should immediately remove the auditing requirements associated with the history and physical exam elements of both the 1995 and 1997 E/M documentation guidelines. Documentation of the history and physical exam should continue to be a key component of the patient visit but they should not be associated with the auditing requirements. This is aligned with CMS' additional proposal—which ACP supports—to address redundancy that will allow clinicians to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting a defined list of required elements such as review of a specified number of systems and family/social history. However, our recommendation would further expand on this policy. Once these elements are no longer required for auditing purposes, then the level of service would be determined by the complexity of the medical decision making for that encounter and thus allow physicians to focus on documenting what is necessary based on the unique needs of their individual patients.

Concurrent to the removal of the history and physical examination requirements, CMS must then immediately work to ensure that the auditing guidelines and procedures also are updated and aligned to focus on the medical decision making elements of the visit – and applied consistently by all auditing organizations. 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 differing interpretations on what is required. To that end, CMS must recognize one standard tool for auditing purposes, such as the Marshfield Clinic audit tool to ensure medical decision making audits are based on the same criteria.

Understanding that updates to the auditing requirements may not be feasible in time for implementation in 2019, ACP would be supportive of using the current MDM guidelines, but move into working with specialty societies and other stakeholders throughout 2019 to ensure that these auditing guidelines and procedures are appropriately redesigned while reducing the documentation burden for clinicians.

Again, we understand that CMS' proposal that ties the documentation options to a single payment level is intended to address auditing concerns (i.e., having levels 2 through 5 be set at the same base RVU rate means that clinicians would only need to document the history and physical at level 2); however, our alternative addresses this issue—thus allowing CMS to in fact decouple documentation revisions from any type of flat-rate payment proposal. Under our proposal, clinicians would document MDM consistent with the documentation guidelines/auditing standards for the level of visit being billed (which would vary from level 2 up to level 5). Because each visit level could be distinguished upon auditing to ensure program integrity is protected, ACP's recommended changes to reduce E/M documentation burden can and should be implemented without finalizing a flattened payment structure.

To reiterate, ACP's short-term recommendation is a blending of CMS' first two proposed documentation options but with one key difference: CMS would remove the auditing requirements for the history and physical exam elements of the current 95/97 guidelines but maintain the current MDM auditing requirements. The College believes that this type of short-term approach will provide the immediate administrative relief needed by clinicians so they can focus on providing high-value care to patients—ultimately benefiting the patient and improving patient care overall.

Meanwhile, CMS should work with all necessary stakeholders, including medical specialty organizations and the Current Procedural Terminology (CPT) Editorial Panel to further restructure and improve E/M documentation over the longer term. Together these groups could create specialty-specific frameworks outlining general principles of care that are beneficial and appropriate for medical specialties in describing the varying approaches to patient care for the current levels of E/M codes. These general principles of care would incorporate the existing medical decision making elements of the 1995 and 1997 E/M documentation guidelines in order to determine the level of service for the existing E/M codes, thus having clinical documentation tied to program integrity and auditing practices. The College would welcome this opportunity to work with CMS and all necessary stakeholders on developing these MDM frameworks and collaborating further on E/M documentation reform as we fully understand the complexity of the issue and the need to maintain program integrity. Once these MDM frameworks and underlying principles are developed and agreed upon, EHR vendors should then be required to build in an attestation based on the principles of care and the information captured within the EHR would be tracked to support the care delivered by the clinician—thus relieving burdensome and duplicative documentation requirements.

Finally, the College is supportive of CMS offering a time-based billing option to clinicians, as we agree that there are instances where time may be an appropriate indicator of the complexity of

the visit or patient. Along these lines, ACP recommends in our short term approach the use of time as proposed by CMS with some modification. The focus must be on time personally spent by the billing clinician face-to-face with the patient. Clinicians would be required to document the medical necessity of the visit and show the total amount of time spent face-to-face with the patient by the billing clinician. The billing clinician would document the total time by recording the start and stop times spent face-to-face with the patient for the appropriate level of CPT code billed. The billing clinician would report the typical time for the CPT code reported while not having to document counseling or coordination of care; the AMA's CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed would not apply. This would allow the physician the opportunity to capture the more complex patients based on time and open the opportunity to use the prolonged service code described later in this letter.

As discussed in this letter, ACP believes that any changes in the underlying payment structure for E/M services must preserve the principle that cognitive care of more complex patients be appropriately recognized with higher allowed payment rates than less complex patients; therefore, we are not of the opinion that the only two options on the table are (1) to preserve the current structure and status quo of paying for E/M services, and the existing and burdensome documentation associated with them or (2) replace the existing structure and associated documentation with CMS' proposals for a flat, blended payment rate for levels 2-5 E/M services. Instead, ACP is open to developing and pilot-testing of certain blended payment alternatives, in lieu of CMS's flat fee proposals, provided that they:

- Would allow for differentiation in payment rates so that more complex E/M services are paid more than less complex ones:
- Simplify documentation requirements while addressing CMS's program integrity concerns.

Later in this letter, we discuss an alternative approach CMS should consider *testing, in lieu of the current blended flat fee proposal,* which would involve a different approach to blended payment rates for cognitive services while allowing for higher payment for more complex visits. This alternative would lend itself to a slightly modified approach to updating the documentation as well—but would still maintain a focus on the importance of medical decision making based on the individual patient's needs.

iii.Reducing Redundant Documentation

CMS Proposal: CMS proposes to expand policy regarding the history and exam for established patients such that, for history and physical, clinicians would only be required to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting a defined list of required elements such as review of a specified number of systems and family/social history. Clinicians would still conduct clinically relevant and medically necessary elements of history and physical exam and conform to the general principles of medical record documentation in the 1995 and 1997 guidelines. However,

clinicians would not need to re-record these elements (or parts thereof) if there is evidence that the clinician reviewed and updated the previous information.

Also, for both new and established patients, clinicians would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. The clinician could simply indicate in the medical record that they reviewed and verified this information.

ACP Comments: ACP is encouraged by the proposal to reduce documentation burdens on physicians by requiring them to only document changed information for established patients and to sign-off on basic information documented by practice staff. ACP strongly supports these changes and calls for them to be implemented on January 1, 2019—in conjunction with additional documentation improvements outlined above—as they will reduce the documentation burden on clinicians, limit redundant information in the medical record, and cut down on duplicative time spent on re-documenting existing information. Implementing this change along with focusing on medical decision making and preserving the principle that more complex and time-consuming E/M services must be paid appropriately (e.g., more than lower level and less time-intensive services) will allow CMS to move forward on simplifying E/M documentation and still ensure program integrity. This further provides CMS the ability to uncouple payment from documentation.

iv. Eliminating Extra Documentation Requirements for Home Visits

CMS Proposal: Home visits paid for using CPT 99341 – 99350 currently are paid slightly higher than office visits. There is not a homebound restriction on the patient; however, the medical record must include documentation of medical necessity of a home visit in lieu of an office or outpatient visit. CMS proposes to remove this documentation requirement for home visits.

ACP Comments: The College supports this proposal to reduce the required documentation related to providing home-based care and appreciates that CMS has recognized this issue as a challenge for clinicians who wish to provide the best quality of care to their patients' at the most appropriate place and time.

v.Billing for Same Day Visits

CMS Proposal: The Medicare Claims Processing Manual states, "As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off-campus outpatient hospital, or oncampus outpatient hospital setting which could not be provided during the same encounter." CMS is seeking comments on potentially eliminating this, including limitations on when this might be appropriate.

ACP Comments: ACP strongly supports eliminating this unnecessary burden—for both the clinician and the patient. This will allow the clinician or a practice to more appropriately serve the patient's needs—at a time that is feasible and convenient for the patient—rather than requiring that the patient come back to the office on a different day if the second visit is not completely unrelated to the first.

vi.New E/M Payment Structure

CMS Proposal: CMS calls the system of ten visit codes for new and established office visits "outdated" and proposes to retain the codes but simplify the payment by applying a single payment rate for level 2 through 5 office visits. Clinicians would still bill using the existing CPT code structure, but there would be a single set of RVUs for new patients for levels 2-5 visits (CPT codes 99202-99205) and a single set for level 2-5 visits for established patients (CPT codes 99212-99215). CMS considered eliminating CPT codes for office visits and creating a single G code. However, logistical considerations related to secondary payers led CMS to propose to continue to use existing CPT structure.

The proposed blended payment rates for office-based/outpatient E/M payments would apply to all clinicians, regardless of which documentation option they choose for all visits using CPT codes 99201-99215. For levels 2 through 5, CMS would only require medical record documentation to support a level 2 visit under the new payment structure. However, clinicians could choose to document additional information for clinical, legal, operational, and other purposes, and CMS anticipates that most will choose to still document according to the level of E/M visit being billed.

Current and Proposed Payment Rates for Office-based and Outpatient E/M Visits

CPT Code	CY 2018	CY 2019 Proposed	
New Office Visits	Non-Facility Payment Rate	Non-Facility Payment Rate	
99201	\$45	\$44	
99202	\$76	\$135	
99203	\$110		
99204	\$167		
99205	\$211		

CPT Code	CY 2018	CY 2019 Proposed
Est. Office Visits	Non-Facility Payment Rate	Non-Facility Payment Rate
99211	\$22	\$24
99212	\$45	\$93
99213	\$74	
99214	\$109	
99215	\$148	

(The 2019 Medicare Physician Payment Schedule Conversion Factor is \$36.0463)

vii. Add-on Codes GPCIX and GCG0X

CMS proposes to use two HCPCS G-code add-ons to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits.

- New primary care code: GPC1X is intended to reflect visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services. CMS believes that a primary care visit is partially defined by an ongoing relationship with the patient, this code would describe furnishing a visit to an established patient. HCPCS code GPC1X can also be reported for other forms of face-to-face care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding. CMS anticipates that this code would be billed with every primary care-focused E/M visit for an established patient. [RVU of 0.07, physician time of 1.75 minutes, a PE RVU of 0.07, and an MP RVU of 0.01. --- this represents ~ \$5.40 add-on to each office visit].
 - CMS noted that while the definition of primary care is widely agreed upon by the medical community and they intend for this G-code to account for the resource costs of performing those types of visits, this code still could be used regardless of Medicare enrollment specialty. However, they are also seeking comment on how best to identify whether or not a primary care visit was furnished, particularly in cases where a specialist is providing those services.

- New specialty code: GCG0X is intended to reflect visit complexity inherent to evaluation and management associated with:
 - o Endocrinology,
 - Rheumatology,
 - Hematology/oncology,
 - Urology,
 - Neurology,
 - Obstetrics/gynecology,
 - Allergy/immunology,
 - Otolaryngology,
 - o Cardiology, or
 - o Interventional pain management-centered care.

Given their billing patterns, CMS believes that these are specialties that apply predominantly non-procedural approaches to complex conditions that are intrinsically diffuse to multi-organ or neurologic diseases. [To establish a value for this add-on service to be applied with a standalone E/M visit, CMS is proposing a crosswalk to 75 percent of the work and time of CPT code 90785 (Interactive complexity), which results in a work RVU of 0.25, a PE RVU of 0.07, and an MP RVU of 0.01, as well as 8.25 minutes of physician time based on the CY 2018 valuation for CPT code 90785. --- this represents ~ \$14 add-on to each office visit].

viii. Multiple Procedure Payment Reduction (MPPR)

As part of their proposal to make payment for the E/M levels 2 through 5 at a single PFS rate, CMS is proposing to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier -25. The Agency states that they believe that the efficiencies associated with furnishing an E/M visit in combination with a same-day procedure are similar enough to those accounted for by the surgical MPPR to merit a reduction in the relative resources of 50 percent.

ACP Comments: The College strongly opposes the above proposals to blend E/M payment rates for levels 2 through 5 for both new and established patients, even with the proposed add-on codes and payment for prolonged services. We also oppose the MPPR. As noted earlier, we understand CMS' perceived need to flatten the payment in order to require only level 2 documentation of history and physical; however, our alternative documentation relief proposals outlined above address these issues as they still require the clinician to document the MDM to the appropriate level of visit. Again, over the longer term, our documentation relief proposal is contingent upon the auditing tools and procedures being fully aligned and consistently applied across all auditing organizations.

With regard to the blended E/M payment rates for levels 2 through 5 combined with the proposed add-on codes, the College has reviewed the impact tables provided by CMS; data analyses developed by other specialty organizations; and data specific to internal medicine as a

whole, primary care internal medicine, internal medicine subspecialties, and even specific practices within our membership. While on average it appears that internal medicine as a whole would come out "even" in terms of their annual payments from CMS, this does not tell the whole story. Every single practice across the country would feel this impact differently based on the make-up of their patient population—and those that do have more complex patients would be hit with unnecessary and inappropriate reductions in their overall payment, even with the add on codes and prolonged services codes being considered. This is true of many internal medicine sub-specialties as well as primary care internists, even if they have been identified as a specialty that would qualify for the higher payment associated with the specialty code add on. The specialty of internal medicine involves inherently complex cognitive services, and, as such, ACP believes that internal medicine physicians and all IM subspecialties should be treated as cognitive specialists in terms of any add-on codes being considered. Also, primary care internal medicine practices are seeing the complexity of their patient population increase significantly as the country's overall population continues to age and individuals now live with multiple chronic conditions over the course of many years.

The incentive created by this approach would be structured such that physicians would be inclined to have shorter visits with the more complex patients, particularly those that typically require level 4 or 5 visits (except for a few limited times when the clinician could reasonably bill the newly proposed prolonged services code). In these cases, the physician would need to have those patients come back to the office more often in order to continue to meet their needs. This is not an acceptable approach to patient care—and far from patient-centered. The blended payment approach also creates an incentive for physicians to adjust their practice population to Medicare patients that are not as complex (in order to be able to receive the now higher paid level 2 and 3 services, particularly with the permitted add-on)—or potentially stop seeing Medicare patients altogether. Many physicians (and their practice administrators) may conclude that CMS's proposal leaves them with no viable choice other than to make such undesirable changes in their patient mix and number and duration of visits. We strongly believe that CMS, must not implement changes in payment for E/M services that force changes in practice that are not in the best interest of patients.

The counter argument to physicians moving toward less complex or shorter patient visits is that the reduction in documentation burden would open up additional time in the day for them to be able to see more patients, or extend time with current patients. However, it is not clear that this would be the result. This concern is best outlined via a quote from one of the College's chapter governors (i.e., the leadership from one of our state chapters):

There is no way to balance the decrease [in] payment by just seeing more patients per day since our administrative documentation burden will be lighter. Because of the nature of the complexity of our patients and because our schedules are already packed and overflowing there is no room for adding on; we are already staying late to add on and sometimes coming in on days off to care for our patients. Because of this we are doing our documentation at the end of the day, evenings, and weekends (and vacations)

and, although easing that may give us more time at home with family and exercise, etc., it will not open slots in our schedules.

Beyond the unintended incentive consequences outlined above, at its core, this approach of valuing the services provided to more complex patients the same as those provided to much less complex patients is fundamentally flawed in concept. Putting the add on codes aside for a moment—which, as currently structured, still do not make the value for those more complex services "whole" relative to the current fee schedule—the idea that the needs of a patient who has multiple chronic conditions (and potentially an exacerbation of those conditions or the need for active management) and the services provided to that patient are considered the same in value by Medicare as the needs of a much more straightforward patient, perhaps with a single condition or acute need, is not logical and even offensive to both the patients and their clinicians. This argument is not addressed by the structure of the currently proposed add-on codes, as they are valued the same whether applied to a level 2, 3, 4, or 5 visit. The specialty add-on is a higher rate and thus intended to address the needs of more complex patients. However, as proposed, this add-on code also can be used across all levels of the blended E/M services, as long as the physician is one of the allowed specialties, regardless of the level of complexity of the individual patient.

The approach taken to this blended E/M payment structure also fundamentally goes against the structure upon which it is build—i.e., the resource-based relative value scale (RBRVS). "The RBRVS is based on the principle that payments for physician services should vary with the resource costs for providing those services."8 These resource costs are made up of (1) physician work, (2) practice expense, and (3) professional liability insurance. The physician work component alone includes the time it takes to perform the service, the technical skill and physical effort, the required mental effort, and judgment and stress due to the potential risk to the patient. Therefore, there is simply no justification under the current RBRVS system that would allow for a complex level 5 E/M service to have the same value as that of a level 2 E/M service. Given this, it is clear that the blending the levels of E/M services together under the same valuation, even with currently proposed add on codes, is simply not an acceptable approach to implement across the physician fee schedule. And, as noted above, it is not necessary to make this change in order to address documentation burden. As is outlined later in this letter, there are different ways that CMS could consider testing new payment approaches for cognitive care—even using the current E/M structure with revisions as a base but this needs to be done in a smaller scale with volunteer practices, ideally via a program within the CMS Innovation Center.

ACP strongly opposes the proposed MPPR for an office visit and a procedure. This would be inappropriate because overlapping elements of physician work and practice expenses have already been eliminated in recent years from CPT codes typically reported together by the RUC's practice expense sub-committee. In the proposed rule, CMS indicated that that implementing the MPPR would allow them to allocate those RVUs toward the values of the

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⁸ https://www.ama-assn.org/rbrvs-overview

add-on codes that reflect the additional resources associated with E/M visits for primary care and inherent visit complexity; however, even if this were to be implemented, it would be unlikely to achieve their goals.

ACP instead recommends an alternative approach that would achieve savings that could be allocated to support the Agency's goal of appropriately paying for cognitive and/or prolonged and complex services. CMS noted that they are seeking comment on whether or not it might be reasonable to assume that many visits included in the valuation of 10-day global packages are not being furnished, or whether there are alternative explanations for what could be a significant level of underreporting of postoperative visits. CMS is also seeking comment on the best approach to 10-day global codes for which the preliminary data suggest that postoperative visits are rarely performed by the clinician reporting the global code. Along these lines, the College would recommend that CMS change the global period for both 10- and 90-day global codes to 0 (zero) day global and remove the allocated RVUs and review the code valuation. The RVUs allocated to post-operative visits should be reallocated to E/M services to provide increased RVUs to physicians caring for patients in the office and other outpatient settings as a means to begin a rebalancing of the physician fee schedule. As the rule points out, it seems apparent that many of the post-operative visits are not being performed and the RVUs are being paid to clinicians performing procedures but not caring for the patients post-operatively.

ix.Alternative Approaches to Addressing Payment for Cognitive Services

ACP Comment: As noted above, ACP is open to developing and <u>pilot-testing</u> of certain blended payment alternatives, *in lieu of CMS's flat fee proposals*, provided that they:

- Would allow for differentiation in payment rates so that more complex E/M services are paid more than less complex ones:
- Simplify documentation requirements while addressing CMS's program integrity concerns.

Any such approach, though, that that involves blending of the current E/M payment levels needs to ensure higher payment for complex cognitive care and should be done in a smaller scale with volunteer practices, ideally via a program within the CMS Innovation Center.

Additionally, any testing of such a model must include the active involvement of and input from all key stakeholders, including front-line clinicians, medical specialty societies, patients, other payers, and EHR vendors. To take this even further, such a payment approach could build on the concept of blending E/M code payment levels as a basis (perhaps even via a capitation-type of approach), with appropriate risk adjustment and/or add on codes to ensure patient complexity is addressed, reduced documentation, improved methodologies for measuring quality and cost, and more innovative delivery models, and then test it as a true potential advanced Alternative Payment Model (APM), rather than trying to fit it within the current RBRVS system.

The College's idea is based on what would be a blended payment rate, potentially for levels 2 through 5 of E/M services that unlike CMS's proposal, would explicitly allow for higher reimbursement for levels 4 and 5 E/M visits than less complex visits. This could be accomplished through a different approach to the proposed add-ons that could be tested even as we are working toward more sophisticated and appropriate risk adjustment (that not only takes into account patient complexity, but also socio-economic factors that are associated with social determinants of health) that could be applied to create a prospective risk-adjusted global primary care capitation option as an alternative to the current E/M payment structure. Assuming that the payment rate for what is now considered a level 2 or 3 service would be higher under this blended model than current fee-for-service, as CMS is currently proposing, we would recommend that there be no add-on code applied to those services and that instead, the work RVU for the add on code would be increased and applied only to what is currently considered a level 4 or 5 visit. This recommendation would result in a single add-on code for primary care services and specialty services with the value of the add-on code being increased over what CMS has currently proposed (i.e., ~\$5.40 and ~\$14 to perhaps as high as ~\$16) at no additional cost to the system—and would thus assign an increased value to services provided to the more complex patients, while also sustaining an increased value for less complex patients. Testing could determine if there is a need for a differently valued add-on for primary care versus specialty care or not. With regard to documentation based on this scenario, the clinician would then only need to document medical decision making consistent with a level 4 or 5 complex patient (as the base rate is still blended or flat). Ideally, this type of an approach would be tested with a number of other potential documentation improvements (as we have outlined above), as well as innovative approaches to measuring the quality and cost of care that are more patient-centered and less burdensome.

Table 1. CMS vs. ACP E/M Payment Proposals

CMS Proposal for Primary Care

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Code	Current Payment	Proposed Payment	Primary Care Add-On	Prolonged Services	Total Payment	Percent Change		
99201	\$45	\$44	\$0		\$44	-2.27%		
99202	\$76	\$135	\$0		\$135	43.70%		
99203	\$110	\$135	\$0		\$135	18.52%		
99204	\$167	\$135	\$0		\$135	-23.70%		
99205	\$211	\$135	\$0		\$135	-56.30%		
99205*	\$211	\$135	\$0	\$67	\$202	-4.46%		

Code	Current Payment	Proposed Payment	Primary Care Add-On	Prolonged Services	Total Payment	Percent Change
99211	\$22	\$24	\$0		\$24	8.33%
99212	\$45	\$93	\$5		\$98	54.08%
99213	\$74	\$93	\$5		\$98	24.49%
99214	\$109	\$93	\$5		\$98	-11.22%
99215	\$148	\$93	\$5		\$98	-51.02%
99215*	\$148	\$93	\$5	\$67	\$165	10.30%

ACP Proposal for Primary Care

Code	Current Payment	Proposed Payment	Primary Care Add-On	Prolonged Services	Total Payment	Percent Change
99201	\$45	\$44	\$0		\$44	-2.27%
99201	Ş4 5	344	ŞÜ		Ş 44	-2.2770
99202	\$76	\$135	\$0		\$135	43.70%
99203	\$110	\$135	\$0		\$135	18.52%
99204	\$167	\$135	\$16		\$151	-10.60%
99205	\$211	\$135	\$16		\$151	-39.74%
99205*	\$211	\$135	\$16	\$67	\$218	3.21%

Code	Current Payment	Proposed Payment	Primary Care Add-On	Prolonged Services	Total Payment	Percent Change
99211	\$22	\$24	\$0		\$24	8.33%
99212	\$45	\$93	\$0		\$93	51.61%
99213	\$74	\$93	\$0		\$93	20.43%
99214	\$109	\$93	\$16		\$109	0.00%
99215	\$148	\$93	\$16		\$109	-35.78%
99215*	\$148	\$93	\$16	\$67	\$176	15.91%

^{*} Denotes level 5 visits with use of the prolonged services code. Clinicians must reach 47 minutes to bill this code, therefore it will likely be used for the majority of level 5 visits.

Unlike CMS' proposal, which pays the same for more complex level 4 and 5 visits as levels 2 and 3, ACP's suggested alternative would preserve the principle that more complex E/M services should be paid more, because the add-on would apply only to levels 4 and 5, not levels 2 and 3. The result: physicians billing for more complex level 4 and 5 visits would be paid appropriately more, while still testing the impact and advisability of a blended approach to E/M services. Restricting the add-on to levels 4 and 5 would preserve RVUs to allow to pay more for more complex patients — and our data analysis shows that the add-on would most likely be used less than in CMS' current proposal. Moreover, employed physicians who are paid on an RVU or productivity basis would not be inadvertently disadvantaged. This alternative approach also addresses CMS' concerns about program integrity because those using the add-on code for more complex patients would need to document their MDM to that of a Level 4 or 5 in order to support the code. Again, documentation relief for MDM levels 4 and 5 is contingent upon the auditing tools and procedures being fully aligned and consistently applied across all auditing organizations.

The College strongly recommends that CMS consider the ideas we have laid out above, including our idea for a potential pilot-test of an alternative approach to bundling of E/M services that would preserve higher payment for more complex cognitive care. CMS should also solicit other ideas on alternative approaches to the valuation of cognitive care from the medical profession and others; and pilot-test the best ideas on a voluntary basis in a variety of practices types and specialties through the authority granted to CMMI. No proposal that would fundamentally change how E/M services are paid should be implemented without prior testing to determine their "real world" impact on patients and their physicians.

There are a number of additional aspects CMS needs to consider—and that serve as further basis for testing the College's approach. These include the impacts on:

- Primary care workforce
 - Reduced documentation burden and increased reimbursement for more complexity would promote the primary care workforce as younger physicians would experience the documentation relief and how CMS and others are working toward more value-based payment proposals for primary care payment/internal medicine services.
- Gender payment disparities⁹
 - Female physicians that tend to spend more time with patients would benefit from the time-based billing options in support of reducing the gender payment disparities.

A number of organizations, including medical specialty societies, are working on their own and together to develop alternative ideas for the Agency to consider. This includes the American Medical Association RUC/CPT workgroup, on which ACP has members participating along with organizations and health professionals with deep expertise in defining and valuing codes, and

⁹ http://annals.org/aim/fullarticle/2678630

who also use the office visit codes to describe and bill for services provided to Medicare patients. The College believes the charge to this workgroup is to analyze the E/M coding and payment issues, facilitate multiple stakeholder input and, provide direction that can be provided to CMS regarding the Physician Fee Schedule. While ACP is supportive of the AMA work group contributing to the examination of alternatives, we also believe that CMS should engage directly with ACP, and other physician membership organizations, on ideas for alternative approaches that might be tested beyond those that may come out of the work group. We believe that any option identified should be tested (likely alongside other options) before implementation. And, again, any testing should take place outside of the current physician fee schedule structure, ideally via a CMS Innovation Center program.

x.Prolonged Services

CMS proposal: CMS is proposing to create a new HCPCS code GPRO1 for prolonged evaluation and management or psychotherapy service(s) in the office or other outpatient setting requiring direct patient contact beyond the usual service time of the primary procedure or office visit (30 minutes). The Agency is proposing a work RVU of 1.17, which is half the work RVU of CPT code 99354, or \$67.

ACP Comments: The College strongly supports the implementation of the prolonged services code, GPRO1, in 2019, as it has long been recognized that the "first hour" time threshold in the descriptor for the currently available prolonged services CPT code 99354 is difficult to meet and is an impediment to billing these codes. As such, this new code will help fill that gap in time—and it should be finalized independent of the new E/M payment structure that CMS has proposed. In finalizing this code, CMS should apply the American Medical Association (AMA) codebook provision that, for timed services, a unit of time is attained when the midpoint (16 minutes) is passed. Finally, it is important that CMS ensure that the documentation required to bill this code is appropriate to the needs of the patient and physician and not unnecessarily burdensome.

xi. Modification to the Practice Expense (PE) Methodology

CMS Proposal: CMS is proposing to modify the practice expense methodology to compute a PE RVU for the new blended E/M payment rate by blending the PE/Hour across all specialties that bill E/M codes, weighted by the volume of those specialties' allowed E/M services.

ACP Comment: The methodology used for the Practice Expense (PE) in this proposal leads to unintended consequences that creates an inequity between higher practice PE per hour specialty consumers and lower PE per hour specialty consumers. Shifting dollars from the higher PE per hour specialties to the lower PE per hour specialties creates a greater impact to the lower PE specialty consumers. This proposal to collapse payment for office visits included creating a new IPCI solely for office visits, overriding the current methodology for these services by treating Office E/M as a separate Medicare Designated Specialty. This change would also result in the exclusion of the indirect practice costs for office visits when deriving every other

specialty Indirect Practice Cost Indices (IPCI). The proposed policy change would result in a large shift in the specialty-level IPCIs for CY2019 for several specialties and large swings in payment for many services predominantly performed by those specialties. There needs to be time and greater attention given to the modification of practice expense in order to "get it right" to better weight the average PE over all.

C. Recognizing Communication Technology-based Services

i.<u>Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVCI1)</u>

CMS Proposal: CMS is proposing to pay separately for a newly defined type of physicians' service furnished using communication technology. This service would be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit. The proposed code would be described as GVCI1 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion).

As the code description lays out, in instances when the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable. They further propose that in instances when the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service would be considered bundled into the pre- or post- visit time of the associated E/M service, and therefore, would not be separately billable.

CMS states that they believe it is important for patients to consent to receiving these services, and are specifically seeking comment on whether they should require, for example, verbal consent that would be noted in the medical record for each service. The Agency is also proposing that this service can only be furnished for established patients to ensure that the clinician has an existing relationship with the patient, and therefore, basic knowledge of the patient's medical condition and needs, in order to perform this service.

The Agency is also seeking comment on what types of communication technologies are utilized by physicians or other qualified health care professionals in furnishing these services, including whether audio-only telephone interactions are sufficient compared to interactions that are enhanced with video or other kinds of data transmission.

ACP Comments: ACP supports CMS' decision to recognize of services outside of the telehealth restrictions that promote use of communication technology-based services on a broader scale.

ii.Remote Evaluation of Pre-Recorded Patient Information (HCPCS Code GRAS1)

CMS Proposal: CMS proposes creating a new CPT code for the remote evaluation of patient-transmitted video and images. These evaluations may be used to determine whether an office visit is necessary; if evaluation of the information results in an office visit, the remote evaluation would be bundled into the office visit and would not be separately billable. Similarly, if the remote evaluation occurs as a result of a related E/M service from the same physician in the previous 7 days, it would not be eligible for separate billing and would be bundled with the initial E/M service. Services under this CPT code would be exempt from existing 1834(m) Medicare telehealth restrictions.

ACP Comments: The College supports reimbursement for appropriately structured telemedicine communications, whether synchronous or asynchronous and whether solely text-based or supplemented with voice, video, or device feeds in public and private health plans, because this form of communication may be a clinically appropriate service similar to a face-to-face encounter. The expanded use of telemedicine has the opportunity to enhance patient-physician collaborations, improve health outcomes, and reduce medical costs when used as a component of a patient's longitudinal care. CMS' proposal to waive remote evaluations from existing 1834 (m) geographic restrictions is welcomed by ACP as it can increase access to care for those who have difficulties due to illness, disability, or other commitments to physically visit a physician's office. However, ACP emphasizes its belief that telemedicine can be most efficient and beneficial between a patient and physician with an established, ongoing relationship and should be used only as an episodic, intermittent alternative to a patient's primary care physician when necessary to meet the patient's immediate acute care needs.

iii. Interprofessional Internet Consultation (CPT Codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

CMS Proposal: CMS proposes separate payments for 6 CPT codes pertaining to interprofessional telecommunications consultations, including 99446, 99447, 99448, 99449, 994X0, and 994X6. Prior to billing for these codes, the treating physician will be required to get verbal patient consent for these services and must document the consent in the medical record. CMS seeks comment on approaches to protect program integrity and ways to differentiate between legitimate services and activities that benefit the physician.

 99446 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review)

- 99447 (Interprofessional telephone/ internet assessment and management service
 provided by a consultative physician including a verbal and written report to the
 patient's treating/ requesting physician or other qualified health care professional; 11–
 20 minutes of medical consultative discussion and review)
- 99448 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21– 30 minutes of medical consultative discussion and review)
- 99449 (Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review)
- 994X0 (Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes).
- 994X6 (Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time).

ACP Comments: The College thanks CMS for accepting our previous requests that the Agency provide payment for e-consultations through adopting the existing interprofessional consultation codes as well as adding two new g-codes for these services. This proposal would more appropriately recognize the value of primary care physicians' knowledge and skills when consulting hospitalists and other specialists throughout the continuum of care. In the changing environment of patient care, patients are being admitted to hospitals that are likely unaware of the patient's history. Because some hospitals and insurance companies have chosen to exclude the primary care physicians from admitting patients to the hospital, there can be a deficiency in communication between hospitals, hospitalists, and the patient's primary care physician, which may lead to unnecessary or ineffective services (e.g., unnecessary testing, medications prescribed that the patient previously used without success, etc.). This leads to poorer outcomes, unneeded additional office visits, and unnecessary costs that could be avoided if the primary care physician was consulted. 10,11 Allowing for the separate payment of interprofessional telecommunications consultation codes would align with the Agency's broader payment reform efforts to decrease unnecessary testing, numerous specialty consultations, and prolonged hospitalizations, thus leading to decreased costs of hospitalizations and office visits.

