

September 6, 2022

Chiquita Brooks-LaSure Administrator Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies **[RIN: 0938-AU81]**

Dear Administrator Brooks-LaSure:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) Notice of Proposed Rulemaking regarding changes to the Medicare Physician Fee Schedule (PFS), Quality Payment Program (QPP), and other federal programs for Calendar Year (CY) 2023 and beyond. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 160,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

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

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I. Summary of Top Priority Recommendations

(A) Regulatory Impact Analysis

- Conversion Factor: ACP understands that CMS cannot unilaterally address the scheduled CY23 cuts, and we call on Congress to reinstate the positive adjustment, waive the 4 percent PAYGO requirement, and make a significant time and monetary investment into ensuring that those who need care are able to receive it. The College also urges CMS – and congressional leaders – to address the greater challenge of the long-standing issue of budget neutrality.
- ii. **Clinical Labor Pricing Update:** The College is pleased that CMS has implemented a fouryear transition to update clinical labor pricing. ACP encourages CMS to partner with physician organizations to determine how to update the cost data more frequently and fairly compensate physicians for rising rates of clinical labor, including the impact of inflation and increased needs for clinical staff due to demand.
- (B) Rebasing and Revising the Medicare Economic Index; Strategies for Updates to Practice Expense Data Collection and Methodology
 - i. ACP is encouraged by CMS' call for comment on updates to PE data collection and methodology and strongly encourages CMS to collaborate with physician organizations, including both small and large physician practices. ACP further recommends that any updates be postponed until there has been an opportunity to examine *all* possible avenues and stakeholders have had a chance to perform a cost-benefit analysis for each, including assessing the impact to physician practices that provide care for the most vulnerable populations and the burdensome and onerous tasks that may accompany these efforts, particularly if repeated on an ongoing basis. The College also strongly recommends CMS work with congressional leaders to address the fundamental challenges with the PFS system, incorporate specialty society input, and maintain transparency and open communication.
- (C) Potentially Misvalued Services Under the Physician Fee Schedule, and Valuation of Specific Codes
 - i. Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474): The College continues to reiterate to CMS the importance of reimbursement for vaccine counseling, not just administration. ACP strongly urge the Agency to work with stake holders in creating and reimbursing for vaccine counseling codes.
 - ii. Code Descriptor Changes for Annual Alcohol Misuse and Annual Depression Screenings (HCPCS Codes G0442 and G0444): The College supports the proposed modifications to G0442 and G0444 as part of an effort to allow physicians to efficiently furnish the service, absent minimum time requirements. ACP would further recommend that CMS take an additional look at whether G0442 and G0444 should be reevaluated to ensure sufficient reimbursement that supports utilization and increasing need across the beneficiary population.
 - iii. Chronic Pain Management and Treatment Bundles (HCPCS GYYY1 and GYYY2): ACP agrees and supports the proposed revisions to the chronic pain management codes. The College believes it would be beneficial to allow separate payment for pain management

and treatment services. The College would also recommend that CMS consider defining chronic pain as "persistent or recurrent pain lasting longer than one month."

- iv. Behavioral Health Services: The College is deeply supportive of CMS' efforts to improve access to behavioral health services, support health equity, and provide physicians the tools needed to meet the mental and behavioral health needs of diverse communities. ACP also supports reimbursing General BHI services when a CP or LCSW is a focal point of care integration under the direct supervision of the primary care physician.
- (D) Evaluation and Management (E/M) Visits, including Valuation and Split (or Shared) Visits
 - E/M Visits, including Hospital Inpatient and Observation (CPT Codes 99221-99236); Hospital and Observation Discharge Day Management (CPT Codes 99217, 99238, and 99239); and Valuation of Prolonged