Allan H. Goroll, M.D., and Daniel P. Hunt, M.D. "Bridging the Hospitalist-Primary Care Divide through Collaborative Care." N Engl J Med 2015; 372:308-309. http://www.nejm.org/doi/full/10.1056/NEJMp1411416
 A. Chen and H. Yee. Improving Primary Care-Specialty Care Communication ARCH INTERN MED/VOL 171 (NO. 1), JAN 10, 2011. http://archinte.jamanetwork.com/article.aspx?articleid=226311&resultClick=3

D. Expanding Use of Telehealth Services under the Bipartisan Budget Act of 2018 (BBA)

i. Expanding the Use of Telehealth for Individuals with Stroke

CMS Proposal: CMS proposes implementing a provision from the BBA to provide special rules for telehealth services for the purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke, telehealth services). The policy removes restrictions on geographic locations and types of originating sites where acute stroke telehealth services can be furnish. This proposed expansion of telehealth services would be effective for services furnish on or after January 1, 2019.

ACP Comments: The College strongly supports **lifting the originating site geographic restriction for the purposes of identifying and diagnosing strokes through telehealth.** There is a strong evidence base behind the use of telestroke programs, as discussed in ACP's recent position paper in the *Annals of Internal Medicine* on telemedicine:¹²

Benefits from the use of telemedicine in subspecialties are also seen in telestroke services. The Mayo Clinic telestroke program uses a "hub-and-spoke" system that allows stroke patients to remain in their home communities, considered a "spoke" site, while a team of physicians, neurologists, and health professionals consult from a larger medical center that serves as the "hub" site. 13 A study on this program found that a patient treated in a telestroke network, consisting of 1 hub hospital and 7 spoke hospitals, reduced costs by \$1436 and gained 0.02 years of quality-adjusted life-years over a lifetime compared with a patient receiving care at a rural community hospital. 14 A study funded by the Patient-Centered Outcomes Research Institute is enrolling patients with Parkinson disease to measure their ability to connect with neurologists through telemedicine. Research shows that although these patients do better under the treatment of a neurologist, fewer than one half of Medicare patients with the disease see a neurologist due to lack of access. 15 The Patient-Centered Outcomes Research Institute study will test the feasibility of patients being treated in their homes, whether telemedicine reduces caregiver burden, and whether it improves the quality of care and overall patient satisfaction. 16

¹² Daniel H, Sulmasy LS, for the Health and Public Policy Committee of the American College of Physicians. Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper. Ann Intern Med. 2015;163:787-789. doi:10.7326/M15-0498. http://annals.org/article.aspx?articleid=2434625.

¹³ Mayo Clinic . Tests and Procedures: Stroke telemedicine (telestroke). Accessed at<u>www.mayoclinic.org/tests-procedures/stroke-telemedicine/basics/definition/prc-20021080</u> on 5 May 2015.

¹⁴ Demaerschalk BM, Switzer JA, Xie J, Fan L, Villa KF, Wu EQ. Cost utility of hub-and-spoke telestroke networks from societal perspective. Am J Manag Care. 2013; 19:976-85. PubMed

¹⁵ Burke JF, Albin RL. Do neurologists make a difference in Parkinson disease care? Neurology. 2011; 77:e52-3. PubMed CrossRef

¹⁶ Patient-Centered Outcomes Research Institute. Can Virtual House Calls Provide More Patients with High-Quality Parkinson Disease Care? Accessed at <a href="https://www.pcori.org/funding-opportunities/pfa-awards/pilot-projects/notes-from-proje

ii.Expanding Access to Home Dialysis Therapy

CMS Proposal: The Agency proposes to implement a provision of the BBA to allow an individual determined to have end-stage renal disease (ESRD) who is receiving home dialysis to choose to receive certain monthly ESRD-related clinical assessments via telehealth. The individual must also receive a face-to-face visit, without the use of telehealth, at least for the initial 3 months of home dialysis and at least once every 3 months after the initial 3-month period. A renal dialysis facility and individual's home can be considered originating sites for the purposes of monthly ESRD-related clinical assessments via telehealth. Geographic requirements for telehealth services are also removed for purposes of the monthly ESRD-related clinical assessments where the originating site is a hospital-based or critical access hospital-based renal dialysis center, a renal dialysis facility, or the home of an individual. No originative site facility fee is paid when the individual's home is the originating site. This proposed expansion of telehealth services would be effective for services furnished on or after January 1, 2019.

ACP Comments: The College strongly supports implementation of the BBA policies expanding access to home dialysis therapy services via telehealth. Removing the geographic and originating site restrictions to allow patients to receive monthly ESRD-related clinical assessments is critical to patients who require home dialysis therapy.

E. Application of an Add-on Percentage for Wholesale Acquisition Cost (WAC)-based Payments

CMS Proposal: Currently, drugs and biologics paid for under the Medicare Part B benefit include a 6 percent add-on to the average-sales price (ASP) or the wholesale acquisition cost (WAC). The 6 percent add-on is most commonly applied to the ASP; however, the add-on is applied to the WAC in certain circumstances, such as when ASP is unavailable in the first quarter a drug is on the market. The WAC is not inclusive of rebates, discounts, or reductions in price and is typically higher than the ASP. CMS proposes effective January 1, 2019, that WAC-based payments in Part B would utilize a 3 percent add-on in place of the current 6 percent add-on. The 6 percent add-on to WAC would continue to be included as part of payments for single-source drugs.

ACP Comments: ACP recognizes the need to address the rising price and cost of prescription medications and acknowledges the complexities associated with these issues. Although ACP does not have a comment specific to the proposed change in Part B reimbursement, the College encourages CMS to carefully assess the potential impact on patient access or potential adverse unintended consequences such a change would have on small subspecialty practices, independent practices, or those practicing in medically underserved areas. Additionally, CMS should ensure that reimbursement for these medications be adequate enough for the services provided so that additional financial burdens are not placed on practices such as special handling or storage requirements, acquisition of the drug, and administration of the drug inoffice.

F. Clinical Lab Fee Schedule

CMS Proposal: Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) created a new system of determining rates under the Medicare Clinical Laboratory Fee Schedule (CLFS). The new rates are based on private payer rates reported by "applicable laboratories" performing clinical diagnostic laboratory tests (CDLTs), including certain physician office-based labs (POLs), during a data collection period. This data collection and reporting exercise included a 6-month data collection period beginning January 1 through June 30, 2016, and a 3-month data reporting period beginning January 1 through March 31, 2017. CMS later extended the reporting period through the end of May 2017 due to feedback from reporting labs on data quality and insufficient time to collect and report the data. The initial round of payment rates under the new methodology were implemented on January 1, 2018.

For the purposes of data collection, an applicable laboratory must bill Medicare under its own NPI and receive more that 50 percent of its Medicare revenues during the data collection period from the CFLS and/or the Physician Fee Schedule, also called the "majority of Medicare revenues threshold." An applicable laboratory must also be above a "low expenditure threshold," which requires receipt of more than \$12,500 in Medicare revenues from the CLFS for CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

In this rule, CMS proposes to expand the pool of applicable laboratories for future data collection by removing Medicare Advantage (MA) plan revenues from the calculation of the majority of Medicare revenues threshold. This proposal would have the effect of including some additional laboratories that have a significant amount of MA patients in the data collection pool because it would increase the likelihood that a laboratory's CLFS and PFS revenues would constitute a majority of its Medicare revenues. CMS is also soliciting comments on a couple of different approaches that would include hospital outreach laboratories in the definition of applicable labs including defining applicable laboratories using the CLIA certificate rather than NPI.

Additionally, in response to concerns from stakeholders that the low expenditure threshold excludes most POLs and small independent laboratories, CMS is considering changes to the low expenditure threshold. The Agency is seeking comments on reducing the low expenditure threshold by 50 percent to \$6,250 to include data from more POLs and small independent laboratories or increasing the low expenditure threshold by 50 percent to \$18,750 to exclude more laboratories from data collection and provide administrative burden relief. CMS notes that including or excluding additional POLs and small independent laboratories will have a minimal impact on determining the CLFS rates because large laboratories with the highest test volumes will continue to dominate the weighted average of private payer rates. The Agency specifically seeks comments from the physician community on these issues:

- 1. Whether physician offices and small independent laboratories currently have adequate staff levels to meet the data collection and data reporting requirements;
- 2. Whether data systems are currently in place to identify, collect, and report each unique private payer rate from each private payer for each CLFS test code and the volume of tests associated with each unique private payer rate;
- 3. If physician offices and small independent laboratories are generally not prepared to conduct the data collection and data reporting requirements, what is the anticipated timeframe needed for physician office and small independent laboratories to be able to meet the data collection and data reporting requirements; and
- 4. Any other administrative concerns that decreasing the low expenditure threshold may impose on offices and small independent laboratories.

ACP Comments: The College continues to be concerned that the data collection methodology used to establish CLFS payment rates under the PAMA methodology resulted in inaccurate rates. Despite the urging of ACP and other physician organizations, CMS mandated a complicated, confusing, and voluminous data collection process. The retrospective data collection period that was established began six months before the rule outlining the process was finalized. This made it extremely challenging for POLs and small independent labs that were impacted to collect and submit accurate and complete data. Even large reference laboratories struggled to collect and submit accurate data within the specified timeframe, and many were forced to hire additional staff to comply. This flawed collection led to severe rate cuts to critical laboratory services.

To address these flawed rates, ACP reiterates its call that CMS modify the existing PAMA regulations to conduct targeted market segment surveys (reference laboratories, physician office-based laboratories (POLs), independent laboratories, and hospital outreach laboratories) to validate and adjust the final fee schedule payments calculated based on the data collection to ensure Congressional intent—payment rates that accurately reflect private market payments across all market segments—is achieved. While the survey is being conducted and new rates are being established, CMS should revert back to the CLFS rates that were in place for 2017.

As we have noted previously, ¹⁷ ACP is very concerned that absent a revision in how data is collected and rates are established, POLs and small, independent laboratories, especially those in rural areas, will be forced to close, resulting in issues accessing point-of-care testing not only for Medicare patients but also for those with Medicaid and commercial insurance. In a survey of ACP member laboratories, respondents voiced concern that the cuts PAMA would impose on Medicare reimbursements would have a "high impact" on the laboratory services offered to patients, which would lead to POLs "decreasing or stopping" those crucial services at the time of a patient's appointment. Point-of-care testing (near-patient testing) is critical to many patients, especially those who are being treated for an infection, have uncontrollable diabetes, or are receiving chemotherapy, etc., or live in a rural area.

We do not believe that physician office-based laboratories and small independent laboratories have adequate staff levels to meet the current data collection requirements nor are they prepared to conduct the data collection and reporting requirements. They do not have data systems in place to identify, collect, and report each unique private payer rate for each CLFS test code and the volume of tests associated with each unique private payer rate. As CMS notes in the rule, decreasing the low expenditure threshold to include additional physician office-based laboratories and small independent laboratories would have a minimal impact on the CLFS rates because large labs with high volumes will continue to dominate the weighted average. Adjusting the low expenditure threshold will not correct the flaws in the data collection methodology and establishment of rates. Therefore, it is critical that CMS halt implementation of the current rates and conduct market segment surveys and revise the payment rates accordingly.

G. Appropriate Use Criteria for Advanced Diagnostic Imaging

CMS Proposal: Section 201(b) of PAMA requires CMS to implement a program that utilizes appropriate use criteria (AUC) for advanced diagnostic imaging services. In previous fee schedule rules, CMS has established a process for the development of AUC by defining provider-led entities (PLEs) that may be qualified to develop, modify, or endorse AUC. The Agency also identified the criteria for qualified clinical decision support mechanisms (CDSMs) that clinicians may use to consult AUC. An initial list of priority clinical areas that will require AUC to be consulted was also established. After several years of implementation of the AUC program, CMS is required to identify ordering clinicians who are outliers and implement a prior authorization process for advanced diagnostic imaging services for these clinicians.

¹⁷

i.Consultation by Ordering Professional and Reporting by Furnishing Professional

In the CY 2018 PFS rule, CMS finalized that clinicians ordering certain advanced diagnostic imaging must consult specified AUC through a qualified CDSM beginning on or after January 1, 2020, which is a delay from previous rulemaking. The Agency also finalized a requirement that furnishing clinicians must include information on claims submitted on or after January 1, 2020, including which qualified CDSM was consulted by the ordering clinician, whether the service ordered adheres to the applicable AUC, and the NPI of the ordering clinician. Unless an exception applies, AUC must be consulted for every order for an applicable imaging service. AUC may not be available in every CDSM for every applicable service. Therefore, CMS will allow furnishing physicians to meet the requirement by indicating that AUC is not applicable to the service ordered. CMS will treat 2020 as a year-long educational and operational testing period, and claims will not be denied for failure to include proper AUC consultation information.

ii. Clarifications to Applicable Settings and Furnishing Physicians

In this proposed rule, CMS maintains the previously established 2020 start date and proposes a number of changes to previously established policies. CMS proposes to include independent diagnostic testing facilities (IDTFs) in the definition of applicable settings for furnishing advanced diagnostic imaging services. The Agency also clarifies that AUC consultation information must be reported on all claims for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system, and it is not limited to only requiring information on clinician claims. Therefore, claims from the furnishing professionals and facilities (claims for the professional component and the technical component) must include AUC information.

iii.Consultations by Ordering Physicians

CMS also proposes to broaden policies for ordering physicians to allow consultation with AUC through a qualified CDSM to be performed by clinical staff working under the direction of the ordering clinician when not performed personally by the ordering clinician whose NPI will be listed on the order for advanced diagnostic imaging services. Implementation of this policy would be subject to applicable state licensure and scope of practice law.

iv.Reporting AUC Information on Claims

CMS previously discussed creating a unique consultation identifier (UCI) to include information on the CDSM that is consulted and an indication of AUC adherence, non-adherence, or not applicable responses as the Agency determined reporting a UCI would be the least burdensome and preferred approach. CMS has now determined that it is not feasible to create a uniform UCI taxonomy, determine a location on claims forms, obtain the support and permission from national bodies to use claim fields, and solve the underlying issue that a UCI seems limited to claims-level reporting. Therefore, CMS proposes to use a combination of G-codes and modifiers to report the AUC information on claims in order to allow implementation under the current timeframe. CMS will consider future opportunities to create a UCI and engage with stakeholders.

v.Significant Hardship Exception

CMS proposes to adjust the significant hardship exceptions to establish requirements that are unique to the AUC program. Under the proposal, clinicians are not required to include AUC information if any of the following criteria is applicable:

- Insufficient internet access (at location where imaging ordered such as temporary technical issues);
- EHR or CDSM vendor issues (e.g., temporary technical issues, vendor ceases operations, CMS de-qualifies a CDSM); or
- Extreme and uncontrollable circumstances (e.g., natural or man-made disasters, public health emergency).

To claim hardship exception, ordering physicians would self-attest that they are experiencing a significant hardship at the time that they are placing an order for imaging services. Ordering clinicians would provide the information on the hardship to the furnishing physician along with the AUC consultation information. The furnishing then adds a modifier to the claim indicating that the ordering physician experienced a hardship exception. Information on the AUC consultation is not required on the claim in these instances.

vi.Identification of Outliers

CMS seeks comments on data elements and thresholds that should be used to identify outliers who would eventually be subject to a prior authorization process. The Agency intends to address outlier identification more and prior authorization more fully in rulemaking for CY 2022 or 2023.

ACP Comments: The College strongly supports the additional year delay in implementation of the AUC consultation and reporting requirements to January 1, 2020, as was finalized in the 2018 Physician Fee Schedule rule. We also appreciate that CMS will consider 2020 a year-long educational period during which claims will not be denied for failure to include proper AUC consultation information. Awareness of the AUC consultation requirements is very low, and significant lead time will be necessary once all of the policies are finalized in order to educate clinicians and allow them to acquire the necessary technology and make workflow changes to incorporate AUC consultation.

We also reiterate our recommendation that the AUC consultation and reporting requirements be initially implemented as a pilot, with an evaluation of the AUC program occurring before moving to this complex and expensive system including a review of whether the program leads to more appropriate use of advanced imaging and/or better or different billing code selection. As ACP and a number of other physician organizations noted in a recent letter, ¹⁸ we believe that requirements in MIPS make this program largely unnecessary. This is because MIPS is intended to move clinicians into a value-based payment system that is focused on tying quality and cost to performance, so clinicians will already be incentivized to ensure that the services they order and provide are appropriate and necessary. Additional quality and cost measures based on the AUC program requirements could also be developed and incorporated into MIPS to allow physicians the option of having their performance evaluated based on AUC. Requiring QPP participants to also meet the AUC requirements is largely duplicative and adds an unnecessary burden on practices.

The College reiterates its previous recommendations as detailed in our comments on the 2018 physician fee schedule proposed rule¹⁹ that CMS:

- Consider initially limiting the AUC program to a smaller subset of the priority clinical areas, working to phase in additional priority clinical areas over time. This will allow ordering and furnishing physicians to gain experience using AUC through a qualified CDSM and establish the necessary workflows for a smaller set of advanced diagnostic imaging services prior to implementing the program more broadly.
- Allow the work associated with the additional consultation and communication time between the ordering and furnishing physicians and their teams be separately billable for the purposes of the AUC requirement. ACP along with other stakeholders will explore the options for developing codes for payment that describe the services provided by the ordering physician. We further recommend that CMS not make the AUC program mandatory until a code that can be billed and paid by Medicare for the communications necessary to implement this complex system is available for at least 1 year.

¹⁸ https://www.acponline.org/acp_policy/letters/auc_sign_on_letter_2018.pdf

¹⁹

 We also recommend that CMS make information available to allow ordering clinicians to make an informed decision when selecting a qualified CDSM. This includes adding information on which AUC is incorporated into a CDSM, the platform the CDSM uses, the estimated cost of the mechanism, and a link to a website with additional information.

H. Care Management and Communication Technology-Based Services in RHCs and FQHCs

CMS Proposal: CMS proposes to allow rural health clinics (RHCs) or federally qualified health clinics (FQHCs) to bill for communications-based technology services or remote patient evaluation services when at least 5 minutes of those services are provided by a RHC or FQHC and to waive the face-to-face requirement for these services in RHCs and FQHCs. The RHC or FQHC would be reimbursed for services furnished within the previous year.

ACP Comments: ACP is supportive of expanding the use of telemedicine as a way to enhance patient-physician collaboration, improve health outcomes, and improve access to care as well as reimbursement for appropriately structured synchronous or asynchronous technologies that are a clinically appropriate comparable service alternative to a face-to-face encounter. The College believes the most efficient, beneficial use of telemedicine occurs between a patient and physician with whom there is an established, ongoing relationship. ACP supports the provisions in the proposed rule that increase reimbursement for telemedicine services in Medicare, including remote patient monitoring and payments to rural health centers and federally qualified health centers for communication technology based services or remote monitoring or evaluation services. In accordance with ACP policy, a valid patient-physician relationship must be established for a professionally responsible telemedicine service to take place. This can be achieved through a telemedicine encounter as long as appropriate steps are taken to establish a relationship based on the standard of care required for an in-person visit or consultation with a health care professional with whom the patient does have an existing relationship and oversees the patient's care.

I. MSSP Quality Metrics

CMS Proposal: CMS proposes to count two patient experience measures (ACO-45 and ACO-46) that were previously reported on an informational basis and seeks comment on scoring a third (ACO-7). In addition, the Agency proposes to remove 10 measures and add one new quality measure.

ACP Comments: The College supports efforts to streamline the number of quality measures, which aligns with ACP's longstanding Patients Before Paperwork²⁰ and reducing administrative

²⁰ https://www.acponline.org/advocacy/where-we-stand/patients-before-paperwork

burden²¹ advocacy efforts. However, we have certain concerns with the proposal to remove nine at-risk population measures. ACP has always been a vocal advocate for prioritizing more study and attention to social determinants of health and the role they play in both individual and community health. The College published a position paper²² in April, which found that tackling these issues would reduce health disparities and promote health equity. We urge the Agency to strongly consider the implications that removing so many at-risk population-based measures could have on current health disparities and to ensure that vulnerable patient populations would not be adversely impacted by the removal of these measures before proceeding.

J. Physician Self-Referral Law

CMS proposals: The BBA, enacted as Pub. L. 115-123 on February 9, 2018, amended existing physician self-referral law to codify changes to the writing and signature requirements for specific billing and referral exceptions provided by law. While many of these changes are already CMS policy, CMS proposes a few changes to Section 1877 of the Act in order to align the statutory and regulatory language. CMS proposes updating the language under 42 CFR part 411, subpart j to allow compensation arrangement writing requirements to be satisfied by a collection of documents evidencing the course of conduct between the parties. The special rule under §411.353(g) would be amended so that the signature requirement is satisfied if (1) the signatures are obtained within 90 calendar days of noncompliance; and (2) the compensation arrangement otherwise complies with requirements of the exception. It also removes the limited application of the rule to specific exceptions and removes the restriction of only being able to invoke the special rule once every 3 years. The application of the new rule would be backdated to enactment of the BBA so that beginning February 9, 2018, those prevented from using the special rule due to the three year limitation would be permitted to use it.

ACP Comments: The College supports CMS' proposal to align statutory and regulatory language making it easier to satisfy writing and signature requirements for exceptions to billing and referral restrictions. As CMS moves towards value-based payments under QPP, existing self-referral law becomes inappropriate for the current system and an impediment to achieving the goals of QPP of coordinating care to provide high value care. The leniency provided under this proposal will reduce administrative burden and enable more physicians participating in the Medicare program to provide higher quality and lower cost care. ACP calls on CMS to take a step further and consider expanding the exceptions and waivers to self-referral law that maintain the integrity of the Medicare program while also promoting increased innovation and participation in new-value oriented payment models.

²¹ https://www.acponline.org/acp-newsroom/acp-calls-for-continued-efforts-in-reducing-physician-burdens-in-second-red-tape-relief-initiative

²² http://annals.org/aim/fullarticle/2678505/addressing-social-determinants-improve-patient-care-promote-health-equity-american

III. Updates to the Quality Payment Program

A. Low Volume Threshold

CMS Proposal: CMS proposes to add a third criterion for clinicians to qualify for the low-volume threshold: providing 200 or fewer covered professional services to Part B-enrolled individuals. The Agency also proposes to allow clinicians, groups, and APM Entities the option to opt-in to MIPS participation should they fall below one or two of the low-volume threshold criteria (but not all three). Those wishing to opt-in would have to indicate this to CMS through the QPP portal prior to submitting data and the decision would be considered final for the performance period. APM Entity-level designations would occur at the APM Entity level.

ACP Comments: ACP has long advocated for an "opt-in" option to MIPS for clinicians and groups that fall below the low volume threshold and applauds CMS' proposals responding to stakeholder engagement to both add a third criterion to the Low-Volume Threshold and allow for optional participation for those that would have been automatically exempted.²³ Combined, the policies allow CMS to drastically expand participation in the program by a more diverse range of practice sizes and specialties, incentivizing more practices to move toward value-based reimbursement, while minimizing administrative burden, particularly on small practices. Given historic MIPS performance data will eventually be used to calculate future performance benchmarks, this proposal will also help to ensure the mean or median performance score is a more accurate representation of MIPS performance across a more diverse range of practices. The College urges CMS to finalize these provisions as proposed.

B. MIPS Determination Period

CMS Proposal: CMS proposes to streamline the various eligibility determination periods for the low-volume threshold, non-patient facing, small practice, hospital-based, and ambulatory surgical center-based status into a single MIPS determination period that would feature two sequential segments that would each last one year and align with the fiscal year. The first would begin on October 1 of the calendar year two years prior to the applicable performance period and end on September 30 of the calendar year directly preceding the applicable performance period. The second would begin October 1 of the calendar year directly preceding the applicable performance period and end on September 30 of the applicable performance period. The first segment would feature a 30-day claims run-out, the second would not. The facility-based and virtual group eligibility determinations would utilize only the first segment including a 30-day claims run-out.

ACP Comments: ACP strongly supports these proposals to consolidate the varying eligibility determination periods within MIPS. The College agrees with the Agency's reasoning that the

²³

https://www.acponline.org/acp policy/letters/cms comment letter re cy 2018 macra qpp proposed rule 20 17.pdf

varying periods created unnecessary confusion for clinicians and also agree that aligning this period with the fiscal year will help to provide further clarity.

C. Partial QPs within Virtual Groups

CMS Proposal: CMS proposes to clarify that electing to participate as part of a virtual group prior to the start of an applicable performance period would no longer constitute an automatic election to participate in MIPS for clinicians or APM Entities that later achieve Partial Qualified Participant (QP) status. They would be considered excluded from MIPS if they subsequently achieve Partial QP status and do not elect to participate or report any data.

ACP Comments: The College supports CMS' proposed clarification to not count a prior election to participate in a virtual group as an automatic election to participation in MIPS for clinicians or APM Entities that later achieve Partial QP status. We support CMS' logic that groups who participate in Advanced APMs to such a degree that they achieve Partial QP status should not be deprived of the choice to participate or not participate in MIPS that they earned because they voluntarily designated to participate in a virtual group before they were informed of their Partial QP status.

D. Virtual Groups

CMS proposal: CMS proposes to allow virtual groups to register through the existing QPP platform. The virtual group eligibility determination period would align with the first segment of the MIPS determination period, from October 1 of the calendar year two years prior to the performance period until September 30 of the calendar year directly preceding the performance period, with a 30-day claims runout. Starting in 2020, groups would be able to request preliminary estimates of TIN sizes through the QPP Service Center prior to making a virtual group election. These preliminary estimates would be for informational purposes only and subject to change.

ACP Comments: ACP supports CMS' proposal to facilitate virtual group determinations through the QPP platform, as opposed to over email. We agree this will be less burdensome for virtual groups and will facilitate a more seamless user experience as clinicians already interact with CMS through the QPP portal. We similarly support CMS aligning the virtual group eligibility determination period with the first segment of the MIPS determination period for consistency, and we support the availability of a preliminary virtual group election so that groups have this information to consider when registering.

E. MIPS Performance Period

CMS proposal: CMS proposes no changes to performance periods. The Quality and Cost Categories would remain a full calendar year and the Promoting Interoperability and Improvement Activities Categories would remain a minimum of 90 consecutive days up to and including a full calendar year two years prior to the MIPS payment year.

ACP Comments: ACP urges the Agency in the strongest possible terms to reconsider its proposed minimum full-year quality reporting period for the Quality Category and to instead align the performance periods for the Cost and Quality Categories with the minimum 90-consecutive day reporting period of the Promoting Interoperability and Improvement Activities Categories. The College has repeatedly made the case for instituting a minimum 90-day reporting period across all MIPS categories, ²⁴ and the proposal also has widespread support from the wider physician community because it would create consistency and alignment within the QPP, minimize administrative burden on practices and facilitate more timely feedback about performance, as explained in greater detail below. ²⁵

- A 90-day timespan is sufficient to capture sufficient data to ensure high validity for the vast majority of measures, and importantly, would only be a minimum. Requiring reporting beyond this merely places an additional administrative and financial burden on practices and is counter the Agency's stated goals for the "Patients Over Paperwork" and Meaningful Measures Initiatives to reduce unnecessary burden. We are receptive to CMS' concerns about data integrity, and encourage the Agency to conduct and release a thorough analysis of an appropriate length of performance where a significant majority of clinicians and groups would have sufficient data to be considered reliable and valid, isolating the impact on smaller and specialty practices. Additionally, practices could always report for longer if necessary to satisfy denominator requirements.
- Reducing the minimum performance period to 90 days would also help to facilitate the growth and adoption of new technologies that facilitate data tracking and drive quality improvement because practices would have more flexibility to update or implement new, innovative technologies throughout the course of the performance period without fear of penalty for failure to capture an entire year's worth of data. Reducing the required performance period would also increase the number of clinicians who report data to CMS because they would not have to apply for nearly as many hardship exceptions due to issues that inhibit their reporting for a portion of the applicable performance year, such vendor-related technology issues, which are particularly common in the first quarter of new performance years as new measure specifications and other system capabilities are being deployed. The likelihood of malfunctions would be especially high next year if CMS moves forward with its proposal to require 2015 Edition CEHRT. This flexibility would also help to account for any delays in updating resources and information for the current performance year. For the 2018 performance period, many resources on the CMS QPP website were not updated until halfway through the performance year.

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https://www.acponline.org/acp policy/letters/cms comment letter re cy 2018 macra qpp proposed rule 20 17.pdf

²⁵ https://searchlf.ama-assn.org/undefined/documentDownload?uri= percent2Funstructured%2Fbinary %2Fletter%2FLETTERS%2F2018-MIPS-Reporting-Period-Sign-Final.pdf

- Establishing a 90-day minimum reporting period for Quality would also minimize scenarios where clinicians or groups are unable to report and must claim exceptions, thereby increasing overall participation in MIPS. Expecting clinicians and groups to report continuously year after year with no disruptions to the data flow is unrealistic and disadvantages small and rural practices that often face unique challenges. While we appreciate CMS' recognition of certain adverse consequences by offering opportunities to claim hardship exceptions, many groups may want to participate in MIPS but may have no other choice if a natural disaster, or any number of other unexpected issues arise, such as an ACO unexpectedly dissolving and the practice suddenly having the responsibility to gather data and report. If the minimum quality reporting period were 90 days, practices could still participate in MIPS, even if they experienced some reporting difficult at some point throughout the year, by simply selecting another 90-day period. By reducing the minimum reporting period, CMS would collect more MIPS data from a more representative sample of practices of all sizes, types and locations, and would also maximize participation in MIPS, particularly for small and rural practices.
- Shortening the minimum performance period for all four QPP performance categories would also minimize MIPS complexity and enable CMS to provide more regular performance feedback to practices and shorten the current two-year gap between performance and payment. The current process of not distributing performance feedback until up to 18 months after it was reported and then adjusting payments up to two years after-the-fact creates unnecessary confusion in terms of changing requirements for performance versus payment years and is not responsive to the fast changing world of healthcare in which TINs, particularly for larger healthcare systems, can experience weekly if not daily changes to NPI/TIN combinations. The College recommends that CMS provide at a minimum quarterly performance reports so that practices can use that data to recognize patterns as they are occurring and drive meaningful, impactful changes in their practices that improve care quality and outcomes, which is the ultimate goal of the QPP.

F. Measures and Reporting

CMS proposal: CMS seeks feedback on several proposed terminology changes to more precisely reflect the data submission process, including collection type, submitter type, submission type, and third party intermediaries. CMS would make claims-based quality measure reporting available to small practices, regardless of whether they are reporting as individuals or groups. However, the Agency proposes it would no longer allow reporting via claims by larger groups (those with 16 or more ECs). CMS proposes several changes to the CMS Web Interface, including allowing third party intermediaries to report on a group's behalf, no longer allowing groups to use the CMS Web Interface to submit data for the Improvement Activities and Promoting Interoperability Categories, and possibly expanding the Web Interface option to small groups (those of 16 or more clinicians).

ACP Comment: The College appreciates CMS' intent to provide additional clarity about the MIPS data submission process by defining or redefining several terms. However, we have

concerns that the proposed terminology changes may do more to confuse clinicians than they would help to provide clarity. In particular, the proposed new term "MIPS CQMs" is less clear than the current "registry measures" term. Additionally, "collection type" and "submission type" are not intuitive and add unnecessary complication. From a practical standpoint, practices care about how data is collected and submitted on their end. In what technical format data is eventually submitted to CMS, particularly by a third party vendor, is of little practical importance and only serves to create additional confusion. Additionally, practices are already familiar with the term submission mechanisms. Therefore, we implore CMS to retain the term "submission mechanisms" to refer to the mechanisms through which any clinician or practice staff would collect and submit data for purposes of MIPS, including QCDRs, Part B claims, Web Interface, CAHPS for MIPS survey vendor, administrative claims, EHR, qualified registries, and the QPP online portal. If CMS wants to provide additional technical clarification beyond that point for vendors or other purposes, we encourage the Agency to establish a separate term that is more indicative of that, such as "data type" or "data format." We also encourage CMS to consider focus groups of clinicians and practice staff should it consider any additional terminology changes in the future.

ACP supports CMS' proposal to make claims-based quality measure reporting available to small practices, including those that report as a group. We agree with the Agency's logic that small practices face additional challenges and that moving towards electronic reporting may be more difficult for these practices and limit their ability to participate. However, we strongly oppose the Agency's proposal to limit claims-based reporting to exclusively small practices. We support CMS' proposal to expand Web Interface reporting as an option for smaller practices in that it again increases flexibility and provides them another option with which to participate in the program. We also support CMS allowing third party intermediaries to submit data to the CMS Web Interface on a group's behalf, which alleviates burden on group practices to report the data themselves. We disagree with CMS' proposal to eliminate Web Interface reporting for the Improvement Activities and Promoting Interoperability Categories, as this reduces flexibility for groups and adds unnecessary complexity. Previously, groups could complete their reporting for all of the MIPS performance categories through a single submission type, but under the proposal, they would have to report data through multiple submission types. We urge the Agency to reconsider this proposal and to continue allowing data submission to the CMS Web Interface for the Promoting Interoperability and Improvement Activities Categories in the 2019 performance year.

G. Quality Performance Category

i. Quality Measure Selection

CMS Proposal: CMS will continue to categorize measures according to the six National Quality Strategy (NQS) domains: patient safety, person- and caregiver-centered experience and outcomes, communication and care coordination, effective clinical care, community/population health, and efficiency and cost reduction. The Agency will also categorize quality measures by the 19 Meaningful Measures areas identified on the website through subregulatory guidance to

allow clinicians to see how each measure fits within the framework of the Meaningful Measures Initiative.

CMS proposes to add opioid-related measures to the definition of high priority measures and seeks comment on what aspects of opioids should be measured. Under the updated description, high priority measures are defined as outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures includes intermediate-outcome and patient-reported outcome measures.

CMS will continue to allow reporting specialty/subspecialty measure sets. If a specialty set has fewer than 6 measures, the clinician must report on all measures in the set (but does not have to report additional measures beyond the set). CMS also notes that it will not accept submissions for MIPS using an older version of eCQMs for the quality performance category or the end-to-end electronic reporting bonus

ACP Comments: Overall, quality measurement must move toward becoming more relevant and accurate, and toward effective approaches of measuring patient outcomes. Therefore, the College strongly recommends that CMS collaborate with specialty societies, frontline clinicians, patients, and EHR vendors in the development, testing, and implementation of measures with a focus on integrating the measurement of and reporting on performance with quality improvement and care delivery and on decreasing clinician burden.

Along these lines, ACP is encouraged about the Agency's ongoing efforts under the "Meaningful Measures" and "Patients Over Paperwork" initiatives that are aligned with our goals. We further encourage CMS to consider our framework for analyzing new and existing tasks outlined in ACP's recent position paper, *Putting Patients First by Reducing Excessive Administrative Tasks in Health Care*, ²⁶ as the Agency looks to reform quality measures in the context of burden reduction and the value of measures to patients and clinicians. ACP strongly urges CMS to establish a clear and transparent process for determining which measures to remove and retain, which measures are subject a reduction in value, and how measures are classified within the Meaningful Measures framework.

ACP's Performance Measurement Committee (PMC) has assessed and provided detailed recommendations on many of the performance measures included in MIPS, with a focus on those that are particularly applicable to internal medicine. The PMC recommendations are based upon a scientific review process that involves five domains: importance, appropriateness, clinical evidence, specifications, and feasibility and applicability. Of measures considered relevant to ambulatory general internal medicine, 32 (37 percent) were rated as valid, 30 (35 percent) as not valid, and 24 (28 percent) as of uncertain validity. ACP's PMC has also assessed

²⁶ http://annals.org/aim/article/2614079

²⁷ MacClean CH, Kerr EA, Qaseem, A. Time Out – Charting a Path for Improving Performance Measurement. N Engl J Med 2018; 378:1757-1761. https://www.nejm.org/doi/full/10.1056/NEJMp1802595

a number of additional performance measures with similarly mixed reviews. ²⁸ Based on this assessment, ACP's Performance Measurement Committee calls for improving the measure development process so that performance measures help physicians provide the best possible care to their patients without creating unintended adverse consequences. Therefore, ACP strongly recommends that CMS look to these recommendations first when considering what measures to use for reporting by internal medicine specialists. See Appendix 2 for a complete table of the PMC's comments and recommendations on the MIPS quality measure set. Additionally, please see Appendix 3 for some high-level discussion points on measures proposed for future inclusion in the MIPS program—these points are provided for the Agency's consideration. A more formal assessment, including ACP's official recommendations on those newly proposed measures, will be forthcoming.

The College further recommends that any measures CMS proposes to use outside of the ACP recommendations be measures that are included in the consensus core sets of the Core Quality Measures Collaborative (CQMC)²⁹ and/or recommended by the Measure Application Partnership (MAP). ACP remains concerned that a majority of new measures added to MIPS for the 2019 reporting year have received only conditional support from the MAP, and there are 2017 and 2018 measures that remain on the list for the MIPS program were given a MAP recommendation of "encourage continued development." This MAP designation is reserved for measures that often lack strong feasibility and/or validity data. Therefore, measures given the "encourage continued development" recommendation should be resubmitted to the MAP once the suggested development occurs. Additionally, one new measure that is proposed for 2019, Continuity of Pharmacotherapy for Opioid Use Disorder, received a MAP recommendation of "refine and resubmit prior to rulemaking." While we agree that the opioid epidemic is an important public health area that needs to be addressed, including a quality measure that has not been properly tested and refined for clinician and group level reporting is unlikely to produce meaningful improvements in quality and may create patient safety concerns.

Additionally, ACP continues to believe that all measures, whenever possible and regardless of source, should go through a multi-stakeholder evaluation process—a role that is performed by the National Quality Forum (NQF). This process is important as it involves measures being evaluated against four important criteria—importance to measure, scientifically acceptable, usable and relevant, and feasible to collect.

Given that the approaches outlined above could result in a fewer number of measures available overall, particularly for a number of internal medicine subspecialties and other specialties, the College strongly recommends that CMS reduce the number of required measures for full participation in the Quality Performance Category to three measures. We believe that reducing the number of quality measures that are required for full participation in MIPS is essential to allow CMS to have the space to truly overhaul the existing measures and measure development process to move toward better measures that are meaningful to clinicians and their patients.

²⁸ https://www.acponline.org/clinical-information/performance-measures

²⁹ https://www.ahip.org/ahip-cms-collaborative-announces-core-sets-of-quality-measures/

This will also help enable specialists and subspecialists select a full set of measures that are relevant to their specialty and scope of practice.

ACP also recommends that CMS take concrete actions to provide clear options for those specialties and subspecialties that may be most impacted by too few appropriate measures. These actions, which are detailed in ACP's comments on the MACRA proposed rule, 30 should include:

- Developing a process to determine in advance of the reporting year which quality measures are likely applicable to each eligible clinician—and only holding them accountable for these relevant measures (i.e., weighting performance on the remaining measures higher, rather than penalizing them with a score of zero on unreported measures).
- Putting a process in place, for the short term, to address the significant issues of validity and ability to implement associated with using measures that are not ACP recommended, MAP-recommended, and/or NQF-endorsed.
- Establishing safe harbors for entities that are taking on innovative approaches to quality measurement and improvement as was recommended in a recent article by McGlynn and Kerr. ³¹
- Taking the recommendation regarding safe harbors a step further, the College also calls on CMS to provide clear protections for individual clinicians who participate in these types of activities—this could be done by having the entities register certain measures as "test measures." Eligible clinicians then would not be required to report a specific performance score on these test measures, but their participation testing these measures (as some established subset of the 6 required measures) would not count against them, and in fact could be given some level of points within the quality category and/or counted as an improvement activity.
- Ensuring that the flexibility for QCDRs to develop and maintain measures outside of the CMS selection process is protected (this recommendation is discussed further below).

The College also reiterates our recommendation, as outlined in our response to the draft Quality Measure Development Plan (MDP)³²—that it will be critically important for CMS over the longer term to continue to improve the measures and reporting systems to be used in MIPS to ensure that they measure items of clinical relevance, move toward clinical outcomes and patient- and family-centeredness measures, and do not create unintended adverse consequences.

https://www.acponline.org/acp_policy/letters/comments_cms_draft_quality_measures_development_plan_2016. pdf

³⁰ https://www.acponline.org/acp_policy/letters/comment_letter_macra_proposed_rule_2016.pdf

³¹ McGlynn, E.A. and E.A. Kerr. Creating Safe Harbors for Quality Innovation and Improvement. *JAMA*. 2016;315(2):129-130. http://jama.jamanetwork.com/article.aspx?articleid=2481012

ii. Assessing Performance on the Quality Performance Category

CMS Proposal: CMS initially finalized a 30 percent weight for the Quality Performance Category for the 2019 performance period. However, given that the BBA included a provision to allow the Agency flexibility in weighting the cost and quality categories for an additional three years, CMS proposes to weight the Quality Performance Category at 45 percent of the overall composite performance score in the 2019 performance period, a 5 percent reduction from the 50 percent weight in 2018. The proposed weighting reduction accounts for the increase in the Cost Performance Category from 10 percent to 15 percent in 2019.

ACP Comments: While we appreciate that CMS is using its authority under the BBA to weight cost down and increase quality accordingly, ACP opposes increasing the weight of the Cost Performance Category to 15 percent and reducing the weight of the Quality Performance Category to 45 percent in the 2019 performance period. As discussed in further detail below in Cost Category subsection, ACP does not believe that the current cost measures are adequate to meaningfully measure performance, especially for solo clinicians and those in small group practices. Therefore, we recommend keeping cost at the 2018 weight—10 percent—for the 2019 performance period and setting quality at the current 50 percent weight. Additionally, we strongly recommend allowing for a Quality Performance Category performance period of any continuous 90-day period for both 2018 and 2019.

iii. **Quality Data Submission**

CMS Proposal: CMS proposes to incorporate the new terminology into the quality category. Rather than referring to data submission mechanisms as was done in previous regulations, CMS is updating the submission terminology to reflect the following collection types: Medicare Part B claims measures, MIPS CQMs, eCQMs, QCDR measures, CMS Web interface measures, CAHPS for MIPS survey, and administrative claims.

CMS retains the basic quality reporting requirements from the 2018 performance period. For most data collection types, ECs and groups are required to report on six quality measures including on outcome measure. If no applicable outcome measures are available, ECs and groups must report on a high priority measure. The performance period for the Quality Performance Category is a full year.

CMS is looking to phase out reporting via Part B claims since approximately 69 percent of the Part B claims measures have reached topped out status. While the Agency ultimately wants to move toward electronic reporting, CMS recognizes that there are challenges faced by small practices that might impede their ability to participate. To begin addressing this concern, CMS proposes to limit quality reporting via Medicare Part B claims to clinicians reporting to small practices (those with 15 or fewer ECs) beginning with the 2019 performance period. Additionally, while reporting via claims was limited to individual reporting in the past, CMS proposes to allow small practices to also use the claims-based reporting option to submit data as a group.

For the CMS Web interface, the Agency proposes to remove six measures in MIPS (see Table D). CMS seeks comment on whether to lower the required number of ECs in a group to report using the CMS web interface from 25 to 16 ECs. The Agency notes that smaller groups may struggle to satisfy case minimums for some measures. However, CMS suggests that this could be addressed by only requiring a subset of web interface measures (i.e., preventive measures) for groups with 16 to 24 ECs.

ACP Comments: While the College supports the proposal to allow small practices to use the claims-based reporting option for group reporting, we strongly oppose limiting the claims reporting to only ECs in small practices. As noted previously, because CMS defines small practice as TINs with 15 or fewer ECs, many clinicians are excluded from the special small practice policies despite operating as small practices in all other respects. These include very small practices that join an independent practice association (IPA) organized under a shared TIN. Additionally, there may be circumstances where reporting via claims as individuals is the best option for clinicians in larger multispecialty practices to allow each EC to focus on quality measures most relevant to his/her specialty and scope of practice. Therefore, ACP recommends that CMS retain the claims-based reporting option in the Quality Performance Category for all clinicians regardless of practice size.

ACP also supports allowing smaller practices (those with 16 or more ECs) to report via the CMS Web interface. We think it is reasonable to allow groups with 16 to 24 ECs that elect to use the Web interface to report on a subset of measures.

iv.<u>Process Measures Removal</u>

CMS Proposal: CMS proposes an approach to incrementally begin removing process measures beginning in 2019, with consideration given to impact on specialties, high priority status, promotion of positive outcomes in patients, evaluation of performance data, and extremely topped out status.

ACP Comments: The College encourages CMS to carefully consider each process measure prior to removal and allow for stakeholder comments through proposed rulemaking. Many process measures do have value to clinicians and patients, and arbitrarily removing them from MIPS or reducing their point value without regard to the value of the quality actions that are being measured may lead to slippage in what had been consistently good performance. We urge CMS to approach removal of process measures cautiously and in a clear and transparent manner, taking into account the ACP recommendations on performance measures ^{33,34} in addition to the factors listed above (specialties, high priority status, promotion of positive outcomes in patients, evaluation of performance data, and extremely topped out status). See Appendix 1 for

³³ Time Out – Charting a Path for Improving Performance Measurement. https://www.nejm.org/doi/full/10.1056/NEJMp1802595

³⁴ https://www.acponline.org/clinical-information/performance-measures

a comparison of the measures CMS proposes to remove with ACP's validity assessment of those measures.

v. Quality Benchmarking

CMS Proposal: CMS proposes to apply benchmarks based on collection type (eCQMs, MIPS CQMs, QCDR measures, Part B claims measures, web interface measures, CAHPS) rather than by submission mechanism. For example, eCQM benchmark would be applied to submissions by individuals, groups, and third-party intermediaries. Specifically, benchmarks will be based on collection type, from all available sources, including MIPS ECs and APMs, to the extent feasible, during the applicable baseline or performance period.

ACP Comments: The College supports CMS' proposals regarding collection type rather than submission mechanisms but we have concerns with the proposal to incorporate APM data into benchmark calculations for MIPS participation. It is likely that those participating in APMs are higher performing and therefore may serve to set the benchmark too high for those participating in MIPS. We urge CMS to consider this possibility calculating the benchmarks for quality measures within MIPS

vi.CAHPS for MIPS Survey

CMS Proposal: CMS does not notify practices that intend to submit the CAHPS for MIPS survey of their inability to meet the sampling requirements and therefore that they are unable to have their performance assessed on CAHPS until late in the performance period. In order to address these concerns, for groups that register to submit CAHPS for MIPS and are subsequently determined to have insufficient cases to meet the sample size, CMS will reduce the denominator for the quality performance category by 10 points. Therefore, practices will not be penalized in their overall score and would not be forced to select an additional quality measure to fill this space. CMS seeks comment on whether to limit this policy to a single performance period for groups to avoid scenarios when groups may sign up with advance knowledge that they are unlikely to meet the sampling requirements.

ACP Comments: The College supports reducing the denominator in the Quality Performance Category for practices that are determined to be unable to meet the sampling requirements for the CAHPS for MIPS survey. It is important to avoid penalizing practices for circumstances beyond their control, especially when they arise near the end of the performance period when there is little that can be done to rectify the issue. We do not think that it is necessary to allow this option for a single performance period only.

Additionally, in order to more cohesively address the issue of patient experience, the College recommends that CMS consider an approach recently outlined by McGlynn, Schneider, and Kerr, ³⁵ which calls on measure developers to actively consider how to integrate patient

³⁵ Elizabeth A. McGlynn, Ph.D., Eric C. Schneider, M.D., and Eve A. Kerr, M.D., M.P.H. "Reimagining Quality

preferences and goals into measure design—this would involve investments in new methods and systems with a focus on having quality measurement be part of care delivery "rather than existing as a parallel."

As CMS considers developing additional patient experience measures such as patient-reported outcomes measures (PROMs), the College reiterates its recommendations from our letter on the draft Quality Measure Development Plan that CMS ensure any PROMs being developed undergo substantive testing to ensure they are valid and reliable, do not place additional burdens on physicians in the collection and reporting of data, are minimally burdensome on patients, and are actually shown to have an evidence base that indicates they are measuring quality improvement.

Additionally, to decrease the burden on patients and physicians, CMS should make PROMs as flexible as possible by allowing for multiple methods and modes of administration to best fit with the unique needs of both the patient and physician practice (i.e., computer/internet access, smart phone technologies, computer software/programming, EHR interfaces, etc.). CMS should also ensure that patients and families/caregivers be included throughout the PROM development process. It is important that the patients and families who will be tasked with reporting any data be involved in providing input in any patient measures being developed to ensure that the burden on patients is minimized and the measures being developed are evaluating outcomes that matter to the patient.

vii.Topped Out Measures

CMS Proposal: The Agency proposes to maintain the 4-year cycle for removing measures that are considered to be topped out. Beginning with 2019, measure benchmarks identified as topped out in two consecutive years will receive a maximum of 7 points in the second year. Final determination of benchmarks that will be subject to the 7-point cap in 2019 based on topped out status will not be available until late 2018 when the 2019 benchmarks are published. CMS proposes that for measures that have reached "extremely topped out status" (e.g., average mean performance within 98th to 100th percentile), the Agency may propose removal in next rulemaking cycle regardless of where the measure is in the 4-year topped out cycle. The Agency also seeks comment on how to score CAHPS pertaining to topped out measures.

ACP Comments: The College continues to be concerned with the policy of reducing the maximum amount of points that can be achieved for reporting a topped out quality measure in the second year. This policy is being implemented without regard for the value of the quality actions that are being measured. We reiterate our previous recommendation that CMS keep topped out quality under the same scoring standards as other measures, at least for the first two performance periods. Creating separate scoring standards for different subsets of

measures adds complexity to scoring the quality category at a time when CMS is seeking solutions to reducing complexity.

viii.Data Completeness, Case Minimum, and Benchmark Requirements

CMS Proposal: CMS proposes maintaining the 2018 data completeness requirements in the 2019 performance period. Therefore, clinicians submitting quality data via Part B claims submission must report on 60 percent of their eligible Part B patients in 2019. Clinicians using eCQMs, MIPS CQMs, and QCDR measures must report on 60 percent of their eligible patients from all payers. Groups reporting using the CMS Web interface or the CAHPS for MIPS survey must meet the data completeness requirements that are specific to those submission mechanisms.

For the 2019 performance period, CMS proposes to maintain a 3-point floor for quality measures with sufficient data submitted to be scored against the benchmark (data completeness criteria and 20-case minimum are met). CMS plans to revisit this policy in future rulemaking. Beginning with the 2020 performance period, CMS proposes to assign zero points to measures that are submitted that fail to meet the data completeness requirements. For small practices (those in TINs with 15 or fewer ECs), CMS proposes to maintain for all future years the 3-point value for measures that do not meet data completeness requirements but may revisit this policy at some point in future rulemaking.

ACP Comments: The College reiterates its previous recommendation that CMS set the data completeness requirements for quality reporting at 50 percent of patients. Given that CMS simultaneously extended the performance period from 90 days to a full year, an increase in the data completeness requirements to 60 percent of patients for the 2018 and 2019 performance periods significantly increased the data collection burden. As CMS focuses on implementing policies that reflect its "Patients Over Paperwork" initiative, ACP recommends reducing the data completeness requirements for quality reporting to 50 percent for 2018 and 2019. As noted above, we also recommend pairing this with a 90-day performance period for the Quality Performance Category. Given that CMS did not post the quality measures in the QPP portal until July, practices do not have sufficient time to select measures for 2018 reporting and collect data, especially for those clinicians using claims to report quality data.

The College further recommends that any increase data completeness requirements beyond 50 percent is phased in only after review has determined that doing so is both appropriate and feasible to do so. This review should include analysis of data to determine whether a significant number of clinicians are meeting the existing data completeness requirements, including an evaluation by data collection type, measure, and practice size as well as clinicians in rural and underserved areas.

At a minimum, CMS should implement a 50 percent data completeness threshold for small practices and those in rural areas and HPSAs for several years to allow CMS to analyze their uptake in full data reporting. Increasing the data completeness criteria before a significant

amount of ECs are able to participate at the current levels will create substantial barriers while ECs are trying to learn the basics of the QPP requirements and add unnecessary administrative burden, especially given that CMS has already determined that the 50 percent data completeness standard is sufficient to attain a reliably valid performance score.

ACP reiterates its recommendation that CMS establish the 3-point floor for quality measures for all clinicians, including those who fail to meet the data completeness criteria, for the 2018 and 2019 performance periods. As ECs and groups continue learning to meet the new and changing requirements under MIPS, we believe that it is important to maintain stability in the policies under which they are being scored. Changing the point floor for quality measures for clinicians also adds complexity to a scoring methodology in MIPS that is overly complicated. As such, we oppose the Agency's proposal to award zero points to practices with 16 or more ECs that report as a group beginning in 2020. If CMS does not establish a 3-point floor for all clinicians, the Agency should at least maintain the policy of awarding one point to larger group practices that fail to meet data completeness requirements. We appreciate that CMS proposes to maintain the 3-floor for quality measures for ECs in small practices and encourage CMS to maintain that policy.

ix.Clinical Guidelines Changes During the Performance Period

CMS Proposal: CMS is concerned that clinical evidence and guidelines may change during a performance period, resulting in a quality measure that is no longer reflective of current clinical evidence and potentially contrary to patient well-being. To address these concerns and better align MIPS with other programs such as the Hospital VBP Program, CMS proposes to suppress a measure without rulemaking if it is significantly impacted by clinical guidelines changes or other changes that may pose patient safety concerns during a performance period. Measure stewards would be relied upon to notify CMS of guidelines changes, and the Agency would publish on its website suppressed measures when technically feasible, no later than the beginning of the data submission period.

Should measures be suppressed during the performance period, CMS would score zero achievement points for the measure and reduce that total available achievement points for the Quality Performance Category by 10, effectively removing the measure from impacting the clinician's score.

ACP Comments: The College strongly supports the proposal to suppress quality measures without rulemaking if clinical guidelines changes impact reporting of the measures and reduce the total quality score accordingly. It is important that clinicians are protected from any adverse impacts on their scoring when they are following updated clinical guidelines to ensure proper patient care and safety. In instances when suppression of a measure is necessary, CMS should automatically suppress the measure and adjust the quality scoring accordingly for any EC that submits quality data on the measure. We also recommend that CMS establish an attestation process through the EIDM system to allow ECs the option to attest to their intent to report on the measure. If the guideline changes occur prior to the reporting year, the affected measures

should just be eliminated from the list and should not be included as a reporting option. The measure stewards/developers should work on updating and testing the measure according to the guideline changes. If guideline changes occur during the reporting year, then the EC should be able to attest to their intent to report on the measure and CMS should adjust the score accordingly. The ECs who attest to their intent to report can report on the measure during the testing period and should receive credit during this time. This attestation process should be developed with input from all necessary stakeholders, including MIPS clinicians, and could include specific parameters or reasons for the attestation, including the cost of reporting, etc. Additionally, this attestation could be used not only for issues related to guideline changes, but also for new testing results that demonstrate unintended consequences as a result of measure implementation. This is especially useful for the new measures proposed by CMS for inclusion in the 2019 list where CMS did not present any testing information. A good example is the sepsis measure that PMC reviewed last February:

"While implementation of the Surviving Sepsis Campaign has been associated with improved clinical outcomes, there is no literature on the unintended consequences of this measure. ACP should advocate for research on post-marketing surveillance (similar to that of the CAP antibiotics measure³⁶) to weigh the benefits of early diagnosis against the potential harms of treating patients who appear to be infected, but in fact are not."

ACP does not believe that notification of a measure that is impacted by clinical guidelines changes should be limited to measure stewards. In many instances, the measure steward is not the same as the developer of the clinical guideline and therefore may not be aware of guidelines changes as they are updated. Clinical guidelines developers and medical specialty societies, which often develop guidelines, may be more in tune with existing clinical guidelines and any related performance measures and be tracking revisions. Therefore, ACP recommends that CMS broaden the policy on who can submit a quality measure impacted by clinical guidelines changes for consideration of suppression to include measure stewards, systematic reviewers, clinical guidelines developers, and medical specialty societies at a minimum.

x.Scoring for ECs Not Meeting Quality Performance Category Criteria

CMS Proposal: Due to changing terminology from data submission mechanism to collection type, CMS proposes to only apply the validation process to MIPS CQMs and claims collection types regardless of the submission mechanism. Therefore, submitters using eCQMs would not be subject to validation for available and applicable quality measures even if submitting via the registry.

ACP Comments: We encourage CMS to consider ways of addressing situations in which clinicians may not be aware of measures that are available and applicable by providing

 $^{36}\ http://annals.org/aim/fullarticle/741439/public-reporting-antibiotic-timing-patients-pneumonia-lessons-from-flawed-performance$

guidance on how clinicians could approach determining whether additional measures are applicable. This could be by providing lists of measures commonly reported by each specialty, lists of measures commonly applicable across many specialties (i.e., cross-cutting measures), and the unreported measures that are commonly identified as applicable through the validation process as well as information on how CMS determines applicable measures through the validation process.

xi.Small Practice Bonus

CMS Proposal: For the 2018 performance period, CMS finalized a small practice bonus of 5 points, which will be added onto the final score for small practices (generally TINs of 15 or fewer ECs) that submit data on at least one performance category. Observations using historical data indicate that small practices are less likely to submit quality performance data and have lower performance rates than others in quality. Given that CMS already has special policies in place for small practices to allow a hardship exemption in PI and double points in Improvement Activities, the Agency proposes to move the small practice bonus to the Quality Performance Category in 2019 and future years. Under this proposal, small practices that submit at least one quality measure would earn an additional 3-point bonus added onto the numerator in their total Quality Performance Category Score. CMS notes that awarding 3 points toward the general quality score (which is out of 60 possible points based on the six-measure requirement) represents 5 percent of the Quality Performance Category score.

ACP Comments: ACP does not support CMS' proposal to relocate the small practice bonus to the quality category, which reduces its relative worth by 25 percent and results in only 2.25 points to the total MIPS composite score, as opposed to a full 3 points. This bonus is critical to offset the unique challenges small practices face and we do not feel the Agency offers sufficient explanation for this proposed move. We discuss our concerns in more detail in our comments on the overall MIPS scoring proposal section of this letter.

xii.Incentives to Report High-priority Measures

CMS Proposal: CMS proposes to maintain the current cap on high-priority measure bonus points for the quality performance category in 2019. This means that the bonus points achieved for reporting additional high priority measures cannot be more that 10 percent of the total possible quality score (10 percent of the denominator). CMS also proposes to discontinue awarding bonus points for additional high-priority measures for clinicians reporting via the CMS Web interface. Because data indicate that practices reporting through the CMS Web interface generally perform better than other practices, the benefit of bonus points is limited. Additionally, Web interface reporters are required to submit data on all measures and are not subject to policies pertaining to limited points for topped out measures. Therefore, CMS does not believe that Web interface reporters should be eligible for high-priority measures bonus points. Groups reporting via the Web interface may still receive bonus points for electing to report via the CAHPS for MIPS survey. CMS may consider removing high-priority measure bonus points for all collection types after the 2019 performance period.

ACP Comments: We understand CMS' reasoning behind removing bonus points for reporting additional high priority measures through the CMS Web interface. Given that the Web interface has different requirements than other data collection types including that groups are required to submit data for all measures in the Web interface, there is not a choice as to whether or not to submit additional high priority measures to earn bonus points.

xiii. Incentives to Use CEHRT for Quality Reporting

CMS Proposal: CMS proposes to continue to allow 1 bonus point for each quality measure reported using end-to-end electronic reporting for the 2019 performance period. In light of the proposed terminology changes, CMS also clarifies that the end-to-end reporting bonus only applies to the subset of data submitted by direct, log in and upload, and CMS Web interface. The Agency intends to consider no longer offering the end-to-end reporting bonus points after the 2019 performance period, but CMS will continue to find ways to incentivize and encourage reporting using CEHRT and seeks comments on ways to encourage this.

ACP Comments: While the College is appreciative of CMS offering opportunities for bonus points for end-to-end reporting, we believe there is little additional value in end-to-end reporting for all measures vs. one measure, especially if the result is just sending more data to the same location using the same method. Solving interoperability at the practice level requires dealing with multiple reporting targets with varying requirements. Therefore, rather than the approach CMS has taken to-date of awarding a point for each measure, the College recommends that additional 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.

CMS and ONC should partner with physicians that use direct EHR reporting specifically to gather instances of errors in value set logic and/or value set implementation. Incentives could include additional bonus points in the PI category. As ideal as direct EHR reporting appears—and ACP is supportive of the option of direct EHR reporting overall—it still has issues with accuracy that are not readily apparent and need to be addressed. These issues are not present or as problematic with registry reporting or reporting from manual chart abstraction (that is then manually uploaded into a web form).

xiv.Scoring Improvement in the Quality Performance Category

CMS Proposal: CMS proposes to continue the policies for scoring improvement in quality performance that were established in rulemaking for 2018. Therefore, clinicians may be eligible to receive points for improvement in performance over the previous year if they fully participate in the Quality Performance Category in 2019. Generally, fully participate means submission of the required six quality measures including an outcome measure or other high priority measure if an outcome measure is not available or submitting a complete set of data that meets the CMS Web interface requirements. Data must meet the applicable data

completeness requirements. If a clinician or group received less than a 30 percent score in the previous period, CMS will assume a score of 30 percent for comparison purposes. The maximum score for improvement in the Quality Performance Category is capped at 10 percentage points.

ACP Comments: The College reiterates its support for including points for improvement in the Quality Performance Category through category-level improvements. Given that ECs and groups may report different measures year-to-year, especially in the early years of MIPS while clinicians are adjusting to the new requirements, in addition to the changes to the quality measures that are available through the Meaningful Measures initiative, scoring category-level improvements is important. ACP encourages CMS to consider how those ECs and groups that are consistently high achievers can still be adequately awarded for improvement relative to those who have more room to improve. We also encourage CMS to consider additional ways of incentivizing improvements for clinicians and groups that are incrementally increasing performance toward full quality measure requirements. Given the current concerns with many of the quality measures and the Meaningful Measures initiative, it is important that there be multiple ways of awarding points for improvement outside of full participation in the Quality Performance Category.

xv. <u>Future Considerations for Scoring the Quality Performance Category</u>

CMS Proposal: CMS does not propose changes to the calculation of total measure achievement and bonus points for the Quality Performance Category for 2019. However, the Agency does seek comment on potential future approaches to scoring the Quality Performance Category to simplify the scoring by reducing the burden and increasing the value of the measures that CMS is collecting.

- Set point total without specific measure requirements: Restructure quality
 requirements to set a pre-determined denominator (e.g., 50 points) but do not set any
 specific parameters around the number of measures or type of measures that must be
 submitted. Clinicians could determine the number of measures and type of measures to
 submit to achieve a desired score.
- Categorizing measures by value: Revise the structure to classify measures as a
 particular value (i.e., gold, silver, bronze) and points are awarded based on value of
 measure. Clinicians could submit fewer measures by selecting to report those that are
 higher value (similar to improvement activities). To encourage reporting of high-value
 measures, CMS may limit the number of low-value measures that could be reported or
 require a certain number of high-value measures be report. For example, the tiers might
 be structured like this:
 - Tier 1 gold measures Up to 15 to 20 points. Includes higher value measures such as outcome measures, composite measures, or measures that address agency priorities (i.e., opioids) as well as CAHPS.

- Tier 2 silver measures Up to 10 points. Includes process measures that are directly related to outcomes and have a good gap in performance or topped out outcome measures.
- Tier 3 bronze measures Up to 5 points. Includes lower value measures such as standard of care process measures or topped out process measures.
- **Keep current requirements with measure values:** Clinicians would be required to report 6 measures including a high-priority measure worth up to 10 points each, but measure achievement points would vary based on the measure's value tier. High-tier measures might have a high priority bonus and/or higher potential floor (e.g., 5 points rather than the 3-point floor); low-tier measures might have a lower potential floor (e.g., 1 point rather than the 3-point floor).
- Remove validation process for measure availability and applicability: CMS is looking to
 potentially remove the validation process by which the Agency determines the
 availability and applicability of measures to a clinician. This could involve moving to sets
 of measures with criteria to define the clinicians for whom the measures are applicable
 or moving to a policy with a defined point total but fewer restrictions on the number
 and type of measures that are required.
- Create QCDR benchmarking approach: CMS is seeking comments on how to develop
 QCDR benchmarks based on historical data. The Agency has heard that reporting levels
 for some QCDR measures are low because they do not have an established benchmark
 and clinicians are concerned that if a benchmark cannot be established based on data
 during the performance period, only three points can be earned for reporting the
 measure. To establish benchmarks based on historic data, QCDRs would need to be able
 to extract historical data from only MIPS ECs and groups.

ACP Comments: The College believes that the scoring of the quality category needs to be overhauled to allow for measurement that is truly meaningful to physicians and patients. We appreciate that CMS is open to considering some options for doing so. As the Agency works with stakeholders to reform the quality measures through the Meaningful Measure initiative, improving the scoring methodology will be important as the number and type of measures available is likely to be very different than the current MIPS measures.

Once a more meaningful set of measures is available with sufficient measures for specialists/subspecialists, ACP supports the concept of setting a point total for the Quality Performance Category and removing specific requirements pertaining to the number and type of measures that must be reported to fully participate in the category. As quality measures evolve, it will be important to allow physicians flexibility in choosing measures that are relevant to their specialty, scope of practice, and patient population.

In the near term, the College opposes moving to a system in which there are tiers of quality measures that have varying values and maximum points that can be achieved based on the current measures available. Bluntly categorizing measures into tiers based on topped out status or outcome v. process measures does not take into account the value of the action being performed to clinicians and their patients. If CMS does choose to move to a system of valuing

measures differently, much more deliberate thought must be factored into how a "high value" measure is defined. For example, measures that are NQF-endorsed and part of a Core Quality Measures Collaborative measure set might be high value. Additionally, measures that are strongly supported and recommended by stakeholder groups (e.g., physician specialty organizations) with established measure evaluation criteria might also be in the high value tier. These would include measure recommendations such as those from ACP's Performance Measurement Committee. It is also important that any system of valuing measures go through notice and comment rulemaking to allow for stakeholder input on the criteria.

ACP opposes maintaining the current 6-measure requirement while moving to a system of tiering measures based on their value. As noted earlier in this letter, the College believes that the number of required measures should be reduced to three measures in the near term to allow for the MIPS measure set to be truly evaluated and improved. This process will naturally result in fewer available measures as stakeholders identify areas for additional measures to be added and new measure development. Significant work is needed to revise the current set of MIPS measures before CMS could even consider moving to tiering based on value.

The College would be supportive of removing the validation process if it is tied to a scoring structure where there is a maximum point total for the Quality Performance Category without requirements on the number or type of measures that must be submitted. In this scenario, there must be sufficient measures available for specialists/subspecialists to achieve the maximum points for the category while reporting on measures relevant to their specialty/subspecialty. Removing the validation process without sufficient measures that are available and applicable to all specialties would result in penalizing those specialties that lack measures by not allowing them an opportunity to achieve full points in the Quality Performance Category.

ACP supports promoting increased collaboration between QCDR vendors to collect data on QCDR measures for more robust benchmarking. This could be achieved through the development of a resource that allows QCDR vendors to search for QCDR measure that are in the pipeline development stage. QCDRs could use this resource to identify other vendors developing similar QCDR measure concepts. Vendors could collaborate earlier in the development phase to co-create measures or license measures to increase more broad adoption of QCDR measures across multiple QCDRs. CMS should not pursue mandating that QCDR measure owners license use rights to any approved QCDR vendor in an effort to improve QCDR benchmarking. In the event that a QCDR measure is based on an existing MIPS measure (e.g., eCQM version of registry MIPS measures), CMS should also consider the appropriateness of using the original MIPS measure as a benchmark for the QCDR measure version.

H. Cost Category

CMS proposal: CMS proposes to increase the weight of the Cost Category from 10 percent to 15 percent. The weight of the Quality Category would decrease to 45 percent accordingly. CMS intends to increase the weight of the Cost Category by 5 percent each year until it reaches the

required 30 percent in the 2022 performance year. However, CMS seeks comment on alternatively maintaining the weight of the Cost Category at 10 percent for the 2019 performance year, given it also proposes to introduce eight new episode based measures. In accordance with the BBA, CMS will not factor improvement into the Cost Category score until the 2022 performance year.

As noted above, CMS proposes to add eight new episode-based measures. Episode costs would be payment standardized and risk adjusted for more accurate comparison across clinicians. CMS notes that each measure was conditionally supported by the MAP, contingent on NQF endorsement. CMS intends to submit the measures for NQF endorsement in the future. The eight measures would meet the previously finalized reliability threshold of 0.4 for the majority of clinicians and groups at the proposed case minimums of 10 for procedural episode-based measures and 20 for acute inpatient medical condition episode-based measures. CMS seeks comment on alternatively setting the case minimum for the Simple Pneumonia with Hospitalization measure at 30 and expanding the performance period for the Cost Category from one to two years to increase measure reliability.

For acute inpatient medical condition episode groups, CMS would attribute episodes to each MIPS eligible clinician who bills inpatient E/M claim lines during a trigger inpatient hospitalization (identified by a particular MS-DRG) under a TIN that renders at least 30 percent of the inpatient E/M claim lines in that hospitalization, which differs from the previous policy that would attribute episodes to TIN/NPIs who individually exceed the 30 percent threshold, while excluding all episodes where no TIN/NPI exceeds the 30 percent threshold. For procedural episode groups, CMS would attribute episodes to each eligible clinician who renders a trigger service as identified by Healthcare HCPCS/CPT procedure codes. The measure score for a TIN would be based on all of the episodes attributed to a TIN/NPI in the given TIN. In both cases, if a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode would only be counted once in the TIN's measure score.

CMS proposes to conduct annual evaluations to ensure accuracy of measure specifications. Every three years the agency would conduct comprehensive measure re-evaluations to ensure measure reliability and validity and consistency with measure priorities. Changes in coding, risk adjustment, and other factors would be addressed through ongoing maintenance and evaluation. CMS would publish any substantial changes through the formal rulemaking process, including submission to the Measure Applications Partnership. In accordance with new provisions under the BBA provisions, CMS would list any cost measure under development and related information no later than December 31 of each year.

ACP Comments: The College appreciates CMS recognizing the need to develop and test new episode-based cost measures and appreciates the Agency's solicitation for stakeholder feedback throughout the development process. However, we have significant concerns about the new episode-based measures.

First and foremost, the measures are not endorsed by the NQF and are only conditionally supported by the Measure Applications Partnership (MAP). Stakeholder input is absolutely critical and NQF and MAP endorsement are crucial steps to ensure measures accurately measure value through evidence-based protocols, improve patient safety, and achieve better outcomes. CMS should not move forward with finalizing any new cost measures until they have the full approval of both the NQF and MAP.

In particular, we believe that the episode-based measures require further development and testing to fully understand their validity and reliability, particularly for internal medicine physicians and subspecialists, before they are counted toward the Cost Category score—and if they are deemed to be unreliable or not valid, they should not be used in any way that directly impacts physician payment. Accordingly, we urge CMS to make these measures pay for reporting in the 2019 and 2020 performance years so that the validity and reliability of these measures can be better understood and the measures can undergo possible refining before these measures impact a clinician's MIPS score. This would align with existing policies CMS has in place for the CMS Web Interface.

Should the Agency move forward with using these measures that still need further testing and improvement, we ask it reconsider the required reliability rating of 0.4, which is unacceptably low considering these measures would have a direct impact on physician payments, as mean reliability ratings below 0.5 are generally considered "poor" reliability. The College recommends CMS set a minimum reliability of 0.75, which is considered by expert researchers to be the minimum standard for "good" reliability.³⁷ Notably, only three of the proposed eight episodebased cost measures have a mean reliability above 0.75, which is further cause for concern. We urge the Agency to also set a minimum requirement that at least 75 percent of TIN/NPIs and TINs meet the reliability standard. CMS could achieve this by increasing case minimums to improve reliability, score all or certain episode-based measures only at the TIN-level, or consider removing and continue studying certain measures that are particularly low on reliability. We do not support CMS' alternate proposal to increase the performance period for the cost category to two years. Increasing the performance period for only cost measures would create further dysfunction and confusion when it comes to which performance period aligns with which payment year, moves further from efforts to streamline the program and reduce burden. It would also result in even less frequent feedback on cost performance, rendering the data less and less useful for informing ongoing cost containment efforts. CMS should be looking to provide more frequent feedback on cost, not less. We understand CMS' point that this is a tradeoff between reliability and the number of clinicians that would meet the case minimum; however, we feel that reliability of cost measures should be the number one priority considering performance on these measures is proposed to impact the reimbursement of physicians across the country. In fact, it would be counterintuitive to seek to apply low-reliability measures to a wider set of physicians.

³⁷ Koo, Terry K., and Mae Y. Li. "A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research." *Journal of Chiropractic Medicine*15, no. 2 (June 2016): 155-63. doi:10.1016/j.jcm.2016.02.012.

We have concerns over the attribution and risk adjustment methodologies for both the new episode-based measures and existing Medical Spending Per Beneficiary and total per capita cost measures. The College supports CMS' emphasis on team-based care for attribution methodology for inpatient medical condition episode groups. However, we suggest that CMS increase the threshold for inpatient E/M claim lines to 50 percent. Basing attribution on a plurality will increase the accuracy of patient attribution for these measures and also better align with patient attribution policies for the existing claims-based cost measures. We have similar concerns over the proposed attribution methodology for procedural episode groups as we do for the total per capita cost measure in that attribution can be triggered by a single code, including by a specialty clinician. Attributing patients based on a single service code is an inherently flawed concept and these types of patient attribution methodologies should be revisited. Requiring even two "triggering" codes would drastically increase the accuracy of patient attribution for these measures. In any case, this is all the more reason for CMS to further test and refine the attribution methodologies for these measure before adversely penalizing physician payments based on them. The College wishes to reiterate our past concerns³⁸ (pg. 38-39) over the accuracy of the two current claims-based cost measures, which inappropriately attribute broad-based costs to physicians for services that are outside of their control and that they do not have the ability to impact such as costs associated with hospitalizations and other care settings that occur outside of the physician's practice.

All cost measures also lack proper risk adjustment methodologies such as adjustments for socioeconomic status. Failure to properly risk adjust creates a system that inappropriately penalizes physicians with higher numbers of lower income or frailer patients, which could force physicians to choose between turning away high-risk patients and remaining in business and lead to access issues for vulnerable patient populations.

Accordingly, we urge CMS to not increase the weight of the cost category beyond 10 percent until these issues can be addressed. We appreciate the concern of CMS of gradually increasing the weight of the cost category so that clinicians are not jolted from 10 to 30 percent in a single year, however, we underscore that unless the measures themselves are of sound reliability and validity including having appropriate risk adjustment and patient attribution mechanisms in place, increasing the weight of the Cost Category for flawed measures would be worse. Rather, adjusting these measures with ongoing input from the medical community should take precedence.

ACP supports CMS' proposals for consistent evaluations of cost measures for continued accuracy, measure validity and reliability, and consistency with measure priorities. The College believes that all measures should be regularly reviewed for clinical and statistical accuracy. We also support CMS' posting of measures under consideration for future development as outlined

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in the BBA and believes this level of transparency and ongoing stakeholder feedback in all MIPS performance categories and measures is essential to a well-functioning program that is adaptive to changing clinical guidelines and technologies.

I. Improvement Activities Category:

CMS Proposal: CMS proposes to add six, modify five, and delete one improvement activity, as summarized in Tables A and B of Appendix 2. CMS offers some explanation regarding how it distinguishes between high- and medium-weighted activities, which is that in order for an activity to be considered high-weighted it must meet one of several criteria, including: the extent to which it aligns with PCMH protocols and other transforming clinical practice priorities, whether it requires multiple actions, if it entails participation in a state Medicaid program or addresses public health priorities, and whether it requires a significant investment of time and resources. The Agency invites public comment on the need for additional transparency and guidance regarding its policies for weighting improvement activities as medium or high and intends to these policies in next year's rulemaking.

CMS proposes to expand the timeframe by which submissions for new activities would be submitted, proposed and implemented over two full years, which would delay implementation of new activities by one year but would align with the timeline for the Annual Call for EHR Measures for the PI Category and expand the Annual Call for Activities submission period by four months. To help address the opioid crisis, CMS proposes to add addressing a public health emergency as criteria for considering new activities. The Agency proposes to remove activities considered for an Advancing Care Information bonus if the new scoring methodology for the Promoting Interoperability category is finalized, but seeks comment on applying high-weighting for any activity employing CEHRT.

CMS proposes to rename the "CMS Study on Burdens Associated with Reporting Quality Measures" as the "CMS Study on Factors Associated with Reporting Quality Measures." The agency also proposes to increase the minimum sample size to 200 MIPS eligible clinicians (from 102) and to limit focus groups to a subset of 200 participants. Regarding study measure requirements, CMS proposes to eliminate the requirements to submit one outcome measure and one patient experience measure and instead require one high priority measure starting next year.

CMS proposes to clarify that ECs and groups in PCMHs or comparable specialty practices must attest in order to receive full credit towards the Improvement Activities Category.

ACP comments: The College supports CMS' proposal to add six new Improvement Activities to fill current voids in applicable activities for certain subspecialties and reward innovation and improvement in the important areas of behavioral and mental health, patient engagement, care coordination, patient safety, and population management. ACP also supports the proposed modifications to five measures to include more specialty-specific examples and agrees this will add clarity for specialty clinicians. We also agree with the proposed removal of

PM_9 based on CMS' logic that it is nearly identical to PM_17 which are both titled Participation in Population Health Research with the only difference being that the description for PM_17 specifically notes that clinicians can meet this activity through participation in federally and/or privately funded research.

The College appreciates CMS' reasoning that the current timeline for soliciting, proposing, and finalizing new Improvement Activities is rushed and we support CMS' proposed modified timeline, which will provide the industry with a longer window to submit proposals, and more advance notice to implement new activities that have been finalized. We also appreciate that aligning this Annual Call for Activities with the Annual Call for EHR Measures will reduce complexity within the QPP.

ACP appreciates that CMS offers some explanation in this proposed rule regarding how it distinguishes between high- and medium-weighted activities. The College is further encouraged to see CMS solicit feedback on the need for greater transparency regarding its weighting methodologies. The College reiterates our earlier recommendation that CMS should work to develop a transparent, evidence-based system for weighting improvement activities that features clearly defined quantifiable criteria, undergoes rigorous testing and evaluation, and solicits stakeholder input throughout the development process. We offer our full support and assistance toward these efforts as CMS looks to overhaul its weighting methodology in the future. In the interim, we reiterate our recommendation that the Agency do away with its current arbitrary distinction between high and medium-weighted activities and award all improvement activities 20 points.

The College strongly supports CMS' proposal to add addressing a public health emergency as criteria for considering new activities. In the past, the College has supported awarding credit in this performance category for participation in public health efforts and has been a vocal advocate of the importance of incentivizing clinicians to address the nation's opioid epidemic. The College supports CMS' proposal to encourage the use of CEHRT by high-weighting any activity that uses CEHRT and encourages the Agency to continue to look for ways to award cross-category credit where appropriate.

We do not support CMS' proposal to remove bonus points in the PI Category for reporting certain Improvement Activities via electronic end-to-end reporting. While we appreciate CMS' intent to simplify scoring for that category, we do not feel incorporating bonus points adds an undue amount of complexity to the scoring and that the goals of incentivizing the use of CEHRT and awarding cross-category credit, thereby minimizing reporting burden on clinicians and synergizing quality and cost goals amongst performance categories, far outweigh these concerns. We urge CMS to move in the direction of incorporating more opportunities for cross-category credit, not removing the few opportunities that currently exist. Accordingly, we urge the Agency not to finalize this proposal and to instead maintain opportunities for earning bonus points in the PI Category for reporting certain Improvement Activities via CEHRT. Once the PI performance category score is calculated using the proposed performance rate scoring methodology, these cross-category bonus points could be then be added to the final PI score.

In lieu of attestation on a case-by-case basis, ACP urges CMS to work with national and regional accreditation, recognition, and certification bodies to obtain a list of all enrolled PCMHs or comparable specialty practices. We feel this will both simplify the information flow to CMS and reduce administrative burden on practices. Individual PCMHs or comparable specialty practices could then verify their status online and report any discrepancies. We additionally implore the Agency to more fully recognize the wide range of transformative activities practices are engaging in by awarding credit toward the Improvement Activities Category for activities and data reported by other third party sources, such as Maintenance of Certification Programs. The College continues to support ongoing accommodations for small practices, those in rural areas or HPSAs, and non-patient facing clinicians.

J. Promoting Interoperability Performance Category

CMS Proposal: CMS renamed the Advancing Care Information (ACI) Performance Category under MIPS to the Promoting Interoperability (PI) Performance Category and proposes a number of scoring and measurement changes including removing, combining, and adding new measures as well as removing the previous scoring subcategories. The Agency is maintaining the 90-day reporting period for PI in 2019 that was finalized in previous rulemaking and the PI performance category will remain at 25 percent of the overall MIPS composite score.

ACP Comments: ACP is encouraged by CMS's focus on interoperability and improving patient access to health information and the subsequent renaming of the Medicare and Medicaid EHR Incentive Programs to the Promoting Interoperability (PI) Programs to highlight this focus. The renaming of the PI performance category, along with the scoring and measure proposals, aligns the structure of this PI program with that of the hospital program which is helpful for those physicians participating in multiple Medicare programs. However, we remain very concerned about a number of other aspects of the PI performance category, and the PI program overall, which are outlined in more detail in the below sections.

Regarding the 90-day reporting period, the College believes that a 90-day reporting period for PI is a sufficient amount of time to capture the necessary information required and also allows flexibility for participating practices and physicians upgrading or replacing their EHR systems to be able to select the 90 days of data that reflects the highest utilization. **ACP strongly supports** the 90-day reporting period for the PI Program and recommends CMS consider maintaining the 90-day reporting period beyond 2020. This shorter PI reporting period allows for the opportunity to update or implement new and innovative technology throughout the course of the calendar year without the fear of negatively impacting performance data.

i.2015 Certified Electronic Health Record Technology

CMS Proposal: CMS proposes to require the use of 2015 Certified Electronic Health Record Technology (CEHRT). In the past, CMS has been flexible in allowing EPs to use either the 2014 or 2015 Edition of CEHRT. CMS explains it considers 2014 Edition certification criteria out-of-date

and insufficient for physician needs in the evolving health IT industry. One of the specific functionalities required in the 2015 Edition is Application Programming Interfaces (APIs), which are an important aspect of promoting interoperability between systems and facilitate the flow of information between physicians and patients, in line with CMS' MyHealtheData Initiative – Blue Button 2.0.

ACP Comments: The College supports the requirement for use of 2015 CEHRT in 2019 and agrees that moving to more up-to-date standards and functions is important — especially in an effort to better support the exchange of health information. We would like to reiterate our previous concerns regarding the significant cost associated with implementation and the large amount of time these types of system upgrades take to roll out, including effectively deploying the new technology, staff training, and workflow adjustments — all leading to potential risk to patient health. Therefore, we recommend that CMS allow for at least six months, if not a full year, for physicians to implement the upgrades once the 2015 CEHRT is ready and available from their vendor before they are graded on their use of the technology. The College is also supportive of the hardship exceptions for uncontrollable circumstances (including vendor issues) within these proposals. We urge CMS to clearly communicate to participating clinicians these hardship options and make the application process as simple and streamlined as possible. In addition to a hardship exception for those who choose to accept it, we urge CMS to provide more assistance to small practices that are willing to try to integrate information technology, but cannot accomplish the task without additional help and resources.

In this proposed rule, CMS specifically addresses the API functionality included in the 2015 CEHRT requirement as a needed and necessary step in order to further advance interoperability. 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. However, we would also like to highlight that the use of APIs is not the sole answer to what fixes the issues with interoperability and that there is still room for improvement in this space. 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 with the potential of information overload. Additionally, there have been recent reports from application developers that there are exorbitant costs associated with running their applications on some of the larger EHR systems. As the use of APIs becomes more widespread, these costs for developers need to be monitored as this will have downstream effects on the consumers of these applications as well as stifling innovation in the marketplace if the costs are too high for developers to compete due to these unreasonable fees.

ii.PI Scoring Methodology and Measures

CMS Proposal: CMS proposes to do away with the separate "base," "performance," and "bonus" categories within the current scoring methodology and instead proposes a performance-based point system in which the numerator and denominator of each measure would translate to a performance rate for that measure and be applied to the total possible

points. The new scoring methodology does not remove the "all-or-nothing" aspect of the previous ACI performance category, as failure to report a numerator/denominator of one or more or reporting a "no" response for any of the six required measures would automatically result in a score of zero for the entire PI performance category. CMS is still requiring the Security Risk Analysis be done but proposes not to include the analysis as a measure that would count towards the overall PI performance category score. Failure to conduct the Security Risk Analysis would result in a score of zero for PI.

The PI Category objective and measure proposals would use only the 2015 CEHRT objective and measure set, which is comprised of four objectives (e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange) and six required measures, unless an exclusion is claimed for a particular measure. Exclusions are available for the e-Prescribing, Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Incorporating Health Information, Provide Patients Electronic Access to Their Health Information, and two of the Public Health and Clinical Data Exchange measures. CMS also proposes to add two new opioid-related measures to the e-Prescribing objective that would count as bonus points for the 2019 performance year and they propose requiring them in 2020.

ACP Comments: ACP appreciates CMS's attempt to simplify the PI scoring methodology with the removal of the different base, performance, and bonus categories. This proposal, along with the specific measure change proposals, aligns with the recently finalized PI Program for hospitals. As noted above, this alignment is helpful for clinicians participating in multiple Medicare reporting programs. The proposed scoring simplification is also a step forward for simplifying both the PI category and overall scoring of MIPS and that scoring simplification was one aspect of our previous recommendations; nonetheless, there is still much more that needs to be done to improve this performance category.

As noted in our comments in the IA performance category section, we strongly recommend that CMS maintain opportunities to receive bonus points in the PI category for using CEHRT to perform improvement activities. Even with the proposed new scoring methodology for PI, these bonus points could be added to final the PI performance score without having to reweight other PI measures. Further, the College is extremely disappointed that the PI measures and measure change proposals still have a minimum threshold requirement of one or "yes" and that the category remains "all-or-nothing" if participants do not report on one of the six required measures. This requirement is technically more than what was required under the base category in 2018 and the College does not support the idea that a single misstep by a participating clinician or practice could still eliminate any opportunity to score well with PI. ACP has called for removal of the thresholds in previous comments on Meaningful Use Stage 3³⁹ and

³⁹ ACP Comments on Meaningful Use Stage 3 Final Rule: https://www.acponline.org/acp_policy/letters/acp_mu_stage_3_comments_2015.pdf

the ACI performance category^{40,41} as a way to promote the collection of data on the use of EHRs and health IT (instead of grading clinicians on how they use the technology) – and compare that data to outcomes and patient satisfaction. Unfortunately, the proposed changes to the scoring methodology and measures follow the same logic as the previous EHR reporting programs that we believe is fundamentally skewed.

The College recommends that the PI performance category not be limited to a small set of required measures or objectives but instead allow for some flexibility and for clinicians to select from a somewhat larger list of measures or activities. Clinicians need the ability to select measures that are relevant and that move them forward in using health IT to improve value of care and they are going to need health IT capabilities that they do not yet have. The PI program should be used as a vehicle to help them make the needed transitions with the end goal of improving patient care. A potential unintended consequence of the proposal to remove the separate performance category option under PI is that there will be less flexibility in the PI category to achieve a higher score based on what is relevant to the clinician's specialty or practice. Clinicians will be unnecessarily focused on churning out numerators and denominators for the required measures instead of focusing on ways to use their EHRs to improve patient care. As a way to provide more flexibility within the category, ACP recommends that the PI performance category incorporate, much like the IA performance category, a list of optional, but clearly defined, health IT-specific activities from which a clinician can choose that are appropriate to their specialty. This type of approach was discussed in the Inpatient Prospective Payment System (IPPS) proposed rule⁴² under the "Promoting Interoperability Program Future Direction" section where CMS described creating a set of priority health IT activities that would serve as alternatives to the PI program measures, much like what ACP has strongly recommended in the past and reiterates in this letter. CMS must consider this same strategy for the PI performance category within MIPS if they truly intend to move beyond the burdensome reporting elements of the legacy EHR reporting programs that have hindered health IT and EHR innovation and left physicians dissatisfied with their EHR systems.

Examples of health IT activities include:

- EHR/Health IT educational activity developed/endorsed by medical specialty or professional societies;
- Patient Engagement (e.g., develop a case report describing a patient engagement problem and the actions the practice took, including the use of health IT, to resolve the problem);
- Precision Medicine/Learning Health System (e.g., participation in practice-based research or other observational study efforts);

https://www.acponline.org/acp_policy/letters/comment_letter_macra_proposed_rule_2016.pdf

⁴⁰ ACP Comment Letter to CMS on MACRA Proposed Rule:

⁴¹ ACP Comment Letter to CMS Regarding CY 2018 Medicare Physician Fee Schedule Proposed Rule: https://www.acponline.org/acp_policy/letters/cms_comment_letter_re_cy_2018_macra_qpp_proposed_rule_20_17.pdf

⁴² CMS Inpatient Prospective Payment System Proposed Rule: https://www.gpo.gov/fdsys/pkg/FR-2018-05-07/pdf/2018-08705.pdf

- 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);
- 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).

Note: The health IT activities listed above are described in more detail in our previous recommendations⁴³ on the QPP.

These activities are very much in line with CMS' proposals for cross-category credit and the concept of multi-category measures while allowing for participants to focus in on a key aspect of care delivery while touching on multiple points of measurement within MIPS. In recent discussions at the 2018 ONC Interoperability Forum, this same approach to measuring interoperability was discussed as an important piece to improving interoperability and definitely an aspect that CMS should consider for future performance years. Development of these types of multi-category measurement models would require input from all stakeholders – including practicing clinicians – and have the potential to reduce the burden of reporting, promoting interoperability, and most importantly, promoting the use of health IT to improve patient care.

ACP could also support the current requirement to report on EHR functional use — but only where the EHR functional-use requirements do not contribute to poor EHR usability, where the numerator and denominator were auto-calculated, and where there were no base thresholds or performance requirements. ACP also supports the required Security Risk Analysis attestation as long as ONC and CMS continue to make sure that satisfaction of this requirement is simple enough for ECs in small practices to do, and not costly or time consuming. The College urges CMS to provide more specific guidance regarding what is and is not acceptable in the risk analysis and we seek clarification from CMS on whether the Information Blocking attestation, required in previous performance periods, is still a requirement within the PI category or whether that will be addressed within the ONC Information Blocking pending regulation.

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 supports practical interoperability. In the meantime, we have specific comments and concerns about the proposed PI measure set that are outlined in the below table.

⁴³ ACP Comment Letter to CMS on MACRA Proposed Rule: https://www.acponline.org/acp_policy/letters/comment_letter_macra_proposed_rule_2016.pdf

ACP Comments on Proposed PI Category Objectives and Measures

Objective: e-Prescribing

Measure: e-Prescribing

ACP Comment: Continued improvement of ePrescribing 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 they require the 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 their system. ACP supports this measure as long as there is no minimum threshold requirement and no performance measurement.

Objective: e-Prescribing

Measure: Query of Prescription Drug Monitoring Program (PDMP) (Optional/Bonus)

ACP Comment: ACP 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 EHR systems, this type of EHR-functional-use measure will be burdensome and require multiple actions outside of the clinical workflow. Regarding implementation of this measure, we seek clarification on whether the query can be run by staff and reviewed by a physician — or if the physician themselves is required to run the query. Additionally, the Agency may come across varying state requirements when implementing this measure. For example, in Kentucky, a physician can write an acute prescription for a controlled substance and then query the PDMP after writing the prescription. For chronic controlled medications, the PDMP must be queried prior to the initial prescription and then every 90 days thereafter (with some established exceptions). These variations in state requirements must be addressed before this measure is ever a required aspect of the performance category. ACP supports this measure as long as there is no minimum threshold requirement and no performance measurement.

Objective: e-Prescribing

Measure: Verify Opioid Treatment Agreement

ACP Comment: The College seeks clarification on the 6-month look back period and whether that would require a patient to sign a new contract every six months. Resigning an agreement every six months and incorporating that into the EHR system would be extremely burdensome and there is little evidence in the literature that these types of contracts or agreements do anything positive for patient outcomes. **Therefore, ACP opposes this new measure proposal and recommends that CMS not implement.**

Objective: Health Information Exchange

Measure: Support Electronic Referral Loops by Sending Health Information

ACP Comment: The College does not believe that measuring and promoting interoperability should focus on sending 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. **The College supports this measure**

ACP Comments on Proposed PI Category Objectives and Measures

as long as there is no minimum threshold requirement or performance measurement.

Objective: Health Information Exchange

<u>Measure</u>: Support Electronic Referral Loops by Receiving and Incorporating Health Information

ACP Comment: 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 from care transfers from any clinician to any other clinician and 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. **Therefore, ACP opposes this new measure proposal and recommends that CMS not implement.**

Objective: Provider to Patient Exchange

Measure: Provide Patients Electronic Access to Their Health Information

ACP Comments: ACP believes that all patients should be offered timely access to their own health information. **The College supports this measure as long as there is no minimum threshold requirement and no performance measurement.**

Objective: Public Health and Clinical Data Exchange

Measure: (Choose two of the following)

- Immunization Registry Reporting
- Electronic Case Reporting
- Public Health Registry Reporting
- Clinical Data Registry Reporting
- Syndromic Surveillance Reporting

ACP Comments: 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. ACP supports this measure as long as there is no minimum threshold requirement and no performance measurement.

K. Request for Information (RFI) on Promoting Interoperability and Electronic Health Information Exchange (HIE)

CMS Proposal: In an effort to further promote interoperability and electronic HIE, CMS is considering revisions to the current CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid Programs (Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities).

ACP Comments: The College believes that updating the requirements within CoPs is a good option when/if the requirements for interoperability are easy to measure and do not create new and ongoing reporting burdens; however, the College still has concerns that CMS is not focusing on the useful, practical aspects of interoperability that would truly enhance high-value care. When looking at clinical data exchange in the context of routine care delivery, CMS' policies are on the right track – specifically, policies allowing physicians to constrain the information in the summary care record to support transitions of care; allowing physicians to use their judgment in deciding which items present on the problem list, medical history list, or surgical history list; and allowing hospitals and CAHs to use any document template within the consolidated clinical document architecture (C-CDA) standard to ensure the relevant information is included. The College believes these proposals should apply in all routine care delivery situations as an industry-wide best practice – not just related to participation in the PI Program or any other particular Medicare program. That said, the clinical note is still not coded in a way that can be easily carried over and shared – even within the Fast Healthcare Interoperability Resources (FHIR) standard. The push to structure and code clinical data has resulted in a decline in the ability of health IT systems to manage what clinicians feel is most important – the narrative text. Clinicians need to be able to easily find and read the clinical narratives, such as the history of present illness (HPI) and the Assessment and Plan. Clinicians want to know what other clinicians think about the patient and use that information to analyze and link together the other medically complicated and technical aspects of the record, and take action to provide the best possible patient-centered care. Management and sharing of the clinical narratives is integral to interoperability and ACP strongly recommends that CMS, ONC, and all relevant stakeholders focus on this key aspect or the industry will never achieve true, practical interoperability.

When discussing interoperability more broadly, including other purposes of clinical data exchange outside of routine care delivery, (e.g., Health Information Exchange [HIE] repositories, clinical data registries, private payer billing and payment requests, and patient requests), we believe there is a fundamental misconception that sending all data everywhere is promoting or enhancing interoperability. From a technical perspective, once the full set of clinical data is sent from the source, it is considered historical data. Something may have changed since the latest copy was received that would cause a change in decision making about the patient. It would be unsafe to make clinical decisions based upon the latest C-CDA without going back to the source to ask if there is anything new that is relevant. One example where this could be an issue is if

certain payers plan to develop and practice care delivery plans based on this reported, historical data. And unfortunately, a system in which an abundance of clinical information is consistently, securely, and electronically transferred still does not address the burdensome issues clinicians face with their EHRs. It is important to recognize that access to every aspect of a patient's information does not help with the issue of access to useful and actionable information at the point of care. Interoperability should not be measured by volumes of data moved from place to place. A better approach, and one that ACP strongly recommends, is for CMS to account for the clinical perspective in their attempts to measure interoperability and focus that measurement on clinicians having the ability to query other health IT systems for specific and up-to-date answers to their specific clinical questions.

L. APM Scoring Standard for MIPS APMs

CMS Proposal: The Agency proposes to clarify that each distinct track of an APM will be considered separately regarding whether it meets the criteria to be a MIPS APM and that the first performance year for an APM begins on the date when participants must report on quality measures under the terms of the APM. Based on this criteria, CMS expects the following APMs to qualify as MIPS APMs in 2019: the Comprehensive ESRD Care Model (all Tracks), Comprehensive Primary Care Plus Model (all Tracks), Next Generation ACO Model, Oncology Care Model (all Tracks), MSSP (all Tracks), Bundled Payments for Care Improvement Model, Advanced Independence at Home Model (if extended), Maryland Primary Care Program, and the Vermont Medicaid ACO Initiative.

CMS proposes to modify its policy regarding exceptions for when an MSSP ACO fails to satisfactorily meet all MIPS quality reporting requirements, solo practitioners may report quality data on any available MIPS measures, including individual measures. CMS proposes to allow MIPS eligible clinicians participating in MSSP ACOs to report Promoting Interoperability Category data at the individual or group levels. MSSP participants would be able to assess performance feedback at the TIN-level. CMS additionally proposes that in cases where an APM Entity fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, the CAHPS for ACOs survey would be counted as the APM Entity's quality performance category score and the TIN-level reporting exception would not be triggered.

ACP Comments: The College agrees that it would be counter to ongoing administrative burden efforts to require duplicative reporting of quality measures for both the APM and MIPS and therefore supports CMS' proposed clarification that the first performance year for an APM would begin on the date that that the APM begins requiring quality data. ACP also supports CMS' proposed clarification that it would evaluate APM tracks separately for purposes of whether it meets the criteria to be considered a MIPS APM. This will allow for maximum flexibility and allow APMs to offer different risk levels and design elements to appeal to the broadest range of potential participants and will foster APM development and innovation.

The College supports CMS proposals to increase flexibility for MSSP ACOs, including allowing solo clinicians the option to report individual quality measures should an ACO fail to report on their behalf, the ability to assess performance feedback at the TIN-level, and the ability to report PI data at the individual or group levels. MSSP ACOs come in a variety of sizes, organizational structures, and ownership and we are pleased CMS recognizes that one-size-fits-all policies are not appropriate for APMs, and to build some flexibility into its evaluation of the program.

However, we urge CMS not to finalize its proposal to automatically count CAHPS for ACOs survey data as an ACO's entire quality category score in the event the ACO fails to report complete quality data so that the exception would not be triggered. The College has conducted a rigorous evidence-based review of certain CAHPS measures and concluded that they were of uncertain statistical and clinical validity.⁴⁴ Therefore, basing an MSSP ACO's entire quality score solely on these volatile metrics would be inaccurate and irresponsible, particularly when quality is worth such a substantial portion of an MSSP ACO's total MIPS score. We urge CMS to reconsider this proposal and to instead allow participating TINs the option to submit additional quality data on their own behalf in the event their ACO does not fully report quality data. In terms of practical implications, we expect this would result in little additional work for CMS, but could make a world of difference to individual TINs that find themselves in this unfortunate circumstance through no fault of their own. Furthermore, this policy would help TINs to be less apprehensive about participating in the MSSP.

We further recommend that the Agency make permanent the full credit in the Improvement Activities Performance Category that has been given to MIPS APMs in years 1 and 2, rather than undergoing a review each year. In the event that new APMs are added that do not include sufficient activities to receive full credit for improvement activities, CMS should separately point out that the specific APM receives only partial credit. In general, participants in MIPS APMs should be able to operate under the assumption that they will receive full improvement activities credit for their APM participation year-after-year unless CMS informs them otherwise.

M. MIPS Scoring

CMS Proposal: CMS proposes to increase the weight of the Cost Category to 15 percent and to lower the weight of the Quality Category to 45 percent. The Improvement Activities and PI Categories would retain their current weights of 15 percent and 25 percent, respectively. In general, the Agency proposes to retain its separate scoring methodologies for each performance category, though CMS proposes to overhaul the scoring methodology for the PI Category and offers several approaches to potentially revamping scoring for the Quality Category in the future.

The MIPS Performance Threshold would increase from 15 to 30 points and the MIPS Exceptional Performance Threshold would increase from 70 to 80 points under additional

⁴⁴ https://www.acponline.org/clinical-information/performance-measures

flexibilities granted by the BBA following ACP advocacy. All MIPS eligible clinicians with a final score at or below 7.5 points would receive the maximum penalty of -7 percent.

The three-point complex patient bonus would continue for the 2019 performance year while CMS develops a long-term policy. The Hierarchical Condition Category (HCC) scores would be determined during the second segment of the MIPS eligibility determination period. CMS proposes to include the small practice bonus within the Quality Category in lieu of adding it to the final total MIPS composite score.

CMS plans to make modifications to MIPS payment adjustment calculations and regulatory language to codify changes made under the BBA that MIPS payment adjustments apply only to covered professional services furnished by a MIPS eligible clinician and not to Part B payments made for other items or services, such as drugs. Starting in 2017, CMS proposes to specify that the MIPS payment adjustment factors would not apply to certain model specific payments. CMS would denote which models are subject to this new policy by posting them to the QPP website and the Federal Register.

ACP Comment: For reasons elaborated on more fully in the Cost Category section, the College strongly urges CMS to not increase in the weight of the Cost Category beyond 10 percent and to maintain the weights of the various performance categories at their consistent levels.

We are aware that due to time constraints, CMS used performance data from the legacy programs to model performance thresholds for 2019 for purposes of the proposed rule and intends to recalculate performance numbers based on 2018 performance for the final rule. We also understand the need to potentially increase the performance threshold over time to appropriately calibrate positive and negative adjustments in this budget neutral program. However, proposing to not only increase but double the current performance threshold, which has wide-reaching implications both for individual clinicians and practices as well as MIPS as a whole, would be irresponsible without concretely substantiating these decisions based on MIPS performance data and doing so through a transparent process with sufficient opportunities for stakeholder input and advance notice for clinicians, none of which would occur given that the proposed threshold included in this rule was not based on the 2017 MIPS data. The only way for a program of this scale to succeed over time without causing potentially significant adverse consequences, particularly for small and rural practices, is to introduce changes that are both gradual and grounded in data. Ensuring a smooth transition is more important to the long-term stability of MIPS and transition to value-based reimbursement than prematurely rushing to increase the performance threshold before the data can be properly analyzed, particularly given CMS received an additional three years of flexibility in setting the threshold under the BBA. Moreover, it is paramount that CMS make the raw 2017 MIPS performance data publicly available so that stakeholders can replicate the findings and study it to further refine and improve the program, particularly in these initial years of implementation. To ensure the longterm viability and legitimacy of MIPS, we urge CMS in the strongest possible terms not to move forward with its proposal to double the current performance threshold for the 2019

performance period and to substantiate any future performance threshold increases with transparent, data-driven reasoning that can be easily replicated.

We appreciate and support CMS' proposal to maintain the complex patient bonus and believe it is necessary to not aversely penalize physicians who treat more complex patients and to avoid patient access issues. However, we do not support CMS' proposal to relocate the small practice bonus to the quality category, which reduces its relative worth by 25 percent and results in only 2.25 points to the total MIPS composite score, as opposed to a full 3 points. This bonus is critical to offset the unique challenges small practices face and we do not feel the Agency offers sufficient explanation for this proposed move. We urge the Agency to reconsider this proposal and to also consider extending this bonus to practices located in rural or HPSAs, which face unique challenges of their own.

We appreciate the Agency's proposal to amend the MIPS payment adjustment factor and make other conforming changes to codify changes made under the BBA, including only applying MIPS payment adjustments to covered professional services, and not to Part B payments for other items or services, such as Part B drugs. ACP supported these changes in the bill and believes this was within the original spirt of the law and we appreciate CMS implementing these conforming changes. The College appreciates and supports the Agency's clarification that the MIPS payment adjustment factors would not apply to certain model-specific payments. We agree that by causing payment amounts to differ, such as the care management fee paid to Comprehensive Primary Care Plus Model, it would alter model incentives and therefore compromise objective evaluation of the model. ACP encourages CMS to denote which models are subject to this new policy on the QPP website and Federal Register as soon as possible.

We appreciate CMS' stated goals of minimizing burden on MIPS ECs, while emphasizing simplicity and allowing for accountability and alignment across the performance categories. However, we feel that unfortunately, the Agency misses several opportunities to more fully realize these goals. For instance, CMS should simplify and standardize MIPS scoring by assigning values for each measure or activity that are proportionate to their overall worth respective to the MIPS composite score, such that the available points within the PI Category would total 25 and the available points within the Improvement Activities Category would equal 15, and so on. This simple solution would allow clinicians to better gauge performance on each measure or activity and more fully understand how it impacts their overall MIPS score.

While we appreciate the Agency's proposals to simplifying scoring methodologies for individual performance categories, this still does not address the overarching problem that each performance category has its own unique scoring methodology completely siloed from one another, so that clinicians must not only familiarize themselves with four unique sets of measures and activity specification, they must also master four distinct, complex scoring methodologies. In retiring the three legacy programs and establishing the QPP, the goal of MACRA was to create a single, streamlined program in MIPS that minimized confusion and administrative burden. We urge the agency to explore additional opportunities to streamline scoring across all of the performance categories. The College considers the Agency's potential

future proposal to remove the six-measure minimum for the Quality Category and to award points for each reported measure similar to the Improvement Activities Category a positive step in this direction and we strongly urge the Agency to consider extending this same approach to the PI Category.

The College also encourages CMS to award cross category credit where appropriate. This would incentivize practices to align limited resources toward key strategic objectives to meaningfully improve quality and cost outcomes in key areas, rather than fragmenting resources to report on at least 14 different, mandatory measures to avoid a payment cut. One of the areas requiring the most immediate attention in the healthcare space is addressing our nation's opioid epidemic. An example of how this could be applied would be by awarding credit in the improvement activities category for evidence-based interventions that are proven to improve quality outcomes, such as transferring care plans to specialty clinicians, reporting medication data to a state prescription drug monitoring programs, or evaluating patients for risk of opioid misuse, as well as reporting through their EHR performance on related quality outcomes measures such as documentation of signed opioid agreements, clinicians can be rewarded for high-value care by earning credit towards all of their MIPS performance categories while taking a targeted, multifaceted approach to combating the nation's opioid epidemic. At the same time, the same measures intrinsically support key administration priorities including promoting interoperability of EHR systems, coordinating care across settings, reporting data that will guide future research, and evaluation based on tangible, outcomes-based quality metrics all while reducing MIPS complexity and therefore administrative burden on clinicians. If all of the performance categories ultimately share the same goal to drive high-value care, there is no reason incentives and rewards should not be aligned across performance categories.

ACP appreciates the Agency's interest in better accounting for social risk factors, driving improvements in health equity, and mitigating unintended consequences for vulnerable populations. This is a top advocacy priority of the College's and we offer our full support towards these efforts.

N. MIPS Exceptions and Reweighting

CMS Proposal: CMS proposes to extend indefinitely its automatic extreme and uncontrollable circumstances policy, under which MIPS eligible clinicians affected by extreme and uncontrollable circumstances affecting entire regions or locales would have all MIPS performance category scores (including Cost) reweighted to zero and would be held harmless from MIPS payment adjustments. If a MIPS eligible clinician in an affected area does submit data, he or she will be scored on each performance category for which he or she submits data. For clinicians that may have already submitted some quality data via the Part B claims submission type prior to submitting a hardship exemption for extreme and uncontrollable events, they would only be scored if they then submitted data for at least one other performance category. CMS would reweight the Cost Category to zero even if it receives claims data that would enable it to calculate a Cost Category score. Groups would also be able to submit applications for exceptions at the TIN-level, which CMS would evaluate on a case-by-

case basis. CMS seeks comment on how this policy would apply to third party intermediaries who may submit data on a clinician's or group's behalf.

In general, CMS would redistribute the weight of a performance category or categories to the quality performance category and would redistribute the weight of the quality category to the Promoting Interoperability and Improvement Activities Categories. The Agency seeks comment on redistributing more weight to the Improvement Activities or Cost Categories in future years. CMS proposes to establish a Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration that would allow eligible clinicians to be excluded from QPP reporting requirements and payment adjustments if they participate to a sufficient degree in a combination of Qualifying Payment Arrangements with Medicare Advantage Organizations (MAOs) and Medicare Advanced APMs during the performance period, but fall short of qualifying as QPs or Partial QPs and are not otherwise excluded from QPP participation. The thresholds would be based on percentage of payments received or patients seen through qualifying models and would align with the thresholds for qualified participation in Advanced APMs under the Medicare Option (25 percent of payments and 20 percent of patients in 2018 and 50 percent of payments and 35 percent of patients in 2019-2020). To prevent gaming, eligible clinicians who elect to participate in the Demonstration and meet the thresholds would be prohibited from reporting MIPS data. The demonstration would start with the 2018 performance year and run for five years.

Beginning next year, CMS proposes that an eligible clinician who joins an existing TIN during the final three months of the calendar year that is not participating in MIPS as a group or was newly formed during those final three months would not be subject to a MIPS payment adjustment. For groups submitting data at the TIN-level, CMS would apply the final group score to all of the TIN/NPI combinations that bill under that TIN during a proposed 15-month window from October 1 prior to the MIPS performance period through December 31 of the performance period year.

ACP Comments: ACP supports CMS' proposal to extend indefinitely the extreme and uncontrollable circumstances policy. We appreciate the intent behind CMS' proposals to score a performance category should CMS receive data for that category, and to score prior submitted Part B claims quality data only if data for at least one other performance category is received. We also appreciate the Agency's interest in possible scenarios in which data is submitted by third party intermediaries despite groups or clinicians securing hardship exceptions. For reasons explained below, we encourage CMS to count performance category data towards an exempted clinician or group's final MIPS score only if it has a neutral or positive impact, which is consistent with other CMS policies to use data that yields most advantageous score.

As CMS points out in the 2018 final QPP rule: "the performance period for improvement activities is only 90 days, whereas it is 12 months for the quality performance category, so an issue lasting three months may have more impact on the availability of measures for the quality performance category than for the improvement activities performance category, because the

MIPS eligible clinician, conceivably, could participate in improvement activities for a different 90-day period." Therefore, a clinician could report data for the Improvement Activities or PI Categories during an unaffected 90-day period during the performance period, but if the Quality Category requires a full-year reporting period, the quality data would likely be incomplete and therefore a clinician or group's total MIPS score could be adversely impacted. If a clinician or group has submitted and been approved for a hardship exception for genuine hardships that are outside of their control, they should be rewarded, not penalized for sending in data for other MIPS performance categories. We would like to underscore that this is another powerful reason to reduce to minimum reporting period for the Quality Category so that it is consistent with the other MIPS performance categories.

Similarly, we would not want clinicians who secured hardship exceptions for circumstances beyond their control to be adversely penalized in the event a third party intermediary submits data erroneously. We encourage CMS to consider our alternative policy to only count data for a MIPS performance category only if it has a net neutral or positive impact on a clinician or group's overall MIPS performance score in cases where data is reported despite the clinician/group having been approved for a hardship exception. We feel this policy mirrors existing CMS policies and would minimize potential adverse consequences to the greatest extent.

We similarly appreciate the intent behind CMS' proposal to not count the Cost Category even if a score could be calculated for those clinicians, considering likely adverse impacts on cost outcomes that would have resulted from a natural disaster or other uncontrollable circumstance. However, in the event that a clinician's or practice's MIPS score would be positively impacted by scoring the Cost Category, these clinicians should be recognized for their efforts to bring down costs. Accordingly, we ask that CMS extend the same policy to the Cost Category and only apply the Cost score if it would have a neutral or positive net impact on the overall MIPS score for clinicians or groups that have been approved for MIPS hardship exceptions.

The College supports CMS' proposal to allow hardship applications at the TIN-level. We agree this would cut down on administrative burden and redundancy when in all likelihood all of the clinicians in the practice will be facing the same barriers and the practice will want to be prioritizing what remaining resources it has to get back to providing critical services for their communities.

The College generally supports CMS' proposed reweighting policies. Consistent with our comments in the Cost Category section of this letter, we urge CMS not to redistribute more weight to the Cost Category until all of the measures have been tested and evaluated for validity and reliability.

The College appreciates CMS' proposal to reward participants with a substantive portion of their revenues coming from value-based contracts with Medicare Advantage plans by excluding them from MIPS. We support the Agency's efforts to continue to look for ways to reward

clinicians for their participation in innovative new payment models, as well as reduce administrative burden by not requiring clinicians who have demonstrated substantial involvement in innovative payment models that already hold them accountable for cost and quality to be forced to comply with an entirely different set of quality and cost metrics through MIPS. However, as iterated in past comments, 45 the College believes that clinicians and groups participating in Advanced APMs through MA Organizations should be able to qualify for the Advanced APM track via the patient count test, as long as they are able to clearly demonstrate that they are participating in a qualifying payment arrangement that meets the three advanced APM criteria.

The College appreciates CMS' proposals to hold harmless from MIPS payment adjustments certain clinicians who switch practices in the final quarter of a MIPS performance period. We understand CMS' logic that it needs the necessary data to calculate special status and other eligibility determinations. However, we worry that creating a distinction between existing TINs that report individually versus as a group adds even more unnecessary complexity to MIPS and inconsistently rewards or penalizes clinicians based on circumstances beyond their control. Additionally, we worry that extending this neutral payment adjustment policy to all clinicians who switch TINS in the last quarter of a performance period (including those that move to TINs reporting as a group) would create yet another arbitrary distinction between clinicians that switch in September versus October of a reporting year that would result in entirely different policies for how a clinician's payment adjustment would be determined potentially based on switching practices on September 30 versus October 1. This adds unnecessary complexity and could create false incentives to switch practices at certain points throughout the year. Moreover, once a clinician leaves a practice, there is no guarantee that their previous practice will continue to report his or her quality data. Considering the reporting period for the Quality Category is a full year, this could be detrimental to a clinician's score regardless of what time in the year he or she switches practices, not because he or she delivers low quality care but because their previous practice would have no incentive to expend already strained resources to report that data on his or her behalf. Therefore, we urge CMS to hold harmless from a MIPS payment adjustment clinicians who switch TINs during a performance year. Different practices have different reporting approaches, reporting mechanisms, and individual products and each takes weeks if not months of training to master, there will inevitably be a negative impact on a clinician's MIPS score, particularly in the Quality Category as it requires a full year's worth of data. It is also important to note that practices consider past performance on MIPS metrics in their hiring decisions. A one-year neutral payment adjustment will not impact a clinician's performance on metrics long term nor will it sway a practice into hiring a clinician with poor performance, as their metrics will start to count in the very next year performance year. However, this policy would offer a clear cut answer that is drastically simpler than how CMS currently calculates MIPS payment adjustments for clinicians who switch practices and would

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https://www.acponline.org/acp policy/letters/cms comment letter re cy 2018 macra qpp proposed rule 20 17.pdf

help to mitigate almost entirely negative impacts on clinicians' MIPS scores due to the inevitable learning curve that comes with joining a new practice.

O. Facility-Based Scoring Option

CMS proposal: CMS proposes to add a facility-based scoring option that would utilize quality data from the Hospital Value-Based Purchasing (VBP) Program and in some cases, eliminate the need to report MIPS data. The agency proposes to limit facility-based reporting to the inpatient hospital setting for the first year, but seeks comment on expanding it to additional facility types in future rulemaking, particularly post-acute care and End-Stage Renal Disease (ESRD) settings. The facility-based standard would apply to MIPS eligible clinicians who furnish 75 percent or more of his/her covered professional services in sites of service identified by POS codes 21 (inpatient), 22 (outpatient), or 23 (emergency department) based on claims during the first segment of the MIPS Determination Period. However, the clinician would have to bill at least one service under POS code 21 or 23 to qualify. A facility-based group would be a group in which 75 percent or more of its eligible clinician NPIs qualify for facility-based measurement as individuals. If CMS is unable to identify a facility with a Value Based Purchasing Program score to attribute a clinician's performance, then that clinician would not be eligible for facility-based measurement. The facility-based measurement eligibility determination period would align with the first segment of the general MIPS determination period and run from October 1 of the calendar year two years prior to the applicable performance period to September 30 of the calendar year directly preceding the applicable performance period, with a 30-day claims run out.

A clinician would receive a score for the facility at which the clinician provided services to the most Medicare beneficiaries during the determination period. A facility-based group would receive a score for the facility at which the plurality of clinicians would have their scores determined under facility-based measurement as individuals. In both cases, if an equal number of Medicare beneficiaries are treated at more than one facility, CMS would use the highest score.

CMS proposes to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible, unless it receives another submission of quality data and the combined Quality and Cost Category scores of that submission results in a higher score. Practices that submit data for the Improvement Activities or Promoting Interoperability Categories at the TIN-level would be measured as a group. Otherwise, clinicians would be scored as individuals under the facility-based measurement option. CMS would determine the percentile performance of the facility in the Hospital VBP Program for the specified year, then award a score associated with that same percentile in the MIPS Quality and Cost Categories. CMS would not count improvement for eligible clinicians who are scored by facility-based measurement one year but not the next.

ACP comments: ACP supports the concept of using a hospital or facility's quality measure scores to serve as a proxy in the MIPS Quality and Cost components for ECs and their groups.

We commend the Agency for taking important steps such as this to eliminate duplicative reporting and reduce administrative burden on practices. In addition, models that were developed and tested specifically for facilities may better capture the quality of care physicians and other clinicians in those settings provide to patients. Further, shared accountability measures better reflect the collaborative and team-based environment of facility settings. We support the proposal to align the eligibility determination period for facility-based measurement with the first segment of the general MIPS determination period and agree this will reduce complexity. We support the facility attribution proposals and agree that using a plurality of clinicians reinforces the connection between individual clinicians the facilities at which they practice and is also easily understandable and predictable.

The College supports CMS' new proposal to automatically apply facility-based measurement to ECs and groups who are eligible, unless it receives another submission of quality data and the combined Quality and Cost Category scores of that submission results in a higher score. However, we have some concerns about the potential impact this type of policy could have on the MIPS payment adjustment distribution and how it might disadvantage non-facility-based clinicians. Therefore, we urge the Agency to closely monitor and evaluate the impact of including the facility based scoring option on the distribution of MIPS payment adjustments to facility-based versus non-facility-based practices and to consider policies to address any notable discrepancies in future rulemaking.

We agree that automatically applying measurement in lieu of requiring an attestation while allowing the opportunity to submit additional data achieves the same end result while minimizing burden on facilities and clinicians. Similarly, we support CMS' proposal that it would use data reported for the PI or Improvement Activities categories to indicate whether to measure clinicians at the TIN- or NPI-level for purposes of facility-based measurement, but we additionally urge CMS to consider establishing an optional attestation through the QPP portal in the event that a practice does not wish to submit PI or Improvement Activities data or has an exclusion for one or both categories, but still wishes to be evaluated as a group. While we expect these circumstances to be relatively rare, we feel establishing an optional attestation would balance minimizing burden while offering maximum flexibility.

We agree that CMS' proposal to determine the percentile performance of the facility in the Hospital VBP Program for the specified year, then award a score associated with that same percentile in the MIPS Quality and Cost Categories is an appropriate way to crosswalk VBM performance to the MIPS program.

P. Third Party Intermediaries

CMS proposal: CMS proposes to allow third party intermediaries, which include QCDRs, qualified registries, health IT vendors, or CMS-approved survey vendors, to report MIPS data for the PI, Quality, or Improvement Activities Categories on behalf of a MIPS EC or group. The Agency introduces several new criteria for CMS-certified certified vendors and proposes to require QCDRs have clinical expertise in medicine and quality measure development. CMS

would also require QCDR measure owners to agree to allow any approved QCDR to use that measure and strengthen its oversight authority of third party intermediaries, including removing its intermediary probation policy and extending its notification requirement to all deficiencies and data errors.

ACP Comment: The College fully supports CMS' proposals to allow third party intermediaries to submit data on behalf of MIPS ECs and groups. We agree with the Agency that this is a valuable way to streamline data reporting and minimize burden on clinicians. ACP recognizes that requiring QCDR vendors to agree to make their measures available to any vendor may help to promote measure harmonization, and allow for more robust benchmarking for QCDR measures. However, ACP does not support requiring QCDR measure owners to allow any approved QCDRs to use their measure for the purpose of MIPS reporting. QCDR measure owners invest significant resources into measure development, data collection, and validation. Additionally, QCDR measure owners develop these measures for use beyond MIPS reporting (e.g., research, guideline development, quality improvement, etc.). Requiring QCDR measure owners to license measures to approved QCDRs may unintentionally result in de-incentivizing QCDR measure development. QCDR measure owners have concerns about protecting their intellectual property, resource investment, data collection, and quality review and validation oversight capabilities. CMS should support and promote increased collaboration between QCDRs in measure development and harmonization without mandating QCDR measure owners to license use rights to any approved QCDR. Additionally, QCDRs should not be required to license a measure from original QCDR measure owners in lieu of developing their own measure.

Finally, we endorse proposals to strengthen criteria for CMS-certified survey vendors and QCDRs, require QCDRs to have clinical experience in medicine and quality measure development and strengthen oversight of third party intermediaries, particularly those to remove the probation policy and extend notification requirements. We have heard dozens, if not hundreds of accounts from members who have contracted with vendors that are not following through with the functionalities or timeline that was promised, leaving physicians on the hook for a MIPS payment cut with little recourse. We are very pleased to see CMS allowing QCDR measure owners to take a more active role in oversight of these vendors to ensure clinicians are protected and are well-informed of any issues with particular products or vendors.

Q. Physician Compare

CMS proposals: CMS has proposed revising the timeline for public reporting of performance scores that provide insight into various quality and patient experience measures for individual physicians and group practices that were implemented in the CY 2018 QPP final rule. The period of time that first year quality and cost measures will not be reported will be extended from one year under current regulations to two years under the proposed rule. Beginning with year 2 of QPP (2018 data available for public reporting in late 2019), the "high" performance rating will be eliminated and combined with the "successful" performance rating for the PI performance category. Beginning with year 3 of QPP (2019 data available for public reporting in late 2020), the ABCTM methodology using historical data will be utilized to create benchmarks for quality,

cost, improvement activities, and PI performance categories while the ABC[™] methodology and equal ranges method will be utilized to create a benchmark and 5-star rating for QCDR measures. Additionally, the terminology has been updated to replace "submission mechanisms" with "collection types."

ACP Comments: The College supports CMS' proposal to extend the period of time that newly used MIPS quality and cost measures be excluded from public reporting from the first year of use to the first two years of use. Doing so will allow for physicians to more actively participate in the MIPS program by reporting new measures without fears of negative repercussions. Further, this extended period of time provides more opportunity for physicians to learn and get feedback on these new measures before being subject to public scrutiny. For any publicly reported quality measures, ACP also reiterates the necessity that regulatory entities establish an adequate quality control and appeals process that ensures the accuracy and validity of the measures, allows for an opportunity for physicians to review the measure before reporting, and enables physicians to appeal and request reconsideration of their measures if they believe they are inaccurate.

When physician performance is publicly reported, the College contends that reporting entities should use the most effective means of presenting performance information to patients so that the data is both useful and useable. ACP agrees with CMS' assessment that the current differentiation between the "high" and "successful" PI performance indicators is unnecessarily complex and supports CMS' efforts to consolidate these two indicators into one. Having only one indicator would still provide useful information as it would adequately convey that a physician is competently utilizing EHRs. At the same time, it would also make the user experience more straightforward and less confusing as the user would not need to decipher numerous similar indicators. Additionally, the College emphasizes the importance of educating patients on the meaning and limitations of reported differences among providers and on how to effectively use this information to make informed healthcare decisions.

The College is also supportive of CMS using the ABCTM methodology to create a benchmark for MIPS and QCDR measures, as well as create a 5-star rating for QCDR measures, beginning with year three. However, ACP reiterates the need for CMS to be transparent with the methodology used in calculating the benchmark scores and ensure they account for risk adjustment. These benchmarks must not be based on a methodology that interferes with the patient-physician relationship, impedes with the use of best practices, undermine patient care, or negatively penalize those physicians caring for poorer and more complex patients. Further, CMS must be careful about relying on historical benchmarks that penalize those who successfully managed costs at the onset of the benchmark while incentivizing high spenders.

R. Medicare Advanced APMs

CMS proposals: CMS proposes to maintain the current revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities through the 2024 QP Performance Period,

but seeks comment on increasing this threshold in 2025 and beyond. To notify eligible clinicians about their QP status earlier, CMS proposes to shorten the claims runout for each snapshot period from 90 to 60 days. For ECs determined to be Partial QPs at the individual level, the clinician would be subject to MIPS reporting requirements and payment adjustments only if they affirmatively elect to report MIPS data, regardless of if TINs with which they are affiliated report some data on their behalf. CMS proposes that starting next year, 75 percent of ECs (instead of 50 percent) must use CEHRT to document and communicate clinical care with patients and other health care professionals in order to qualify as an advanced APM. Effective 2020, at least one quality measure and one outcomes measure upon which that APM bases payment would have to be a MIPS measure, endorsed by a consensus-based entity, or otherwise be evidence-based, reliable, and valid.

ACP Comments: The College supports CMS' proposal to not increase nominal amount standard beyond 8 percent of Medicare Parts A and B revenues through the 2024 QP Performance Period. We agree this will create stability and predictability that will foster growing participation in existing Advanced APMs, as well as development of new APMs. As iterated in past comments, the College believes that 8 percent of revenue already represents a more than substantial level of risk for individual APM Entities and that raising this threshold any higher would only dissuade more clinicians and practices from participating in Advanced APMs. We urge the Agency to improve the accuracy of the threshold by excluding reimbursement for Part B drugs and counting the inherent and often substantial costs associated with starting and running an APM toward that definition, which are not recognized but represent very significant financial risk for participants.

We encourage CMS to regularly monitor and conduct comprehensive, data-driven assessments on the level of participation and financial performance of various APM Entities. Importantly, we recommend this data be broken down by size, location, ownership type, and other informative demographic variables. Small and rural practices face unique and often greater challenges to participation in APMs, which includes but is not limited to lower levels of financial reserves to make up-front investments in enhanced care coordination protocols and new technologies and to weather financial risk without putting their practice in possible financial jeopardy, and smaller patient populations over which to spread risk. Larger health systems tend to have more reserve capital, more sophisticated infrastructures to support practice transformations, and larger patient populations over which to spread risk. As a result, more APM participants to date have typically been larger systems. Establishing a tiered risk system may be an appropriate way to require a substantive level of risk while not inadvertently creating barriers to entry that are too high for smaller or more rural practices and leaving them behind in the transformation to alternative payment models and high-value care. We ask the Agency to reconsider establishing a separate, lower nominal amount standard for small and rural practices, something the Agency solicited comments on in last year's NPRM but did not ultimately finalize. We recommend aligning the threshold with the Medical Home Model nominal amount standard. In so doing, CMS would facilitate and encourage more widespread participation in APMs by small and rural practices that often care for some of our nation's most vulnerable patient populations and stand to benefit the most from these innovative payment models.

We also encourage the Agency to develop more advance payment models similar to CPC+ or the ACO Investment Model that feature advance payments that are retrospectively reconciled against financial and quality performance. Often, practices have the desire to start or join APMs but doing so requires a significant amount of up-front investments that many practices simply do not have. Providing advance funding sources particularly at the onset of starting a new APM could drastically expand APM participation, particularly among smaller and rural practices.

While we appreciate CMS proposing not to increase the current nominal amount threshold at 8 percent, if clinicians stand any chance of keeping pace with increasing QP thresholds, they need more Advanced APMs to participate in, particularly models geared toward specialty clinicians. Under the MACRA statute, both the Medicare Option and Other Payer Option thresholds increase over time in anticipation of new models being introduced into the market over time. However, we have been at a standstill. Since the NPRM with 2018 updates to the QPP, CMS has proposed just one model that would qualify as an Advanced APM, the Bundled Payments for Care Improvement Advanced Model. In addition, the Agency has introduced some sweeping changes to the largest of the current Medicare Advanced APMs—the Medicare Shared Savings Program—which the College fears is likely to cause a mass exodus from the program. We urge the Agency to continue to devote significant resources towards expediently developing more Advanced APM options, particularly for specialty clinicians.

The Physician-Focused Payment Model Technical Advisory Committee could be an invaluable tool to CMS in facilitating implementation of innovative physician-led APMs. The College is disappointed that out of four models recommended for implementation and six for limited scale testing, none have been adopted to date by CMS for either implementation or limitedscale testing. CMS noted repeatedly in its responses that it would take the valuable feedback PTAC offered and apply it towards development of its own models, yet we have not seen any of these referenced models. The College urges CMS to expediently implement these models under development, and to better leverage its working relationship with PTAC, which should be a valuable pipeline for readying innovative physician-led APMs for implementation on a larger scale. Specifically, we recommend CMS provide more direct, regular feedback to PTAC and stakeholders to ensure they can address concerns and shortcomings earlier in the development process so that developers are not wasting valuable time and resources and the PTAC approval and recommendation process can yield more fruitful results in the form of physician-lead APMs being implemented across the country, which is a win for physicians, PTAC, and CMS alike. We also urge CMS to provide technical assistance to model developers to the maximum extent possible. At a minimum, CMS should make available claims data available to model developers so they can have the information they need to perform robust financial modeling, which is a common criticism both of PTAC and CMS. Moreover, now that CMS has a better sense of the pace at which models are being recommended by PTAC, we urge CMS to establish a clear process and timeline for which it would respond to PTAC proposals in the future, which currently seems to occur on an ad hoc basis. This will provide accountability and therefore lend credibility to the process for model developers. Specifically, we believe that a 60-day window from the date that a recommendation from the PTAC is received would be appropriate. We also encourage CMS to consider ACP's recent comments⁴⁶ to the PTAC in response for its request for public input on processes and requirements.

The College supports CMS' proposal to shorten the claims-run out for Advanced APM snapshots based on CMS' reasoning that the advantage of notifying participants earlier outweighs the 0.5 percent difference in claims processing completeness. The proposed 60-day claims runout would also align with the MIPS determination period claims runout and create consistency across the QPP.

ACP appreciates CMS' concern that as a result of its current policy for partial QPs determined at the individual level, there may be some unintended consequences concerning unexpected participation in MIPS should a TIN submit MIPS data on behalf of the EC without his or her knowledge. However, we also have concerns over confusion that could result from CMS' proposed new policy to not count MIPS data submitted on behalf of an EC unless he/she affirmatively attests to participate in MIPS. Many ECs may not be aware of this additional requirement and may assume that their MIPS data is being reported on their behalf by the TIN, like all of the other assigned clinicians, and have no idea they even qualify as a Partial QP only to find out that they are missing out on a potential positive payment adjustment they worked hard to earn.

We appreciate the sentiment of the proposal, and in that spirit, we propose an alternative that CMS would default apply or not apply the data based on which scenario yields the most advantageous MIPS payment adjustment (or lack thereof). In cases where that clinician would have earned a bonus and clearly would have therefore chosen to participate in MIPS, CMS would apply the MIPS data. In cases where more limited data may be sent on behalf of a clinician perhaps without his or her knowledge that results in a payment penalty but that clinician earned exemption from MIPS through their substantive participation in APMs and would clearly have claimed this exemption, CMS would exempt the clinician. This revised policy would eliminate both types of unintended consequences, including clinicians missing out on MIPS positive payment adjustments that they earned and clinicians being assigned MIPS penalties from data they were not aware was being sent on their behalf when they earned a MIPS exemption. It would also be consistent with other CMS policies to use data that yields the most advantageous score in cases where data is received from multiple sources and with ACP's proposed revised policy for counting a performance category toward a clinician or group's final score only if it has a neutral or positive impact, should that clinician/group have applied for and been approved for a hardship exception based on circumstances beyond their control. These policies do not require an active election of which score to use because it can be reasonably inferred that clinicians would chose the most advantageous score; the same logic applies in this scenario. Importantly, this policy would also further incentivize participation in APMs and reduce burden on both clinicians and CMS because clinicians would no longer have to affirmatively opt-in or opt-out of MIPS and CMS would not have to collect this data. For these reasons, we urge CMS to adopt this revised alternative proposal, which we feel aligns more

⁴⁶ https://www.acponline.org/acp_policy/letters/comments_on_ptac_2018.pdf

with CMS' intent with the proposal to eliminate unintended consequences while also creating consistency with other MIPS policies, incenting APM participation, and minimizing burden on clinicians and CMS.

The College believes that using CEHRT is critical in order to be successful in any type of value-based payment model. However, since CMS is requiring for the first time the use of 2015 CEHRT for the MIPS track of QPP in 2019, they should not also increase the threshold for 2015 CEHRT use for advanced APMs from 50 to 75 percent for at least another year. Maintaining the 50 percent threshold will allow time for all participants in both tracks to implement updated technology and not disincentivize smaller practices who are still in the process of upgrading their systems to participate in advanced APMs. Moreover, CMS proposes to update the policy and wording for CEHRT use under the Other Payer advanced APM to align with the Medicare advanced APM policies while still allowing those All-Payer advanced APM entities or participants to attest to the 50 percent threshold in 2019. ACP recommends CMS further align the CEHRT use requirements across the Medicare and Other Payer advanced APMs and maintain the 50 percent threshold for Medicare advanced APMs in 2019.

The College supports CMS' proposal that effective 2020, at least one quality measure and one outcomes measure upon which that APM bases payment would have to be a MIPS measure, endorsed by a consensus-based entity, or otherwise be evidence-based, reliable, and valid.

S. All-Payer Combination Option

CMS proposals: Consistent with Medicare Advanced APM proposals, CMS proposes to maintain the revenue-based nominal amount standard at 8 percent for Other Payer Advanced APMs through the 2024 performance period. In addition, to qualify as an Other Payer Advanced APM, payers or ECs would have to provide documentation that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of ECs in 2019, and 75 percent thereafter. Starting in 2020, at least one quality measure and outcomes measure would have to be a MIPS measure, endorsed by a consensus-based entity, or otherwise determined to be evidenced-based, reliable, and valid. Payment arrangements submitted for determination to be Other Payer Advanced APMs prior to 2020 would be granted an exception from this requirement for five years, or until the end of the payment arrangement, whichever comes first.

Under previously finalized policies, payers can submit payment arrangements for consideration as Other Payer Advanced APMs through the Payer Initiated Other Payer Advanced APM Determination Process. Medicaid and Medicare Health Plan payment arrangements can make these requests starting in 2018 for the 2019 performance period and commercial and private payers can make requests starting in 2019 for the 2020 performance period. CMS proposes to eliminate the separate process and timeline for CMS Multi-Payer Models. Instead, they would submit through the existing Medicaid, Medicare Health Plan, or private payer arrangement processes. The Agency proposes to reverse its earlier policy to require annual resubmissions of all Other Payer APM Determinations. Rather, beginning with determinations for the 2020

performance year, requesters would only submit information if there are any relevant changes impacting their status as an Other Payer Advanced APM. Otherwise, existing determinations would remain in effect for either the duration of the payment arrangement, or five years, whichever comes first.

CMS proposes to also allow requests for QP determinations at the TIN level (in addition to the EC or APM Entity level) in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity. The Agency would assess QP status based on the most advantageous result for each clinician. CMS also proposes to extend to TINs the same weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level.

ACP comments: The College supports CMS' proposal to not increase the current nominal amount standard of 8 percent of revenues through the 2024 QP Performance Period for Other Payer Advanced APMs. This will create stability and predictability that will foster growing participation in existing Advanced APMs, as well as development of new APMs. We echo our recommendations for the nominal amount standard that 8 percent represents a more than substantial amount of risk and should not be increased, and that CMS should improve the accuracy of this threshold by excluding Part B drugs and including startup and running costs associated with APMs. In general, we support alignment between policies for Other Payer Advanced APMs and Medicare Advanced APMs to create consistency and reduce complexity, as well as foster the development of multi-payer APMs. We implore the Agency continue seizing on opportunities to align policies for the two Options whenever feasible and reasonable. Specifically, ACP appreciates CMS' alignment of the policy and wording for CEHRT use under the Other Payer Advanced APM with the requirements under the Medicare Advanced APM program. As noted in the previous section, in order to truly align and reduce complexity, CMS should maintain the 50 percent threshold for CEHRT use for both the Medicare and Other Payer Advanced APMs.

The College strongly supports CMS' proposal to establish open-ended Other Payer Advanced APM determinations, as opposed to the previously finalized policy of requiring annual resubmissions, even if no information had changed. We agree that by allowing determinations to remain open-ended but requiring submitters to inform CMS of any changes, CMS will still obtain the information it needs to ensure the model determinations are updated and accurate, while drastically minimizing unnecessary burden on both submitters and its own staff. We thank CMS for being responsive to stakeholder concerns and urge the Agency to finalize this policy as proposed.

ACP continues to support CMS' decision to begin counting Medicaid, and Medicare Health Plan arrangements toward Other Payer Advanced APM determinations starting in 2019. However, the College is disappointed CMS does not intend to count private payer models until the 2020 performance year. While we appreciate that CMS does not have the same level of data as it does for Medicaid or Medicare Health Plan models, we feel there are multiple ways CMS could

expedite the approval process for private payer APMs to award them credit for the 2019 performance year. One such option could be a rolling determination period for the 2019 performance period that would allow submitters to submit determination requests after January 1, 2019 but still receive decisions in time to be approved and count toward the 2019 performance period. Creating a simple and understandable attestation process that ideally occurs through the QPP portal would also help to minimize burden on submitters and CMS staff, as well as allow CMS to expedite application approvals. With the five percent lump sum bonus for Advanced APM participation set to expire at the end of the 2022 performance year, clinicians already have a very limited window of time they are up against. Delaying certain Other Payer APMs until 2020 would be a major setback to private sector APM development and growth. We urge CMS to consider expediting the process to approve private payer Other Payer Advanced APM determinations so they can begin counting these APMs toward the All Payer Combination Option starting in the 2019 performance year, as was intended under MACRA.

The College supports CMS' proposal to also allow requests for QP determinations at the TIN level (in addition to the EC or APM Entity level) in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity. We agree with CMS that this adds additional flexibility for clinicians and encourage the Agency to finalize this policy as proposed. We also support CMS' proposal to apply to TINs the same weighting methodology that is currently used to ensure that an EC does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level. We believe this will create consistency between the TIN-level and EC-level evaluations and will offer TINs similar projections.

T. RFI on Price Transparency

CMS proposals: CMS expresses concern about continuing patient challenges due to insufficient price transparency, including surprise out-of-network bills for out-of-network physicians who provide services at in-network hospitals and unexpected facility charges. To promote greater price transparency for patients, the agency is considering ways to improve the accessibility and usability of charge information and to engage suppliers and clinicians in consumer-friendly communication of price to help patients better understand their potential financial liability and compare charges for similar services across clinicians and settings.

ACP comments: The College supports transparency of reliable and valid price information, expected out-of-pocket costs, and quality data that allows consumers, physicians, payers, and other stakeholders to compare and assess medical services and products in a meaningful way. ACP also agrees action should be taken to increase protection for patients who find themselves subject to unexplained or surprise bills through no fault of their own, particularly those incurred during emergency or other medical situations in which additional services are provided by out-of-network clinicians without the patient's prior knowledge.

However, the complexity of medical billing can make it difficult or misleading to come up with a standard or average price for a particular service. Prices can vary widely based on information

unique to the individual patient and visit, including comorbidities, necessary follow-up care or tests, and site of service, among a range of other factors. Pricing for self-pay patients and those privately insured are determined through two distinct processes that would require separate approaches to price transparency. Beyond that, individual hospital-payer contracts can bundle services, treatments, and drugs completely differently, making direct, national, or even regional price comparisons difficult. What matters most to the patient is not the total cost of a service; it is their own out-of-pocket responsibility.

Health plans are in the best position to communicate important coverage information that impacts their customers' total out of pocket cost. The College urges CMS to encourage health plans to share information with clinicians and patients regarding important coverage, cost, and quality information, such as whether a clinician is in-network or out-of-network. Integrating cost, quality, and coverage data into electronic health records systems, quality clinical data repositories, regional health information exchanges, or all payer claims databases, would help physicians to be more effective partners in helping patients to navigate this information and make informed, cost-effective decisions about their care. The growing prevalence of narrow network plans exacerbates this problem and should be separately studied and addressed. ACP also supports state-level efforts to prohibit "gag clauses" and similar contractual arrangements that interfere with the transparency of relevant health data. As noted earlier, ACP also supports the development of APMs, which we feel also show promise in aligning financial incentives to facilitate enhanced communication and coordination between multiple providers and cost-effective referral patterns to high-value, in-network providers.

Price should never be used as the sole criterion for selecting a physician or service; it should always be accompanied by quality information critical to understanding the total value of care, such as metrics about patient safety and health outcomes. If not, patients may simply defer to the lowest-cost providers, which could put them in a vulnerable position. At the same time, quality data released should be thoroughly vetted before being released to the public so as not to adversely penalize providers who care for vulnerable patient populations that are predisposed to worse outcomes, and to not further exacerbate existing social determinants of health. All information should be communicated in a readily accessible way to patients at all levels of health literacy and presented in a way that clearly articulates which services, treatments, and prescription drugs are included (and not included) in a given price, so that patients can make meaningful comparisons across settings of care and providers. Patients should also be made aware of the possibility of added costs due to common complications or add-on treatments. Releasing pricing information that is taken out of context, flawed, or incomplete has the potential to be more harmful to patients than lack of information.

As CMS looks to possibly regulate in this complex and sensitive pricing environment with the potential for wide-reaching implications on payers, providers and patients alike, the College recommends a graduated, targeted approach to any new price transparency initiatives and frequent consultation with stakeholders throughout the process. Gradual implementation will help to minimize the potential for major disruptions to physician payments and therefore patient care.

U. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

CMS Proposal: CMS proposes creating separate payment for a bundled episode of care for treatment of substance use disorders (SUDs) that could include overall treatment management, counseling, and components of medication assisted treatment (MAT) to better leverage services furnished with communication technology.

ACP Comments: In the past, ACP has expressed its support for behavioral health-primary care integration models that emphasize team-based and whole person care as excellent foundations to better manage pain and treat patients with SUD. 47 Accordingly, we support the concept of creating a separate payment for bundled episodes of care for treatment of substance use disorders (SUDs), providing payment is adequate to support the practice infrastructure required to effectively provide such care. The payment model should be developed to reflect the various approaches to behavioral health-primary care integration, 48 from coordinated to co-located care models. Although ACP has not endorsed a specific approach, the Patient-Centered Opioid Addiction Treatment model incorporates a set of bundled payments to reimburse for office-based SUD treatment. We agree that appropriately reimbursing clinicians for providing comprehensive treatment, including counseling and other services, may yield more effective results and save money in the long run by helping to reduce acute admissions. However, additional reforms are needed to facilitate integration and encourage physicians and other health care professionals to engage in substance use disorder treatment.

The College has been an active leader in helping to address the nation's opioid epidemic.⁴⁹ Over the eighteen months we have initiated programs to educate physicians on safe prescribing practices and how to prevent and treat SUDs, published papers on how to facilitate effective prevention and treatment of SUDs, and addressed letters to Congress and the administration with specific suggestions on how to combat this crisis. We urge the administration to review our past comments⁵⁰ for a more robust discussion of our specific suggestions of additional ways to help combat the opioid crisis which we summarize briefly below.

We also urge the administration to look to better integrate behavior health, including screening for possible SUD, into the primary care setting to catch SUD in its earliest stages, or ideally taking precautionary measures to prevent SUD before it even occurs. We recommend that CMS

https://www.acponline.org/acp policy/letters/response to senate finance committee on opioid substance us e disorder treatment policy recommendations 2018.pdf

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https://www.acponline.org/acp policy/letters/response to senate finance committee on opioid substance us e disorder treatment policy recommendations 2018.pdf

⁴⁸ https://www.integration.samhsa.gov/Integration of BH into primary care Annals of Internal Medicine.pdf

⁴⁹ https://www.acponline.org/acp-newsroom/acp-calls-for-continued-action-in-fighting-opioid-crisis-after-encouraging-white-house-summit

remove barriers to evidence-based non-opioid pain management services, improve Medicare and Medicaid patient access to MAT and overdose medications, including naloxone, and work with states to improve Prescription Drug Monitoring Programs by making them less burdensome to use. CMS also should leverage this valuable data to study factors or demographics that predispose individuals to SUD, including social determinants of health, as well as better understanding which treatment options or combinations of treatment options are most effective. However, the College wishes to issue a word of caution against imposing strict dosage caps, prior authorization requirements, and other hard cutoffs that could hinder access to critical pain treatments for patients who need them while placing an undue burden on practices. ACP and other private sector stakeholders⁵¹ have been actively engaged in robust initiatives to educate and train clinicians on safe prescribing practices and there are positive signs these efforts are working. Over a four-year period (2013-2017) opioid prescriptions fell by 22 percent nation-wide.⁵²

IV. <u>Conclusion</u>

ACP sincerely appreciates the opportunity to comment on the CMS notice of proposed rulemaking regarding changes to the Medicare Physician Fee Schedule, QPP, and other federal programs for Calendar Year 2019. We urge CMS to actively consider all of our recommendations in this letter, including:

- Appropriately valuing cognitive care in proportion to other types of services;
- Reducing documentation burden for E/M services;
- Not finalizing current proposals to flatten E/M fees and instead work with the physician community to explore possible alternative approaches;
- Reducing administrative burden in MIPS, including a consistent 90-day minimum reporting period across all categories and more opportunities for cross-category credit;
- Reducing MIPS complexity, including streamlining scoring across categories;
- Maximizing MIPS participation, including finalizing the proposed "opt-in" option for those currently excluded under the low-volume threshold;
- Increasing MIPS flexibility, including a set of optional measures for the PI Category and expanding opportunities for Advanced APM participation;
- Re-conceptualizing the PI performance category and allowing for more flexibility;
 including incorporating a list of health IT activities as well as allowing for significant time for 2015 CEHRT implementation;
- Avoiding low-reliability measures, including proposed episode-based cost measures;
- Reducing and simplifying measure requirements in the Quality performance category
 while reassessing the measures that are available. This should be done consistent with
 the Meaningful Measures initiative and taking into consideration the ACP Performance
 Measurement Committee's recommendations on MIPS measures;

⁵¹ https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/patient-care/opioid-task-force-progress-report.pdf

⁵² https://www.ama-assn.org/ama-sees-progress-declining-opioid-prescriptions

- Continuing a gradual MIPS implementation approach by not increasing the weight of the Cost Category as new measures are introduced nor doubling the MIPS performance threshold based on non-MIPS data; and
- Providing more opportunities for small and rural practices to succeed.

Thank you for considering our comments. The College looks forward to continuing to work with CMS to make improvements to our healthcare payment system and continue the evolution toward rewarding high-value, low-cost care. 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,

Jacqueline W. Fincher, MD, MACP

Chair, Medical Practice and Quality Committee

Jacqueline W Jincher pro

American College of Physicians

Appendix 1 Comparison of Quality Measures Proposed for Removal in PY 2019 with ACP Assessment of Validity

QID	Measure Title	٧	UV	NV	NR
012	Primary open-angle glaucoma: Optic nerve evaluation				Х
018	Diabetic retinopathy: Documentation of presence or absence of macular edema and level of severity of retinopathy				Х
043	Coronary artery bypass graft: Use of internal mammary artery in patients with isolated CABG surgery				Х
048	Urinary incontinence: assessment of presence or absence of urinary incontinence in women 65+		Х		
099	Breast cancer resection pathology reporting: primary tumor and regional lymph nodes categories with histologic grade				Х
100	Colorectal cancer resection pathology reporting: Primary tumor and regional lymph nodes categories with histologic grade				Х
122	Adult kidney disease: blood pressure management			Х	
140	Age-related macular degeneration: Counseling on antioxidant supplement			ĺ	Х
154	Falls: Risk assessment				Х
155	Falls: Plan of care				Х
156	Oncology: Radiation dose limits to normal tissues				Х
163	Comprehensive diabetes care: foot exam			Х	
185	Colonoscopy interval for patients with a history of adenomatous polyps: Avoidance of inappropriate use				Х
204	Ischemic vascular disease: Use of aspirin or another antiplatelet	Х			
224	Melanoma: Overutilization of imaging studies in Melanoma				Х
251	Quantitative immunohistochemical evaluation of HER2 testing for breast cancer patients				Х
257	Statin therapy at discharge after lower extremity bypass				Х
263	Preoperative diagnosis of breast cancer				Х
276	Sleep apnea: Assessment of sleep symptoms			Х	
278	Sleep apnea: Positive airway pressure therapy prescribed				Х
318	Falls: Screening for future fall risk				Х
327	Pediatric kidney disease: Adequacy of volume management				Х
334	Adult sinusitis: More than 1 CT scan within 90 days for chronic sinusitis			Х	
359	Optimizing patient exposure to ionizing radiation: Utilization of a standardized nomenclature for CT imaging				Х
363	Optimizing patient exposure to ionizing radiation: Search for prior CT studies				Х
367	Bipolar disorder and major depression: Appraisal for alcohol or chemical substance use		Х		
359	Pregnant woman that had HBsAg testing				Х
373	Hypertension: Improvement in blood pressure		Х		
375	Functional status assessment for total knee replacement				Х
386	ALS patient care preferences				Х
423	Perioperative anti-platelet therapy for patients undergoing carotid endarterectomy				Х
426	Post-anesthetic transfer of care measure: Procedure room to a post anesthesia care unit				Х
427	Post-anesthetic transfer of care: Use of checklist or protocol for transfer from procedure room to ICU				Х
447	Chlamydia screening and follow up		Х		
	Total:	1	4	4	25

V= Valid UV = Uncertain Validity

NV = Not Valid

NR = Not Reviewed

Appendix 2

ACP Performance Measurement Committee Review of Current MIPS Measures

MIPS ID#	Measure Title	ACP Recommendation
326	Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy	ACP supports MIPS measure #326: "Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy" because implementation may lead to meaningful improvements in clinical outcomes and a performance gap exists. While we support this measure, implementation could result in underuse of appropriately prescribed anticoagulation therapy. Denominator specifications include exclusion criteria for patients with a documented reason for not prescribing therapy. Inclusion of broad exclusion criteria may discourage clinicians from prescribing therapy in patients where the benefits outweigh the risk of harms (e.g., documentation of "fall risk"). Developers should consider explicitly defining exclusion criteria to prevent underuse of anticoagulation therapy in clinically appropriate cases. Additionally, developers cite outdated evidence to form the basis of the measure. Developers should update the denominator specifications to include the CHADs2VASc risk stratification tool.
398	Optimal Asthma Control	ACP does not support MIPS measure #398: "Optimal Asthma Control." Clinicians often underestimate the extent to which asthma affects quality of life and implementation of the measure will likely prevent overuse of emergency department services to treat acute disease exacerbations; however, measure developers did not cite any evidence to form the basis of the measure. Additionally, it is difficult to navigate the measure specifications and it is unnecessarily burdensome for clinicians to report on the six components of asthma control included in the numerator specifications. Furthermore, the measure is not risk-adjusted for disease severity and socioeconomic status and could therefore; penalize clinicians who care for sicker patients. Clinicians who treat severely affected populations may incur financial penalties which could worsen health disparities by penalizing safety-net hospitals and institutions with lower socioeconomic status patients. It is especially important to adjust for socioeconomic status in asthma patients because high co- pays for controller inhaled medications are a potential barrier to medication adherence for these patients. Additionally, while it is burdensome to perform the Asthma Control Test (ACT), it is best practice. However, the ACT is a proprietary assessment tool and therefore, clinicians may encounter.

444	Medication Management for People with Asthma	ACP supports MIPS measure #444: "Medication Management for People with Asthma" because implementation may promote patient adherence to prescribed controller medication therapy and a 50% medication compliance rate is an achievable threshold. Clinicians are well aware of medication adherence issues in patients with asthma and underuse of controller medication therapy is clearly a problem. While we support this measure, we encourage developers to consider several issues that decrease the measure quality. First, we cannot estimate the clinical impact of the measure on quality outcomes because developers do not cite a performance gap. A more meaningful measure may promote appropriate use of controller medication therapy in patients who were not previously prescribed therapy during the measurement year. Second, the measure developers do not cite any evidence to support the Percentage of Days Covered (PDC) threshold. However, we support the <100% PDC threshold to appropriately account for patient adherence issues. Third, the measure is not risk-adjusted for disease severity or socioeconomic status and implementation could unfairly penalize clinicians who treat patients with cost barriers to medication access. Fourth, while denominator specifications include appropriate exclusion criteria for patients with controlled asthma who sparingly use controller medications to alleviate symptoms related to common pulmonary infections (e.g., viral cold, bronchitis), the numerator should clearly specify an appropriate asthma controller medication list. Fifth, the measure could unfairly penalize clinicians who encounter interoperability barriers to data retrieval. Sixth, the measure uses pharmacy data to track medication adherence. However, lower socioeconomic status patients encounter cost barriers to medication access and clinicians often supply sample medications to improve patient adherence. Pharmacy data may not capture sample medication distribution. Finally, the measure intends to assess quality performance at the system lev
116	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis	ACP supports MIPS 116: "Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis" because implementation could lead to measureable and meaningful improvements in clinical outcomes and prevent overuse of inappropriate antibiotic therapy in patients diagnosed with acute bronchitis. Also, measure developers cite appropriate evidence to form the basis of the measure and measure specifications include appropriate exclusion criteria for patients with Chronic Obstructive Pulmonary Disease and immunocompromised patients. While we support this measure, we note the potential for clinicians to manipulate the measure through inaccurate coding of disease classification (i.e., ICD-10).

443	Non-recommended Cervical Cancer Screening in Adolescent Females	ACP supports MIPS measure #443: "Non-Recommended Cervical Cancer Screening in Adolescent Females" because implementation will likely promote appropriate use of cervical cancer screening in adolescents, the measure is well specified, and specifications include appropriate exclusion criteria for women diagnosed with HIV. Additionally, the measure aligns with United States Preventive Services Task Force (USPSTF) recommendations on cervical cancer screening. While we support this measure, current data on cervical cancer screening in women shows that earlier screening recommendations are not as effective as previously indicated in diagnosing HPV in women aged 16-20 years. The evidence base would benefit from re-evaluation as data surfaces on the benefits and risks of screening in women < 20 years old. In addition, the developers do not cite a performance gap in the measure report, and therefore, we cannot estimate the potential impact of the measure on quality outcomes.
113	Colorectal Cancer Screening	ACP supports MIPS measure #113: "Colorectal Cancer Screening" because it represents an important clinical concept and reflects the importance of shared decision-making when selecting a screening test. While we support this measure, as currently specified, it is a crude translation of the guideline recommendations into a performance measure. The developer should update the measure specifications to align with current clinical recommendations on colorectal cancer screening. Specifically, numerator specifications could be more robust and should include the option for clinicians to document emerging cancer screening tests (e.g., stool FIT-DNA, CT colonography). Additionally, measure specifications do not include appropriate exclusion criteria and could promote overuse of screening in patients where the benefits do not outweigh the risk of harms. A better measure would include exclusion criteria for patients diagnosed with dementia, patients with limited life expectancy, patients with advanced comorbidities, and patient refusal. Furthermore, we suggest the developers revise the measure specifications to include some element of risk-adjustment to determine whether the screening benefits outweigh the potential harms.
309	Cervical Cancer Screening (CCS)	ACP supports MIPS measure #309: "Cervical Cancer Screening" because the current evidence supports screening in women 21-64 years of age and this measure is based on the most recent United States Preventive Services Task Force recommendations on cervical cancer screening.
112	Breast Cancer Screening	ACP supports MIPS measure #112: "Breast Cancer Screening" because implementation promotes appropriate use of screening tools, current evidence supports the benefit of biennial screening mammography for women ages 50 to 74 years, and the measure poses low burden because most health systems have robust networks in place to specifically address this issue. While we support this measure, implementation could promote screening overuse. A stronger measure may include exclusion criteria for system and patient related issues (e.g., availability of mammography screening tools, patient preference, and limited life expectancy). Also, while the measure represents a meaningful clinical concept, implementation will likely be less impactful than implementation of other cancer screening measures (e.g., MIPS 113: Colorectal Cancer Screening).

322	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients	ACP does not support MIPS measure #322: "Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients." While this measure promotes appropriate use of cardiac stress imaging in low-risk surgery patients and cites American College of Cardiology/American Heart Association (ACC/AHA) clinical recommendations on perioperative evaluation of patients undergoing non-cardiac surgery to form the basis of the measure, developers do not cite a performance gap. Additionally, the denominator population is not specified for individual clinician use. The denominator population is correctly specified to evaluate quality performance at the cardiac lab level. Also, clinicians may misinterpret the measure as currently written. Developers should consider revising the numerator to include cardiac stress images performed within 30 days preceding low-risk, non-cardiac surgery and the denominator specifications to include asymptomatic patients undergoing low-risk surgery.
324	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients	ACP does not support MIPS measure 324: "Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients" because the numerator is not specified for individual clinician use and the measure does not specify a standardized approach to risk assessment. As written, the numerator relies on the individual clinician's ability to appropriately document level of risk. Measure developers recognize the reliability of certain assessment tools (e.g., Framingham Risk Calculation) to accurately assess level of risk in asymptomatic patients; however, developers also recognize the significant clinician burden associated with these data collection tools, and therefore, suggest clinicians attest to the accuracy of their estimation by submission. A stronger measure may specify a more systematic approach to risk assessment. Furthermore, the developers should consider revising the numerator specifications to include "healthy, low-risk patients." While a performance gap exists to form the basis of the measure and implementation will likely promote appropriate use of cardiac stress imaging in low- risk patients, the measure is currently designed evaluate performance at the cardiac lab level, not at the level of the individual clinician.
374	Closing the Referral Loop: Receipt of the Specialist Report	ACP does not support MIPS measure #374: "Closing the Referral Loop: Receipt of the Specialist Report." This measure represents an important clinical concept; however, implementation may lead to an unintended consequence of encouraging unnecessary care. Also, we note several suggestions for the developers to consider when they submit the measure to NQF for re-endorsement. The specifications are not well defined and should include an evidence-based time interval and some element of risk-adjustment. Additionally, developers do not cite any evidence to form the basis of the measure. Furthermore, the outcome is based on the level of integration of the participating information system rather than on how well the individual clinician tracks the referral. Information can appear to be 100% transmitted in a well-integrated system, whereas an independent practice network does not generate this data trail as a byproduct of its work. Additionally, it is not necessary for clinicians to close all referral loops. For instance, clinicians may refer a patient to a disease specialist for a condition that resolves prior to their appointment date. Also, depending on the urgency to complete the referral within a given time frame, the patient may not see the specialist

		within the measurement period. In this case, the referring clinician would fail the measure. Lastly, the burgeoning use of electronic health records (EHRs) will make this measure become far less relevant in the next several years. This is an important health-IT measure for improving care coordination; however, there is less evidence that this measure will improve care if it is implemented at the individual clinician level.
047	Care Plan	ACP does not support MIPS measure #047: "Advance Care Plan." We support the measure concept and implementation could prevent overuse of unnecessary end of life care interventions; however, it is burdensome for clinicians to annually document an advance care plan for all patients aged 65 years and older. Although the measure is evidence-based and insurers reimburse clinicians for this practice, we object to the 12 month measurement period included in the denominator specifications because it is burdensome and lacks empirical support. While evidence supports the benefit of advanced care planning on patient outcomes, there is no evidence to guide optimal frequency and at what age to begin planning. Furthermore, it may be inappropriate for clinicians to perform this intervention during an initial office visit. We suggest the developers revise the specifications to limit the denominator population to established patient visits only.
046	Medication Reconciliation Post Discharge	ACP does not support MIPS measure #046: "Medication Reconciliation Post-Discharge." Implementation can help to eliminate medication errors that may occur during transitions of care and will not promote over- or underuse and timely reconciliation of discharge medication lists will likely benefit patient outcomes. Also, the measure ties clinical outcomes to the appropriate unit of analysis (patients who were discharged from an inpatient facility AND seen within 30 days of discharge: individual clinician). While developers cite a significant performance gap at the health plan level, individual clinicians are currently 90% compliant with this measure. However, participation results from the 2013 PQRS reporting year do not necessarily represent performance on a national level. While this is a commendable measure concept, there is insufficient evidence to support this as an accountability measure. Interventions intended to improve medication reconciliation processes at patient discharge have not necessarily resulted in improved quality outcomes. This is a "check the box measure." Adherence to a medication reconciliation process does not necessarily improve medication management outcomes. A more appropriate measure may incentivize a standardized, methodological approach to reconciliation that would improve the medication management process. Furthermore, the numerator specifications exclude clinicians who are capable of reconciling medication lists (e.g., pharmacy technician) and excluding practitioners could limit the success of this measure from a health plan/integrated delivery system perspective. Finally, clinicians may encounter interoperability barriers to data access. For example, if the prescribing clinician and the outpatient clinician use different EHRs, the outpatient clinician may have limited access to the discharge medication list during the outpatient visit.

130	Documentation of Current	ACP does not support MIPS measure #130: "Documentation of Current Medications in the Medical
	Medications in the Medical	Record." While this measure represents an important clinical concept, there is a lack of high-quality
	Record	evidence to support its inclusion in accountability programs, it is burdensome for clinicians to
		document complete medication lists at every patient visit, and encouraging documentation at every
		visit could result in underuse of more valuable clinical services. Additionally, interventions intended
		to improve the medication reconciliation process have not necessarily resulted in improved quality
		outcomes. Furthermore, this is a "check the box" measure. Attestation for these visits may become
		routine but does not add value. A more appropriate measure may encourage documentation of
		medication lists according to clinical necessity and incentivize a standardized, methodological
		approach to reconciliation, according to clinician practice level (e.g., physician, nurse, medical
		assistant) that leads to improvements in the medication management process. Furthermore,
		independent patient, system, and practice variables (incomplete patient information, unavailable
		drug information, miscommunication of drug orders, and insufficient information flow) can impede
		the physician's ability to document complete an accurate medication lists. Consequently, clinical
		judgements may be based on incomplete clinical information.
261	Referral to Otologic Evaluation	ACP does not support MIPS measure #261: "Referral to Otologic Evaluation for Patients with Acute or
	for Patients with Acute or	Chronic Dizziness." While implementation may prevent inappropriate medical management of
	Chronic Dizziness	chronic dizziness by audiologists, we encourage developers to consider several issues during the
		update process that could affect the measure quality. First, developers should describe performance
		rates in the updated measure report. We cannot estimate the potential for clinical impact based on
		the current information provided by the measure developers. Second, developers should consider
		the potential for this measure to generate inappropriate referrals for otologic evaluations. Third,
		developers should consider including some element of risk-adjustment in the updated measure
		specifications. Finally, developers should consider revising the numerator specifications to identify a
		more manageable age range (currently aged birth and older). While this measure is appropriate to
		assess the performance of clinicians who specialize in treating chronic dizziness (e.g., ENTS,
		neurologists), it may be an inappropriate accountability measure for general internists.

122	Adult Kidney Disease: Blood Pressure Management	ACP does not support MIPS measure #122: "Adult Kidney Disease: Blood Pressure Management." We cannot estimate the clinical impact based on the information provided by the measure developers and the measure lost NQF endorsement due to a lack of evidence. The American College of Physicians (ACP) guideline states that there is no difference in outcomes between strict blood pressure control and standard blood pressure control (128-133 mmHg vs. 134- 141 mmHg systolic, and 75-81 mmHg vs. 81-87 mmHg diastolic). Also, the measure specifications do not align with clinical recommendations on disease classification. The Renal Association recommends clinicians stratify stage 3 kidney disease into 2 groups (3a or 3b). Furthermore, the denominator population includes all patients with stage 3 kidney disease and above. It is burdensome for clinicians to document a care plan for all patients classified as stage 3 and above without evidence to support the benefit of the intervention on clinical outcomes.
051	COPD: Spirometry Evaluation	ACP supports MIPS measure #051: "COPD: Spirometry Evaluation" because current performance does not meet best practices and there is opportunity for improvement through improved diagnostic accuracy. Furthermore, diagnosing or labeling a patient with COPD without performing or reviewing spirometry results may adversely impact future management. In addition, measure specifications include appropriate exclusion criteria for documentation of medical reason for not documenting spirometry results. While we support this measure, we note that spirometry evaluation is only a confirmatory test. A more meaningful measure may assess for COPD misdiagnosis. Additionally, while this measure represents good clinical practice, implementation could promote overuse of pulmonary function tests (PFTs) if clinicians encounter interoperability barriers to data retrieval across incompatible information systems. Performing PFTs in asymptomatic patients is unlikely to benefit clinical outcomes.

052	COPD: Inhaled Bronchodilator Therapy	ACP does not support MIPS measure #052: "COPD: Inhaled Bronchodilator Therapy." Current performance does not meet best practices, there is opportunity for improvement, and patients with COPD should be prescribed LABA or LAMA monotherapy or combination therapy. However, measure developers cite outdated evidence to form the basis of the measure. There is unclear evidence to differentiate the benefit of specific bronchodilator therapy on COPD outcomes. Large studies demonstrate the benefit of LABA-LAMA combination therapy on decreased exacerbation rates, but therapy does not significantly impact mortality rates. Furthermore, the measure lacks specificity regarding patients' reported symptoms, COPD disease severity to which the measure applies, and recommended bronchodilator therapy details. We suggest the developers revise the numerator specifications to stipulate either short-acting or long-acting inhaled bronchodilator therapy and the denominator should specify FEV1 <60% as opposed to the ratio to account for disease severity. Also, testing results demonstrate weak measure reliability (numerator kappa score: 0.1444 Cl). Moreover, we note several issues around measure feasibility. First, electronic databases may not capture documentation of active symptoms. Second, clinicians may encounter interoperability barriers to data retrieval if pulmonary functions tests (PFT) are documented in proprietary information systems. Third, the measure requires electronic or paper chart data abstraction OR implementation of an automatic PFT data retrieval process, and fourth, it is difficult to report the denominator specifications without specificity regarding patient symptoms.
243	Cardiac Rehabilitation: Patient Referral from an Outpatient Setting	ACP supports MIPS measure #243: "Cardiac Rehabilitation: Patient Referral from an Outpatient Setting" because it is clinically important to refer patients who are likely to benefit from rehabilitative services to outpatient therapy centers. While we support this measure, we advise developers to address the following concerns during the update process to improve the measure quality. First, the measure is nearly capped out. Developers cite a 97% performance rate based on data collected from the PINNACLE registry during the 2011 reporting year. However, this data may inaccurately represent national performance rates because it only represents clinicians who chose to participate in the cardiology registry. Second, implementation of this measure could unfairly penalize clinicians who practice in rural areas and who care for medically complex patient populations. Developers should consider revising the specifications to include a risk-adjustment model for patients with multiple co-morbidities, lower socioeconomic status, and limited access to rehabilitative services. Third, while this measure appropriately assesses performance of clinicians participating in the cardiology registry, it is an inappropriate accountability measure for general internists who do not report data in the PINNACLE registry. Lastly, while this measure is appropriately specified to assess the performance quality of clinicians practicing in metropolitan areas, it may not apply well to clinicians practicing in rural settings where patients have limited access to rehabilitative services. Specifications include exclusion criteria for "no rehabilitation program available within 60 minutes from patient home", but 60 minutes is an unfair expectation. Patients who are faced with significant travel burdens are less likely to adhere to prescribed services.

006	Chronic Stable Coronary Artery Disease: Antiplatelet Therapy	ACP supports MIPS measure #006: "Coronary Artery Disease: Antiplatelet Therapy" because it is clinically important for clinicians to prescribe anti-platelet therapy to patients with CAD and a performance gap exists. Additionally, the measure is reasonably specified. As written, specifications limit the potential for unintended consequences by excluding patients who currently receive warfarin therapy. While strong evidence exists to form the basis of the measure, the evidence base would benefit from re-evaluation as data surfaces on the benefits and risks of aspirin therapy in patients who are already prescribed warfarin therapy. The European Cardiology Society and the American College of Cardiology have divergent recommendations on this area. Lastly, while feasibility of data collection and implementation burden is appropriate, it may be difficult for clinicians to capture over the counter aspirin use unless explicitly stated by the patient.
007	Coronary Artery Disease: Beta Blocker Therapy - Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF <40%)	ACP supports MIPS measure #007: "Coronary Artery Disease: Beta-Blocker TherapyPrior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF < 40%)" because a performance gap exists and the measure represents an important and highly beneficial clinical concept. Additionally, measure specifications include appropriate exclusion criteria for documentation of medical, patient, or system reason for not prescribing beta-blocker therapy. However, skepticism exits surrounding consistency across operating systems to include all billing codes for appropriate exclusion criteria. Furthermore, while the measure is based on clinical recommendations of the ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease, there is some question surrounding the need for continued beta-blocker therapy for three years in low-risk patients in the contemporary era of revascularization. Lastly, while the myocardial infarction (MI) look-back period is limited to those occurring within the past 3 years, the measure specifications do not limit the "documentation of prior LVEF <40%" look-back period. It is unnecessarily burdensome for clinicians to look at all LVEF assessments in a complete patient history. Developers should consider revising the specifications to limit the look-back window and exclude patients with a normal LVEF without history of LVSD.
281	Dementia: Cognitive Assessment	ACP does not support MIPS measure #281: "Dementia: Cognitive Assessment." Although this practice may help clinicians determine appropriate management of patients with dementia, there is a lack of high-quality evidence examining the impact of the assessment of cognitive status on clinical outcomes or on appropriate assessment intervals and it is unclear how clinicians should manage assessment results. Furthermore, the numerator specifications include cognition assessment tools that will not necessarily benefit clinical outcomes. It is burdensome for clinicians to adhere to a formal assessment protocol without evidence to support the benefit of the intervention on patient outcomes. A more meaningful measure may encourage assessments that are likely to lead to meaningful improvements in clinical outcomes. Furthermore, the numerator specifications include proprietary cognition assessment tools (e.g., Mini-Mental State Examination) that are not readily accessible to clinicians who practice in primary care settings.

282	Dementia: Functional Status Assessment	ACP does not support MIPS measure #282: "Dementia: Functional Status Assessment." Although this practice may help clinicians determine appropriate management of patients with dementia, there is a lack of high-quality evidence examining the impact of assessment on clinical outcomes or on appropriate assessment intervals and it is unclear how clinicians should manage assessment results. Furthermore, numerator specifications include functional status assessment tools that will not necessarily benefit clinical outcomes. Physicians don't generally use these tools to assess functional status in an outpatient setting and they do not generally inform clinical decisions. It is burdensome for clinicians to adhere to formal assessment protocols without evidence to support the benefit of the intervention on patient outcomes. A more meaningful measure may encourage assessments that are likely to lead to meaningful improvements in clinical outcomes. This measure may appropriately assess the performance of occupational therapists that are more familiar with the assessment tools included in the specifications.
283	Dementia: Neuropsychiatric Symptom Assessment	ACP does not support MIPS measure #283: "Dementia: Neuropsychiatric Symptom Assessment." Although this practice may help clinicians determine appropriate management of patients with dementia, there is a lack of high-quality evidence examining the impact of assessment on clinical outcomes or on appropriate assessment intervals. Also, implementation may result in overuse of pharmacologic therapy. Non-pharmacologic treatment modalities exist to manage neuropsychiatric symptoms, but implementation requires caregiver involvement. Furthermore, the numerator details do not clearly specify a structured process for documentation of neuropsychiatric symptom assessment and the measure developers do not describe any reliability or validity data in the measure report.
286	Counseling Regarding Safety Concerns	ACP does not support MIPS measure #286: "Dementia: Counseling Regarding Safety Concerns." Counseling of patients and caregivers regarding safety issues is good clinical practice and clinicians can implement interventions that are likely to improve safety outcomes (e.g., PT/OT home assessment, Visiting Nurse Services), and the measure is appropriately specified. Also, the numerator specifications detail an exhaustive intervention list, allowing clinicians to assess for safety concerns that are particularly relevant to a specific patient's venue. However, there is no evidence to support the impact of this intervention on clinical outcomes, the level or intensity of counseling required to change behavior, or the interval at which this intervention should be performed. Finally, this measure could pose burden on clinicians who care for dementia patients and there is a lack of high-quality evidence to support the intervention as an accountability measure.

288	Caregiver Education and Support	ACP does not support MIPS measure #288: "Dementia: Caregiver Education and Support." This measure represents good clinical practice; however, it may be inappropriate for clinicians to advise caregivers on medical concerns without performing appropriate clinical assessments. Furthermore, there is no evidence to support the impact of this intervention on clinical outcomes, the level or intensity of counseling required to change behavior, or the interval at which this intervention should be performed. Also, developers do not present any validity or reliability data within the measure report. Lastly, this measure could pose burden on clinicians who care for dementia patients and there is a lack of high- quality evidence to support the intervention as an accountability measure.
411	Depression Remission at Six Months	ACP does not support MIPS measure #411: "Depression Remission at Six Months." While this is an important clinical concept and we support the development of patient reported outcome 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 the 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.
325	Adult Major Depressive Disorder: Coordination of Care of Patients with Specific Comorbid Conditions	ACP does not support MIPS measure #325: "Coordination of Care of Patients with Specific Comorbid Conditions." While this measure represents an important clinical concept, there is a lack of high-quality evidence examining the impact of disease communication on meaningful clinical outcomes. Additionally, the measure specifications do not include appropriate exclusion criteria for patients with mild or stable depression. Furthermore, it is burdensome for clinicians to retrieve specialists' reports for all patient visits, especially if the primary care clinician did not refer the patient to care.

009	Anti-Depressant Medication Management	ACP does not support MIPS measure #009: "Antidepressant Medication Management (AMM)" This measure has several issues even though the measure concept is important. First, the time frame used in the measure (12 weeks for acute phase and 6 months for continuation) contradicts recommendations from evidence-based guidelines (4-6 weeks for acute phase, 4-9 months for continuation). Second, measure specifications do not consider alternative interventions for depression management such as psychotherapy, electroconvulsive therapy (ECT), or the combination of somatic and psychotherapy. Third, the measure excludes patient choice to switch to another modality of effective therapy due to side effects associated with pharmacological medications. In the management of patients with depression, a provider-patient discussion on the benefits, harms, and costs of treatment is important and not accounted for in this measure. The measure specifications should include exclusion criteria for lack of patient adherence due to the side effects of medication with documentation of alternative therapy. We suggest deleting the requirement for acute phase treatment. Fourth, the measure intends to evaluate quality outcomes at the health plan level, but the measure is currently included in the Centers for Medicare & Medicaid Services Merit-Based Incentive Payment System/Quality Payment Program and intends to assess performance at the individual clinician level. While health plans can easily obtain detailed clinical management data from various information systems (e.g., claims, EHR, pharmacy), clinicians are not privy to the same information. Therefore, clinicians are unaware of information (e.g., medication refill data) related to effective management of medication adherence.
107	Adult major Depressive Disorder (MDD): Suicide Risk Assessment	ACP supports MIPS measure #107: "Adult Major Depressive Disorder: Suicide Risk Assessment" because it is clinically important to assess for suicide risk in patients with MDD. While we support this measure, we note several recommendations that could improve the measure quality. First, the measure is close to being topped out. The measure developers cite a 96% compliance rate. However, this data only represents clinicians who chose to report on the measure for the 2010 PQRS reporting year and therefore, may inaccurately represent nationwide performance levels. Developers should include current, national performance data in the updated measure report. Second, the numerator is not clearly specified. In particular, it is not well defined what constitutes a "recurrent" episode. Developers should consider revising the specifications to stipulate that this is an episode associated with the initiation of new treatment for depression. As currently stated, the measure could apply to all follow-up visits with the mention of even well-controlled depression. Third, this is a "check the box measure" with little potential to shift the quality needle as evidenced by the small performance gap. Lastly, the measure poses significant burden.
009	Antidepressant Medication Management	ACP does not support MIPS measure #009: "Antidepressant Medication Management (AMM)" This measure has several issues even though the measure concept is important. First, the time frame used in the measure (12 weeks for acute phase and 6 months for continuation) contradicts recommendations from evidence-based guidelines (4-6 weeks for acute phase, 4-9 months for continuation). Second, measure specifications do not consider alternative interventions for depression management such as psychotherapy, electroconvulsive therapy (ECT), or the combination

		of somatic and psychotherapy. Third, the measure excludes patient choice to switch to another modality of effective therapy due to side effects associated with pharmacological medications. In the management of patients with depression, a provider-patient discussion on the benefits, harms, and costs of treatment is important and not accounted for in this measure. The measure specifications should include exclusion criteria for lack of patient adherence due to the side effects of medication with documentation of alternative therapy. We suggest deleting the requirement for acute phase treatment. Fourth, the measure intends to evaluate quality outcomes at the health plan level, but the measure is currently included in the Centers for Medicare & Medicaid Services Merit-Based Incentive Payment System/Quality Payment Program and intends to assess performance at the individual clinician level. While health plans can easily obtain detailed clinical management data from various information systems (e.g., claims, EHR, pharmacy), clinicians are not privy to the same information. Therefore, clinicians are unaware of information (e.g., medication refill data) related to effective management of medication adherence.
134	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan	ACP does not support MIPS measure #134: "Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan." While the measure aligns with United States Preventive Services Task Force (USPSTF) recommendations on screening for clinical depression, we suggest the denominator specifications exclude patients who are currently under the care of a mental health specialist for comorbid illness or severe cognitive impairment. Furthermore, developers should consider revising the denominator specifications to reflect patients seen in the calendar year instead of all patients. In addition, measure specifications do not define an appropriate screening frequency. It is not clear whether this measure applies to all patients in a providers' panel or only those seen during the calendar year in a face-to-face visit.
370	Depression Remission at Twelve Months	ACP does not support MIPS measure #370: "Depression Remission at Twelve Months." While this measure represents an important clinical concept and we support the development of patient reported outcome measures, this measure does not account for individual starting points for each patient and there is a lack of high-quality evidence to support the 12 month (+/- 30 days) time interval. 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. The measure may unfairly penalize clinicians caring for severely depressed patients for their inability to satisfy the measure requirements and as such, this measure may encourage clinicians to over treat patients for major depressive disorder. 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 should be adequately specified to account for individual starting points for each patient. Furthermore, we note several issues with the measure specifications. The PHQ-9 is not necessarily the best tool to track patient remission. Developers should consider revising the denominator specifications to include additional depression

		remission tracking tools. Furthermore, we suggest the measure specifications exclude patients with dementia or severe cognitive impairments and patients permanently residing in nursing homes. We would be amenable to using this measure as a tracking mechanism, but oppose any linkage to performance and payment.
371	Depression Utilization of the PHQ-9 Tool	ACP does not support MIPS measure #371: "Utilization of the PHQ-9 Tool." It is clinically important for clinicians who treat patients diagnosed with on-going depression to assess for depression remission on an appropriate time interval. Also, implementation of this measure could lead to the development of an accurate outcome measure by determining well validated levels of depression severity. However, there is insufficient evidence to support the 4 month time interval specified in the denominator. It is unclear whether the 4 month measurement period refers to one measurement within a 4 month period, or every 4 months for patients with an on-going disease diagnosis. We assume the measure intends to encourage reassessment every 4 months for patients with chronic disease; however, we cannot assume that reporting clinicians will interpret the measure as such. Furthermore, evidence supports utilization of the PHQ-9 tool for monitoring the treatment progress in patients with depression, but many clinicians utilize additional remission screening tools that are equally as effective as the PHQ-9. The measure intends to assess performance at the system level. While this measure may appropriately assess the performance of mental health practitioners (e.g., psychiatrist), it may be an inappropriate accountability measure for primary care clinicians. Primary care clinicians may encounter interoperability barriers to accessing patient information necessary to satisfy the measure requirements (e.g., subspecialist reports).
127	Diabetic Foot & Ankle Care, Ulcer Prevention-Evaluation of Footwear	ACP does not support MIPS measure #127: "Diabetic Foot & Ankle Care, Ulcer Prevention — Evaluation of Footwear." Although we recognize the value of proper footwear in diabetic patients, there is a lack of high-quality evidence examining the impact of proper footwear evaluation in primary care on improved patient outcomes. This measure may appropriately evaluate quality performance of podiatrists although; the measure is topped out. Developers cite a 93% provider (podiatrist) compliance rate.

126	Diabetic Foot & Ankle Care, Peripheral Neuropathy- Neurological Evaluation	ACP does not support MIPS measure #126: "Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation." This measure has several issues. First, the measure developer cites a 44% performance gap based on data from the 2012 PQRS reporting year. However, this data only represents clinicians who chose to report on the measure and may inaccurately represent nation-wide performance levels. Second there is insufficient evidence to support a dedicated monofilament examination or the need to repeat the exam once the patient produces negative examination results. Clinical trials have proven the effectiveness of additional neurological assessment tools in diagnosing neurological deficits in diabetic patients. The numerator should specify the utilization of neurological assessment tools that are equally as effective as the mono filament in diagnosing neurological deficits in diabetic patients. Third, there is a lack of high-quality evidence to suggest that regular, comprehensive full lower extremity neurological examinations in the primary care setting improves outcomes for asymptomatic patients. Therefore, while this measure represents good clinical care,
		quality improvement programs should not implement this measure to assess the performance quality of individual clinicians. While we note several issues with this measure, the measure specifications do include appropriate exclusion criteria for patients with previously documented loss of protective sensation, bilateral amputees, and patients with clinical conditions that prohibit accurate response to a neurological exam (e.g., dementia, Alzheimer's).
268	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy	ACP does not support MIPS measure #268: "Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy." The measure addresses a clinical condition that is high- impact (approximately one-half million women with epilepsy are of childbearing age) and the measure developers cite a significant gap in care. However, the developers cite American Academy of Neurology level C evidence to form the basis of the measure where to the interventions could potentially result in harmful patient outcomes. For example, implementation could lead to harmful reductions in pharmacotherapy in women with epilepsy. Furthermore, we note several issues with the measure specifications. First, the denominator specifications should include exclusion criteria for surgically sterile women, women without a history of recent seizure, and women who are not currently prescribed pharmacotherapy. Second, the numerator definition of counseling seems overly inclusive and not necessary in all cases. Requiring six dimensions for counseling could be overly prescriptive, especially in surgically sterile women and women with long-acting reversible contraception therapies who need counseling on breastfeeding and folate supplementation, etc. Developers should consider revising the specifications to allow for selection of appropriate therapy that is most relevant to individual patients (i.e., change the definition to include "or" rather than "and"). Third, the developers should consider revising the denominator specifications to include women aged 45 years and older who are of childbearing potential. While the many of the specifications are flawed, the developers do include validity and reliability data in the measure report. The validation process was successful in identifying error and verifying the accuracy of the data submitted by the testing groups.

238	Use of High-Risk Medications in the Elderly	ACP does not support MIPS measure #238: "Use of High-Risk Medications in the Elderly." While it is clinically important to monitor high-risk medications in elderly adults, implementation may result in underuse of clinically appropriate pharmacotherapy in adults aged > 65 years. Furthermore, developers cite the controversial American Geriatrics Society Beers Criteria to form the basis of the measure, which is based on expert opinion as opposed to high-quality evidence. Moreover, we note several issues with the measure specifications. First, the denominator may inaccurately define "elderly adults" as > 65 years of age. Developers should consider revising the specifications to include a more appropriate definition that would classify "elderly adults" according to mental and functional status or increase the denominator threshold to > 80 years of age. Second, the denominator specifications do not stratify patients into well-defined risk groups. It's conceivable for some patients 66 years and older to tolerate high risk medications as appropriate treatment. Third, the measure specifies medications that are not presumed to be high risk in all elderly adults (e.g., acetaminophen), and fourth, the specifications do not include exclusion criteria for patient preference. Finally, while this measure is appropriate for health plan-level assessment, individual
		clinicians may encounter interoperability barriers to patient information access.
181	Elder Maltreatment Screen and Follow-up Plan	ACP does not support MIPS measure #181: "Elder Maltreatment Screen and Follow-Up." While the problem of inadequately addressed elder abuse makes the case for better research to identify highrisk patients and effective interventions targeted at high-risk adults, implementation could promote overuse of unnecessary, elder services referrals and potentially fracture relationships between clinicians and their patients. Additionally, the measure does not align with United States Preventive Task Force (USPSTF) recommendations on abuse of elderly and vulnerable adults. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening all elderly adults for abuse. Furthermore, the measure specifications are unclear. Developers should consider revising the numerator specifications to clearly define "high risk" as some way other than age (e.g., cognitive impairment, functional impairment). Moreover, the numerator details specify an overly prescriptive screening process. It may be clinically inappropriate to screen all patients over the age of 65 for elder abuse. Developers should consider revising the measure to specifically encourage screening in patients who are dependent on a caregiver or who are otherwise at risk for abuse. It is unnecessarily burdensome for physicians to document maltreatment screening for all patients aged 65 years and older at every visit. Finally, the measure requires clinicians to assess for maltreatment using a screening tool even when abuse may be readily apparent. ACP does not support QPP measure 181: "Elder Maltreatment Screen and Follow-Up." While the problem of inadequately addressed elder abuse makes the case for better research to identify high-risk patients and effective interventions targeted at high-risk adults, implementation could promote overuse of unnecessary, elder services referrals and potentially fracture relationships between clinicians and their patients. Additionally, the measure does not align with United States Preventi

		harms of screening all elderly adults for abuse. Furthermore, the measure specifications are unclear. Developers should consider revising the numerator specifications to clearly define "high risk" as some way other than age (e.g., cognitive impairment, functional impairment). Moreover, the numerator details specify an overly prescriptive screening process. It may be clinically inappropriate to screen all patients over the age of 65 for elder abuse. Developers should consider revising the measure to specifically encourage screening in patients who are dependent on a caregiver or who are otherwise at risk for abuse. It is unnecessarily burdensome for physicians to document maltreatment screening for all patients aged 65 years and older at every visit. Finally, the measure requires clinicians to assess for maltreatment using a screening tool even when abuse may be readily apparent.
435	Quality of Life Assessment for Patients with Primary Headache Disorders	ACP does not support MIPS measure #435: "Quality of Life Assessment for Patients with Primary Headache Disorders." While this measure represents an important clinical concept and evidence supports the benefit of shared decision-making around prophylactic treatment options for chronic migraines on improved patient outcomes, we cannot estimate the measure impact on improved clinical outcomes. Furthermore, we note several issues with the measure specifications. First, denominator specifications include exclusion criteria for patients without insurance to cover assessment costs, reinforcing uncertainty surrounding the intervention's ability to improve quality outcomes. Second, the numerator specifies an assessment tool that is specific to migraine headaches. Therefore, clinicians would have to rely on general quality of life assessment tools for all other headache disorders and results may influence other treatment decision areas. Third, as currently specified, clinicians are required to perform quality of life assessments on all patients with primary headache disorders, regardless of clinical relevance to the patient's primary complaints. Developers should consider revising the specifications to include a principle diagnosis of primary headache. Incentivizing clinicians to perform routine assessments in patients without a principle diagnosis of headache may result in underuse of more meaningful, evidence-based interventions. If quality programs used this measure as a tracking tool, the results would likely encourage appropriate discussions surrounding prophylactic treatment and ultimately result in improved patient outcomes.
419	Overuse of Neuroimaging for patients with Primary Headache and a Normal Neurological Evaluation	ACP supports MIPS measure #419: "Overuse of Neuroimaging for Patients with Primary Headache and a Normal Neurological Evaluation" because implementation will likely promote appropriate use of neuroimaging in patients with primary headache and the data source attributes the measure outcome to the ordering clinician. While we support this measure, the measure developers cite outdated evidence to form the basis of the measure. Additionally, quality reporting programs should be aware of the potential for clinicians to manipulate the measure to work in their favor by documenting an exception to the rule (e.g., "change in the type of headache"). To avoid potential measure gaming, developers should consider revising the specifications to clearly define appropriate exceptions to eligibility.

377	Functional Status Assessment for Patients with Congestive Heart Failure	ACP does not support MIPS measure #377: "Functional Status Assessment for Patients with CHF." It is unclear whether implementation of this measure will lead to meaningful improvements in quality outcomes and the measure developers do not cite a performance gap. While implementation may promote appropriate care by helping clinicians identify patients in need of further intervention, incentivizing clinicians to perform routine assessments in asymptomatic patients may result in underuse of more meaningful clinical interventions. While we support the development and implementation of valid, reliable patient reported outcome measures (PROMs), there is insufficient evidence to support the benefit of this intervention on quality outcomes. Implementation of evidence-based PROMs using validated instruments to assess clinical performance is likely the first step towards collecting PRO data. As currently specified, congestive heart failure is not clearly defined. Developers should consider revising the specifications to clearly differentiate between preserved ejection fraction and systolic dysfunction because this intervention will more likely lead to quality improvements in the latter population.
005	Heart Failure: Angiotensin- Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction	ACP supports MIPS measure #005: "Heart Failure: Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction" because there is good evidence that ACE inhibitors and ARBs improve the health of people with heart failure and LVEF < 40%, and the measure aligns with current guidelines and represents high-value care for patients with chronic heart failure.
008	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction	ACP supports MIPS measure #008: "Heart Failure: Beta-blocker therapy for Left Ventricular Systolic Dysfunction" because the balance of evidence shows that long-term treatment with beta-blockers can lessen the symptoms of heart failure, improve the clinical status of patients, and enhance the patient's overall sense of well- being. Furthermore, the measure aligns with current guidelines and represents high-value care for patients with chronic heart failure.
387	Annual Hepatitis C Virus Screening for Patients who are Active Injection Drug Users	ACP supports MIPS measure #387: "Annual Hepatitis C Screening for Patients who are Active Injection Drug Users" because implementation will likely lead to measurable and meaningful improvements in clinical outcomes, it is clinically appropriate to screen active injection drug users for HCV, and the measure aligns with United States Preventive Task Force (USPSTF) recommendations on HCV screening in patients who are at risk for infection. The measure also aligns with American Association for the Study of Liver Diseases and the Infectious Diseases Society of America recommendations for testing, managing, and treating Hepatitis C, and the measure specifications include appropriate exclusion criteria for patients where the treatment benefits do not outweigh the risk of harms (e.g., advanced liver disease, limited life expectancy). While we support this measure, we advise developers to address the following concerns during the update process. First, while the developers describe the measure's potential to positively impact clinical outcomes, the benefit of diagnosing active injection drug users on injection habits is unclear. Additionally, implementation is

		unlikely to largely benefit population health outcomes because most clinicians treat a low patient denominator for the measure. Second, the denominator specifications may not capture patients who deny injection drug use status. Therefore, it is may be difficult to estimate the true impact of the measure on quality outcomes. Developers should consider revising the denominator specifications to be more inclusive of all patients at risk for HCV (e.g., baby-boomer populations). Third, clinicians may encounter barriers to data access. Information systems may not automatically identify the denominator population unless end users create a specific code to capture injection drug use.
400	One-Time Screening for Hepatitis C Virus for Patients at Risk	ACP supports MIPS measure #400: "One-Time Screening for Hepatitis C Virus for Patients at Risk" because a performance gap exists, it is important to screen for HCV in patients at risk because it is a treatable disease, the measure aligns with Centers for Disease Control and Prevention (CDC) and United States Preventive Services Task Force (USPSTF) recommendations on screening for HCV in patients at risk, and the measure specifications include appropriate exclusion criteria. Additionally, the USPSTF found little evidence on the harms of screening for HCV. While the measure is clearly specified, clinicians may encounter interoperability barriers to patient information retrieval. Also, while we support this measure, we suggest the measure developers re-assess the benefit of screening all patients included in the denominator population during the measure update, particularly patients born in the years 1945-1965.
390	Discussion and Shared Decision Making Surrounding Treatment Options	ACP does not support MIPS measure #390: "Hepatitis C: Discussion of Shared Decision-Making Surrounding Treatment Options." While we support its efforts to encourage shared decision making, this measure ceases to be relevant in an era of superior pharmacologic treatment advancements. Newer treatments have minimal side effects and therefore, decisions about tolerability are no longer applicable. Furthermore, measure developers do not cite any evidence to form the basis of the measure and do not include measurement validity or reliability data in the measure report. Additionally, the numerator specifications are unclear. Developers should consider revising the specifications to define explicit "shared decision making" documentation requirements. Lastly, patients who receive government funded insurance may encounter accessibility barriers to treatment options. It may inappropriate to base treatment options on shared- decision making alone because payers play a significant role in the therapy selection process.
401	Screening for Hepatocellular Carcinoma in Patients with Cirrhosis	ACP does not support MIPS measure #401: "Hepatitis C: Screening for Hepatocellular Carcinoma" because the screening benefits do not outweigh the substantial risks of harms related to radiation exposure and treatment of incidental findings. Furthermore, developers cite weak evidence to form the basis of the measure. A recent evidence review demonstrates insufficient evidence for screening for hepatocellular carcinoma among patients with cirrhosis.

205	HIV/AIDS: Sexually Transmitted Diseases - Screening for Chlamydia, Gonorrhea, and Syphilis	ACP does not support MIPS measure #205: "HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis." Developers cite a significant performance gap based on data from the 2011 PQRS reporting year and implementation will likely lead to meaningful improvements in clinical outcomes. Opportunistic infections are often asymptomatic in adults with HIV (e.g., chlamydia) with potential to result in severe health complications (e.g., infertility in women) if left untreated and the measure aligns with United States Preventive Services Task Force (USPSTF) and Centers for Disease Control and Prevention (CDC) recommendations on the prevention and treatment of opportunistic infections in HIV-infected adults. However, implementation of the measure could promote overuse of screening in asymptomatic patients and in situations where clinicians encounter interoperability barriers to data retrieval. While specifications include an evidence-based time interval, they are flawed in a number of respects. The numerator and denominator envision one test since HIV diagnosis, although new infections and reinfections may occur repeatedly; gonorrhea screening may encompass several loci of infection, which should be listed; and the measure does not include an appropriate exclusion for patients who are not sexually active or otherwise unlikely to become infected. Also, the numerator specifies an indefinite look-back window. Developers should consider revising the specifications to include an evidence-based look-back window. Although the specifications are flawed, it is more problematic to miss these infections and allow them to go untreated.
438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	ACP supports MIPS measure #438: "Statin Therapy for the Prevention and Treatment of Cardiovascular Disease." The performance gap has increased significantly due to new United States Preventive Task Force (USPSTF) and American College of Cardiology/American Heart Association (ACC/AHA) clinical recommendations on treatment of cardiovascular disease to expand the at-risk patient population. Additionally, the balance of evidence provides a strong foundation for the treatment of blood cholesterol for the primary and secondary prevention of atherosclerotic cardiovascular disease in adult men and women. Furthermore, measure specifications include appropriate exclusion criteria for patient intolerance. While we support this measure, we note that implementation of statin therapy alone does not guarantee meaningful improvements in clinical outcomes. A more meaningful measure may examine patient adherence to prescribed statin therapy. Additionally, a high percentage of patients prescribed statin therapy for the management of cardiovascular disease exacerbations (e.g., acute MI) discontinue therapy without consulting their clinician. Therefore, the measure may unfairly penalize clinicians for lack of control over nonadherent patients.

317	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented	ACP does not support MIPS measure #317: "Screening for High Blood Pressure and Follow-Up Documented." While we support the measure concept, the measure developers should update the measure specifications to align with current Joint National Committee-8 (JNC-8), United States Preventive Services Task Force (USPSTF), and American College of Physicians (ACP) clinical recommendations on blood pressure screening and management. JNC-8 and ACP recommend initiating treatment for patients without comorbid diseases and blood pressure measurements of 150/90 mm/Hg or greater. The USPSTF recommends annual screening for patients who are at increased risk for high blood pressure (i.e., > 40 y.o., African Americans, those who have high normal BP, and those who are overweight). Also, the USPSTF recommends obtaining blood pressure measurements outside of the clinical setting for diagnostic confirmation before starting treatment. Variations in blood pressure assessment (e.g., clinical skill level of the clinician assessing the BP, office setting) may contribute to inadequate readings and result in inappropriate BP management. Additionally, the denominator specifications should include exclusion criteria for patients with medical contraindications to treatment (e.g., frail, elderly adults, patients with life limiting diagnoses).
236	Controlling High Blood Pressure	ACP does not support MIPS measure #236: "Controlling High Blood Pressure." Implementation may result in measurable and meaningful improvements in clinical outcomes and there is a known performance gap in the area of blood pressure control. However, while the specifications for the measure under consideration for NQF-endorsement align with American College of Physicians (ACP) and the Eighth Joint National Committee (JNC-8) recommendations on controlling BP in patients aged 18-85 years of age with and without a diagnosis of diabetes, the MIPS measure specifications do not stratify patients into well-defined risk groups (i.e., comorbid disease diagnosis). The American College of Physicians (ACP) guideline states that there is no difference in outcomes between strict blood pressure control and standard blood pressure control (128-133 mmHg vs. 134-141 mmHg systolic, and 75-81 mmHg vs. 81-87 mmHg diastolic). Furthermore, the numerator specifications define office measurements as the preferred monitoring method, while home monitoring is the preferred method to assess for adequately controlled BP. We suggest the developers update the numerator specifications to include an average of several measurement results. Doing so would likely increase the accuracy of the measurement results and reduce the potential for overtreatment. Finally, the measure was created to assess system-level performance where information systems include multiple readings from a variety of settings. The measure may not be an appropriate accountability measure for individual clinicians who do not have access to all BP measurement results. *Note: PMC approves the specifications included in the updated measure proposed for NQF endorsement. If NQF approves the proposed measure updates, we suggest CMS adopt the updated measure.

271	IBD: Preventive Care: Corticosteroid Related Iatrogenic Injury-Bone Loss Assessment	ACP does not support MIPS measure #271: "Preventive Care: Corticosteroid Related latrogenic InjuryBone Loss Assessment." While the measure represents an important clinical concept, measure developers do not cite high-quality evidence to form the basis of the measure and using dexa-scans to assess for risk of bone loss does not necessarily prevent hip fractures in patients prescribed corticosteroid therapy for IBD. Furthermore, implementation could promote overuse of dexa scans and underuse of corticosteroid therapy. The American College of Rheumatology recommends low dose bisphosphonate prophylaxis for patients receiving long-term corticosteroid treatment and alendronate is recommended for patients receiving more than 5 mg of prednisone/day for more than three months. Furthermore, numerator specifications encourage clinicians to screen patients who receive 10 mg/day of prednisone for 60 days, while evidence demonstrates that hip fractures are significantly higher in patients treated with medium steroid doses (2.5-7mg/day) over a duration of time. As written, the numerator could miss patients who are at risk for fracture. Also, it is unclear whether the measure encourages clinicians to screen patients who are currently prescribed prophylactic bisphosphonate therapy for risk of bone loss, which may not be clinically necessary. Lastly, developers should consider revising the numerator specifications to include an evidence-based look-back window for review of medication history. It is burdensome for clinicians to review indefinite data fields for documentation of review of systems and medication history.
441	IVD: All or None Outcome Measure	ACP does not support MIPS measure #441: "IVD: All or None Outcome Measure." The developers did not provide adequate information for us to appropriately review the measure. We rated the measure based on the specifications provided on the MIPS website. We do not support this measure because it disregards patient preferences, specifications do not consider factors beyond the clinicians control (e.g., patient adherence, patient access), and it does not align with the Eighth Joint National Committee (JNC-8) recommendations for hypertension management.
312	Use of Imaging Studies for Low Back Pain	ACP supports MIPS measure #312: "Use of Imaging Studies for Low Back Pain" because inappropriate imaging is not associated with improved clinical outcomes. Implementation will likely prevent prescription of unnecessary imaging in patients with low back pain and unnecessary radiation exposure and treatment. Furthermore, measure specifications include appropriate exclusion criteria and high-quality evidence exists to form the basis of the measure.

442	Persistence of Beta-Blocker Treatment After a Heart Attack	ACP supports MIPS measure #442: "Persistence of Beta-Blocker Treatment after a Heart Attack." 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 topped out. Data from the 2014 HEDIS reporting period demonstrates an 84% compliance rate. *American College of Physicians, American College of Cardiology, American College of Cardiology Foundation/American Heart Association, European Society of Cardiology
109	Function and Pain Assessment	ACP does not support QPP measure 109: "Osteoarthritis: Function and Pain Assessment." While this measure represents an important clinical concept for clinicians treating patients with a principle diagnosis of OA, there is insufficient evidence to support an appropriate assessment time interval and the denominator specifications are unclear. Furthermore, the measure should specify utilization of a validated, standardized assessment tool that demonstrates improvements in quality outcomes. While it's important to assess pain and function in patients with a principle diagnosis of OA, it is burdensome for clinicians to perform this assessment at every visit where OA is not the primary patient complaint. While this measure is appropriately specified to assess the quality performance of clinicians practicing in orthopedic subspecialty areas, it is not an appropriate accountability measure for general internists. Additionally, clinicians may encounter interoperability barriers to data access and embedding data into the information system. Eliminating these barriers will likely improve the feasibility of this measure.
039	Screening for Osteoporosis for Women 65-85 Years of Age	ACP supports MIPS measure #039: "Screening for Osteoporosis for Women 65-85 Years of Age" because implementation will likely result in meaningful and measurable improvements in clinical outcomes, measure developers cite a performance gap based on the 2012 PQRS claims data (mean = 57%), and the measure aligns with United States Preventive Services Task Force (USPSTF) recommendations on screening for osteoporosis. While we support this measure, we note that implementation could promote overuse of screening if patients receive care from multiple clinicians and/or have poor record continuity, and in women who are at lower risk for osteoporosis based on reasonably identifiable factors (e.g., BMI, ethnicity). Additionally, developers should consider updating the denominator specifications to include exclusion criteria for patients who have already been assessed with the FRAX tool and for patients receiving hospice and palliative care where the intervention has the potential to cause more harms than benefits.

418	Osteoporosis Management in Women who had a Fracture	ACP supports MIPS measure #418: "Osteoporosis Management in Women who had a Fracture" because a performance gap exists, the specifications align with current recommendations to screen for osteoporosis in women aged 65 years and older, and specifications include appropriate exclusion criteria for women with fracture related to traumatic injury. While we support this measure, implementation may promote overuse of bone mineral density testing. Developers should consider tapering the fracture definition to only include women with vertebral and hip fractures.
412	Documentation of Signed Opioid Treatment Agreement	ACP supports MIPS measure #412: "Documentation of Signed Opioid Treatment Agreement because it protects clinicians from the repercussions of patients who violate the opioid agreement. Also, considering the magnitude and urgency of the opioid epidemic, quality programs should adopt this measure unless data is otherwise available to describe the negative consequences of this measure. While we support this measure, we suggest the developers update the measure specifications to include appropriate exclusion criteria for patients receiving active cancer treatment, and patients receiving palliative and end-of-life care.
414	Evaluation or Interview for Risk of Opioid Misuse	ACP supports MIPS measure #414: "Evaluation or Interview for Risk of Opioid Misuse" because implementation will likely lead to measureable and meaningful improvements in patient outcomes and prevent the misuse and abuse of opioid prescription therapy. Additionally, the measure aligns with clinical recommendations and state requirements on opioid prescription therapy. While we support this measure, evidence exists to suggest that opioid addiction develops in less than 6 weeks duration of prescribed therapy. As such, this measure could unfairly penalize clinicians who do not initiate opioid therapy (e.g., therapy initiated as part of a post-operative care program). Measure developers should consider updating the denominator specifications to include an evidence-based therapy duration. Also, the opioid measures would benefit from additional testing to determine which interventions are most impactful in preventing opioid misuse and abuse. Finally, a better measure may include exclusion criteria for patients receiving active cancer treatment, palliative care, and end-of-life care.
342	Pain Brought Under Control Within 48 Hours	ACP does not support MIPS measure #342: "Pain Brought under Control within 48 Hours." While this measure represents an important clinical concept, it is unclear whether implementation will produce reliable, meaningful results, and there is insufficient evidence to support the 48 hour time interval. Additionally, the specifications include an assessment tool is that is not well validated. Measure developers should consider modifying the specifications to include a more appropriate assessment tool (e.g., Numeric Pain Rating Scale). While this measure may appropriately assess performance of hospice and palliative care practice clinicians, it is an inappropriate internal medicine accountability measure.

408	Opioid Therapy: Follow-up Evaluation	ACP does not support MIPS measure #408: "Opioid Therapy Follow-Up and Evaluation. This is a "check the box measure." Adherence to a follow-up evaluation program does not necessarily improve quality outcomes. A more appropriate measure may incentivize a standardized, methodological approach to evaluation that is likely to improve the opioid therapy management process and result in improved clinical outcomes. While implementation could prevent overuse of opioid therapy, there is insufficient evidence to support the 6 weeks and 3 months durations included in the denominator and numerator specifications. While the measure aligns with Centers for Disease Control and Prevention recommendations on prescribing opioids for chronic pain, we suggest the developers revise the specifications to include an evidence based-definition of chronic opioid therapy. Furthermore, it is unclear whether clinicians who prescribe therapy for less than 3 months should require patient follow-up earlier than 3 months' time. The measure would benefit from reliability and validity testing prior to implementation and inclusion in quality payment programs
131	Pain Assessment and Follow-up	ACP does not support MIPS measure #131: "Pain Assessment and Follow-Up" because we note several specification flaws: 1) performance rates are close to 100%, 2) the measure distracts from measurement of change in functional status, which is likely a more meaningful measure, 3) implementation of this measure could unintentionally promote overuse of opioid therapy, 4) measure developers cite outdated evidence to form the basis of the measure, 5) specifications do not address the importance of including a functional assessment during the patient visit 6) specifications do not exclude patients who have known diversions to opioid therapy (e.g., substance abuse and alcohol abuse disorders) and this could fuel the opioid epidemic, 7) it is burdensome for clinicians to document pain assessment and follow-up plan at every visit regardless of the patient's primary complaint, 8) referral to a pain management specialist is not practical in every area of the country and 9) the measure language around "eliminating" pain is unreasonable.
321	CAHPS for MIPS Clinician/Group Survey	ACP does not support MIPS measure #321: "CAHPS Clinician & Group Surveys (CG-CAHPS)-Adult, Child." Survey results provide important feedback and enhance the provider selection process for consumers. However, implementation could promote overuse of unnecessary treatments where the potential benefits do not outweigh the risk of harms (e.g., opiate prescriptions, imaging studies). While evidence does not support this claim, we base this assumption on our clinical judgement and personal experiences in clinical practice. In addition, developers do not present any evidence to form the basis of the measure. Improving patient experience is an admirable clinical goal; however, we question the validity of the survey process and the impact of survey results on improving patient outcomes. Also, survey results are likely a poor gauge of clinician performance unless a majority of patients participate in the survey. Finally, individual clinicians should not be held accountable to organizational factors beyond their control (e.g., appointment wait times, friendliness of staff).

154, 155	Falls: Screening, Risk-	ACP does not support MIPS measures #154, 155, and 318 (NQF measure #0101): "Falls: Screening,
-	_	_ · · · · · · · · · · · · · · · · · · ·
& 318	Assessment, and Plan of care to Prevent Future Falls	Risk-Assessment, and Plan of care to Prevent Future Falls." This measure represents an important clinical concept and clinicians should screen for falls in patients who are at risk of falling; however, it is unclear whether implementation will lead to meaningful improvements in clinical outcomes. Developers should consider revising the denominator specifications to include only those patients who are at high-risk of falling. As currently specified, implementation could promote overuse of low-value services in low-risk adults aged 65 years and older. Clinicians should individualize the plan of care and the care plan should be less prescriptive to account for individual patient requirements. Furthermore, the data collection burden associated with the multiple measure components is high and data elements seem unlikely to capture how well the service was performed. The measure relies heavily on CPT-II codes which are not widely used. Commercial electronic health records (EHRs) are not designed to capture these codes in routine work flow. Also, developers should consider updating the specifications to reflect the most current clinical recommendations of the United States Preventive Task Force (USPSTF). The USPSTF does not support inclusion of vitamin D supplementation in falls prevention management programs. Additionally, the evidence-base for what clearly defines best practice is complex. Lastly, while the numerator is clearly defined, it is
		complicated with variable validity and the components of the risk assessment model are not clearly
		defined.
128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up	ACP does not support MIPS measure #128: "Preventive Care and Screening: BMI Screening and Follow-Up." The urgency posed by the obesity epidemic underscores the need for evidence based and clinically meaningful performance measures. However, this is a "check box" measure and the numerator specifies obesity interventions that do not necessarily lead to meaningful improvements in quality outcomes. For example, documenting a nutritionist referral may not be an effective intervention for weight loss management. The measure developers should update the measure specifications to align with current United States Preventive Services Task Force (USPSTF) recommendations on obesity screening and include waist circumference as a screening tool. In addition, there is insufficient evidence to support implementation of obesity interventions for patients with a BMI measurement between 25-30 kg/m². It is burdensome for clinicians to design a follow-up plan for patients with a BMI measurement between 25-30 kg/m² where the evidence is insufficient to support the intervention. As written, the measure pressures clinicians to spend a disproportionate amount of time on a patient's weight, when other conditions should take precedence. Furthermore, there is no evidence about appropriate screening intervals. We advocate for annual versus biennial screening.

305	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	ACP does not support MIPS measure #305: "Initiation and Engagement of Alcohol and Other Drug Dependence Treatment" because the specifications are flawed and the measure is not appropriately specified to evaluate performance at the level of the individual clinician. Developers should consider dividing the numerator statement to form two discrete measures: 1) initiation of alcohol and other drug dependence treatment; and 2) engagement of alcohol and other drug dependence treatment. Also, it is unclear what constitutes a "new episode of drug or alcohol dependency." While it is appropriate for accreditors and regulators to use this measure in programs designed to assess quality at the level of the health system, regulators should not include this measure in accountability programs designed to assess performance of individual clinicians. It is unclear whether individual clinicians will be able to control the outcomes of this measure. Individual clinicians will likely face interoperability challenges to data collection.
402	Tobacco Use and Help with Quitting Among Adolescents	ACP supports MIPS measure #402: "Tobacco Use and Help with Quitting among Adolescents" because Reduction of tobacco use slows the progression of respiratory disease and is a key element in the management of pulmonary disease, tobacco use is a modifiable risk factor and clinical evidence suggests that patient counseling and re-counseling by physicians increase attempts to quit, and the measure aligns with clinical recommendations of the ACP/ACCP/ ATS/ERS*and the United States Preventive Services Task Force on tobacco use and offer cessation interventions. While we support the measure, as currently specified, the denominator population is unclear. The developer should consider separating the measure into two distinct measures: 1) tobacco use screening measure and 2) tobacco cessation measure for patients who screened positive on measure 1. *American College of Physicians (ACP)/American College of Chest Physicians (ACCP), American Thoracic Society (ATS)/European Respiratory Society (ERS)
431	Unhealthy Alcohol Use: Screening & Brief Counseling	ACP supports MIPS measure #431: "Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling" because it is clinically important to screen for unhealthy alcohol use, the measure aligns with the United States Preventive Services Task Force (USPSTF) recommendations on screening and behavioral health counseling interventions in primary care, and the measure does not pose undue burden on clinicians. While we support this measure, we suggest the developers revise the numerator specifications to clearly define "brief counseling".

226	Tobacco Use: Screening & Cessation Intervention	ACP supports MIPS measure #226: "Preventive Care and Screening: Tobacco use: Screening & Cessation Intervention" because reduction of tobacco use slows the progression of respiratory disease and is a key element in the management of pulmonary disease; tobacco use is a modifiable risk factor and clinical evidence suggests that patient counseling and re-counseling by physicians increase attempts to quit; and the measure aligns with clinical recommendations of the ACP/ACCP/ATS/ERS*and the United States Preventive Services Task Force on tobacco use and offer cessation interventions. *American College of Physicians (ACP)/American College of Chest Physicians (ACCP), American Thoracic Society (ATS)/European Respiratory Society (ERS)
developers of measure. Alt glucocortico denominato for patients wir Additionally, the important		ACP does not support MIPS measure #180: "Rheumatoid Arthritis: Glucocorticoid Management." The developers did not provide adequate information for us to meaningfully evaluate the validity of this measure. Although we recognize the importance of managing the lowest effective dose of glucocorticoids and using alternative therapies when possible, both the numerator and the denominator are poorly specified. The measure specifications do not include appropriate exclusions for patients prescribed prednisone therapy for a symptomatic flare. A cleaner measure may specify "patients with rheumatoid arthritis (RA) who are on glucocorticoids" in the denominator statement. Additionally, the current American College of Rheumatology (ACR) clinical guidelines demonstrate the importance of assessing glucocorticoid use, but only in patients who have specifically been prescribed glucocorticoid therapy.
333	Adult Sinusitis: CT for Acute Sinusitis (Overuse)	ACP supports MIPS measure #333: "Adult Sinusitis: CT for Acute Sinusitis" because it is clinically important to promote appropriate use of CT scans in patients diagnosed with acute sinusitis. While we support this measure, developers do not clearly define denominator exclusion criteria and as such, implementation could promote underuse of CT scans in clinically appropriate cases. Developers should consider revising exclusion criteria to explicitly align with Infectious Diseases Society of America (IDSA) recommendations on treatment of acute sinusitis (i.e., patients with symptoms> 10 days, severe or worsening symptoms (102 degrees F fever with nasal discharge) > 3 days, onset with worsening symptoms/double sickening patients (new onset of fever, headache, or increased nasal discharge following viral URI) > 5-6 days).

331	Adult Sinusitis: Appropriate	ACP does not support MIPS measure #331: "Adult Sinusitis: Appropriate Choice of Antibiotic
	Choice of Antibiotic Prescribed	Prescribed for Acute Sinusitis (Overuse)." While it is clinically important to promote appropriate
	for Acute Sinusitis (Overuse)	antibiotic therapy in patients diagnosed with acute sinusitis, we note several issues with this
		measure. First, the numerator specifications do not define an appropriate performance rate and a
		0% performance rate will promote underuse of antibiotic therapy in appropriate treatment cases.
		Furthermore, the numerator specifications define "acute sinusitis" according to typical bacterial
		infection symptoms and it is appropriate to prescribe antibiotics to treat a bacterial infection.
		Developers should consider revising denominator specifications to define "acute sinusitis" according
		to viral symptoms to prevent overuse of antibiotic therapy in viral sinusitis infections. Second, the
		measure does not align with the Infectious Diseases Society of America (IDSA) clinical
		recommendation on treatment of acute bacterial sinusitis. IDSA recommends initiating antibiotic
		therapy in patients with symptoms > 10 days, severe or worsening symptoms (102 degrees F fever
		with nasal discharge) > 3 days, onset with worsening symptoms/double sickening patients (new
		onset of fever, headache, or increased nasal discharge following viral URI) > 5-6 days. Third,
		denominator specifications include exclusion criteria for "medical reason for not prescribing
		treatment"; however, measure developers should explicitly define exceptions according to the IDSA
		guidelines in order to avoid underuse of appropriate antibiotic therapy. Finally, while we support
		inclusion of appropriate exclusion criteria, inclusion of broad exclusion criteria may provide
		opportunity for measure manipulation by reporting clinicians.
332	Adult Sinusitis: Appropriate	ACP does not support MIPS measure #332: "Adult Sinusitis: Appropriate Choice of Antibiotic:
	Choice of Antibiotic:	Amoxicillin with or without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis." While
	Amoxicillin with or without	it is clinically important to promote appropriate use of broad-spectrum antibiotics, numerator
	Clavulanate Prescribed for	specifications do not align with Infectious Diseases Society of America (IDSA) clinical
	Patients with Acute Bacterial	recommendations on treatment of acute, bacterial rhinosinusitis. IDSA recommends amoxicillin-
	Sinusitis	clavulanate as the first line of treatment in patients diagnosed with bacterial sinusitis. Also, the
		measure specifications do not include exclusion criteria for patients who do not tolerate amoxicillin.
		About 30%-40% of patients are bacterial resistant to amoxicillin therapy alone. Developers should
		update the measure specifications to encourage prescription of amoxicillin-clavulanate as first-line
		therapy in patients diagnosed with bacterial sinusitis.

050	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	ACP supports MIPS measure #050: "Urinary Incontinence: Plan of care for UI in Women Aged 65 Years and Older" because a performance gap exists, treatments exist to create meaningful improvements in clinical outcomes/quality of life, and the benefits of reducing the patient disease burden outweigh the clinician measurement burden. While we support this measure, developers cite weak evidence to support the benefit of care plan development on clinical outcomes in women with UI. Additionally, developers should consider updating denominator specifications to include exclusion criteria for patients who refuse care plan services. Lastly, developers created this measure to assess quality performance at the system level where screening results and UI care plans are automatically generated within the electronic system. Individual clinicians may encounter interoperability barriers retrieving this data.
110	Influenza Immunization	ACP supports MIPS measure #110: "Influenza Immunization" because the measure aligns with current Centers for Disease Control and Prevention (CDC) Advisory Committee recommendations. While we support this measure, we note that electronic health record (EHR) information blocking could prevent the transmission of immunization information between competing electronic systems.
111	Pneumococcal Vaccination Status for Older Adults	ACP does not support MIPS measure #111: "Pneumococcal Vaccination Status for Older Adults." While this measure represents an important clinical concept, implementation could promote treatment overuse if patients seek medical care from multiple providers and/or have poor medical record continuity. In addition, the developer should update the numerator specifications to align with current clinical recommendations on pneumococcal vaccination.
310	Chlamydia Screening in Women	ACP supports MIPS measure #310: "Chlamydia Screening in Women" because it aligns with United States Preventive Services Task Force (USPSTF) and the Centers for Disease Control and Prevention (CDC) recommendations on chlamydia screening, evidence supports screening in primary care as feasible and effective, and the denominator is clearly specified to capture all women who are sexually active. Specifications define three methods to identify contraceptive therapy prescription: 1) pharmacy data, 2) claims data, 3) medical records data.

Appendix 3
High-Level Discussion Points on Measures Not Previously Reviewed by the ACP and/or Proposed for Future Inclusion in the MIPS Program

Measure ID#	Measure Title	Comments
MIPS ID #TBD	Ischemic Vascular Disease: Use of Aspirin or Another Platelet	 We are unable to assess the potential impact of the measure on clinical outcomes because the steward does not present current performance data in the measure background materials The specifications are based on clinical recommendations on the management of IVD Specifications include appropriate exclusion criteria for patients with bleeding disorders One additional note is that it may be difficult for clinicians to track adherence to over the counter aspirin therapy.
MIPS ID #TBD	Appropriate Use of DXA Scans in Women Under 65 Years Who do not Meet the Risk Factor Profile for Osteoporotic Fracture	 While developers do not cite performance data to describe the potential impact of this measure on clinical outcomes, our sense is that this does occur in practice. A better measure may evaluate overuse of repeat DXA scans in the over 65 years of age population. New requirements for documenting malnutrition in an inpatient setting as evidence by low albumin results may affect how meaningful this measure is in an inpatient setting The exclusion criteria for white women seem a bit broad. A better measure may promote appropriate use of screening in patients who have risk factors that equate to an x% of developing an osteoporotic fracture (using the FRAX or other validated assessment tools to determine an evidence based threshold)
MIPS ID# 118, NQF# 0066	Coronary Artery Disease: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%)	Only comment is that this measure is close to being topped out
MIPS ID# 024, NQF ID# 0045	Communication with the Physician or Other Clinician Managing On- going Care Post-Fracture for Men and Women Aged 50 Year and Older	 While this measure represents an important clinical concept, it is unclear whether documenting communication with the clinician managing ongoing care will lead to meaningful improvements in clinical outcomes A better measure would focus on ensuring that on-going treatment actually occurred during the appropriate treatment period following fracture Clinicians may encounter reporting challenges related to poor interoperability across EHRs. Data collection will be cumbersome at best.

		 Performance scores are likely to be entirely dependent on the patient populations served by individual clinicians and the setting in which clinicians practice as opposed to differences in quality. For example, implementation has the potential to penalize clinicians who practice in rural or underserved areas of the country while clinicians who work in a clinical setting that participates in a shared electronic system are likely to score high on this measure
MIPS ID# 320, NQF ID# 0658	Appropriate Follow-up for Normal Colonoscopy in Average Risk Patients	 The performance gap is unclear because the developers cite outdated performance data to form the basis of the measure (data from 10 years ago) Evidence exists to support the benefit of documenting the follow-up interval on clinical outcomes A stronger measure of appropriate use may assess how many average risk patients undergo colonoscopies prior to the recommended follow-up date
MIPS ID# 439	Age Appropriate Screening Colonoscopy	 Developers do not cite current performance data on this measure so we are unable to assess the potential impact of this measure on clinical outcomes Although, performance data from within the VHA shows that the rates of clinicians who perform colonoscopies on patients who are over the age of 85 years old are incredibly low, so this is potentially a low impact measure. While this measure represents an important clinical concept and we do support appropriate screening and consideration of appropriate risk factors in patients who are older than 75 years of age, the documentation requirements seem overly burdensome for individual clinicians. It is difficult for individual clinicians to operationalize the documentation requirements of the denominator specifications. The denominator population is likely to be low for individual clinicians
MIPS ID# 275	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti- Tumor Necrosis Factor (TNF) Therapy	 While this measure represents an important clinical concept, developers do not cite current performance data on this measure so we are unable to assess the potential impact of this measure on clinical outcomes QI programs have included this measure as a reporting option for many years and therefore; performance data should exist to demonstrate the impact of this measure on clinical outcomes Developers should present data on the frequency of HBV reactivation with Anti-TNF therapy Citing case reports is not sufficient to document the frequency of reactivation Developers should revise the numerator specifications to define "first course" of therapy

		 Documentation requirements are a bit burdensome because the 1-year look-back period for HBV assessment requires continuity of medical records and a fairly sophisticated coding review
MIPS ID# 117, NQF# 0055	Diabetes: Eye Exam	 The performance gap is well documented Implementation could promote overuse because some modeling studies show that if A1c target is less than some value and prior exams were normal that exams could be more than 2 years apart While poor interoperability across EHRs poses some challenges to retrieving the results of the eye exams, the onus is on the primary care clinician to ensure that patients who are diagnosed with diabetes are referred for an eye exam
MIPS ID# 119, NQF# 0062	Diabetes: Medical Attention for Nephropathy	The performance gap is well documented
MIPS ID# TBD, NQF# 3067	HIV Infection Screening	 To the extent the intent of this measure is to standardize HIV screening, thereby increasing early diagnosis and reducing stigma of testing, including some measure of ever tested seems like a reasonable first step. While evidence suggests the benefit of screening for HIV in all adults on clinical outcomes is high, clinicians may encounter barriers to implementation, including poor access to test results due to poor interoperability across EHRs and confidentially obstacles around patient information. Controlling patient consent to testing is beyond the clinician's control. If clinicians are unable to retrieve previous testing results, they may feel compelled to order additional tests. The specifications should include exclusion criteria for patient refusal, patients with a limited life expectancy, and patients who are already diagnosed with HIV. Time intervals here are questionable. Data are far better for frequent screening of high-risk patients. One time screening is an odd idea for an infectious disease - patients are either at risk, in which case they should be screened, or not at risk, and shouldn't be. This risk is usually not difficult to assess in clinic and the models do not use this type of targeted strategy. Additionally, one-time screening in low-risk settings has mixed data on effectiveness and is highly dependent on the assumptions about underlying prevalence. For example, in the two major papers on the topic, the cost-effectiveness in one is >100K per QALY, in the other it's 15K.
MIPS ID# TBD,	Continuity of Pharmacotherapy for	While a strong argument for measurement of continuity of OUD therapy
NQF# 3175	Opioid Use Disorder	exists, data presented for performance gap is at the state and plan level. We query how valid/impactful this construct will be at the individual

		clinician level.
		 Assessing performance at the plan-level will likely drive improvements in clinical and quality outcomes, but this measure is not appropriate for evaluating performance at the individual clinician level. Questions remain about attribution (e.g., which clinician would be accountable for this measure? For example, PCP vs. prescribing clinician for the MAT?) The measure is not risk-adjusted based on type of insurance, which often drives missed medications. This measure is appropriate for evaluating performance at the plan level of attribution. While evidence suggests the benefit of pharmacotherapy for patients with OUD for a period of 180 days is high, the underlying assumption that clinicians can convince opioid-dependant patients to abstain from opioid use for an extended period of time is questionable. The statistical results for success at the state level are low (median success ~ 0.25) The argument for a 7-day gap seems reasonably well-supported by existing evidence. The total number of eligible patients is relatively small (<1000 pts per state in the most recent data presented.) This is likely to create serious reliability problems when taking this down to the individual clinician level. As OUD pharmacotherapy increases, this may become less of an issue.
MIPS ID# TBD	Zoster (Shingles) Vaccination	 Specifying the lower end of the age parameter as <50 years could be problematic as vaccine availability is low. Clinicians may face barriers to retrieving data on vaccination status due to poor interoperability across EHRs. The measure steward does not present detailed information on the measure specifications, performance gap, testing results, or evidence used to form the basis of this measure, therefore; we cannot meaningfully assess this measure. The fact that the specifications do not include any exclusion criteria is problematic. Developers should revise the specifications to include exclusion criteria (e.g., access barriers, limited life expectancy, or patient refusal.) Developers should define which vaccine is appropriate to meet the requirements of the measure Many patients refuse vaccination because of the high cost, side effects, and painful injection associated with particular vaccines
MIPS ID# 338, NQF# 2082	HIV: Viral Load Suppression	Developers should revise the specifications to include some element of risk adjustment Data presented in the NQF submission material state that ~30%

		of patients who are living with HIV do not have insurance coverage • Data presented in the NQF submission materials appear to support reliability at the individual clinician level of attribution • Specifications should include exclusion criteria for patient refusal and lack of insurance coverage
MIPS ID# 277	Sleep Apnea: Severity Assessment at Initial Diagnosis	 Seems to have a very high burden for reporting with very little yield, but since this is a registry measures presumably this is automated to some extent by the EHR/system OSA is a common diagnosis, however; the developers do not cite a performance gap in the measure details and it seems like this is standard reporting for sleep studies Both the AHI and the RDI are standard tests routinely reported during a sleep study Without a threshold level of abnormality for AHI and RDI, the measure currently lacks the specification to be a useful measure Implementation could cause overuse through repeat testing This is purely reporting and the developers do not cite any evidence to demonstrate the benefit of reporting on clinical and patient outcomes Developers cite that an AHI >15 is correlated with higher CV event risk, but fail to note that the best trial of CPAP showed no evidence of reduction in CV events Developers do not discuss reliability or validity in the measure background materials. A better QI effort may work through other avenues to standardize sleep study conduct and reporting by certifying sleep labs rather than including this concept in MIPS level reporting
MIPS ID# 279:	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy	 This is a common condition, but the developers cite performance data that is based on patient reports for CPAP use vs. objective data. While there is the possibility of improving adherence, the opportunity for improvement is less clear and some of the options included in the measure are no necessarily widely available. It's unclear how to document an objective measure—would clinicians have to scan an image of the "card" in the chart? Would actual values be recorded? Implementation of this measure could address underuse if the specifications required interventions based on the results of the report While we support the inclusion of exclusion criteria that could acknowledge patient experience and preference, the exclusion criteria included in this measure seems a bit broad Success with this measure relies on the patient brining documentation of

		 adherence to the clinic rather than something that the clinician can order or an intervention that the clinician can perform during an office visit, which is an additional step that may be beyond the practice's/clinician's control While this measure represents an important clinical concept, the measure is structured in a way that clinicians can easily game the measure to pass the measure requirements For example, if the patient does not bring the card to their appointment, the clinician can document this as exclusion criteria and receive credit for successfully reporting the measure This measure would likely be more meaningful if assessors implement it at the plan level in order to determine how often patients are actually using the CPAP machines which could therefore; drive improvements in outcomes related to costs
MIPS ID# 337	Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier — National Quality Strategy Domain: Effective Clinical Care	 This measure addresses a very narrow scope with limited potential for impact. Developers do not cite any performance data in the measure background materials Developers cite soft (level B) evidence to form the basis of the measure Developers do not specify which TB tests are acceptable to meet the requirements of the measure Seems like confirmation of TB test administration through the EMR would be reasonable as opposed to confirmation via letter The time interval is consensus based but it's reasonable While we agree it is important for clinicians to test for TB prior to initiation of treatment with Anti-TNF therapy, we are not aware of any evidence for the need to test annually Specifications should mention the use of quant gold as an option for screening Documentation requirements are illogical unless this measure is facilitated by a registry
MIPS ID# 383, NQF# 1879	Adherence to Antipsychotic Medications for Individuals with Schizophrenia	 This measure represents an important clinical concept although the reliability in the proposed use case is low for patient thresholds of < 45 people The measure specifications should include some element of risk adjustment in order to avoid penalizing clinicians who treat a larger proportion of patients with more severe disease This measure may be more beneficial if implemented in plan-level reporting programs where the measure could promote improvement in care management rather than targeting individual clinicians who are doing their best to treat a difficult population We would be more supportive of this measure if the developers cited

		strong evidence for how best to improve adherence among this patients who are included in this population
MIPS ID# 112, NQF# 2372	Breast Cancer Screening	 Developers do not cite performance data to justify the potential impact of implanting this measure Developers designed and tested this measure for use at the plan level of reporting and the measure does not have a track record for improving care if implemented at the individual clinician level of reporting Implementation could promote overuse of unnecessary screening tests Specifications should include exclusion criteria for patients who are diagnosed with life-limiting conditions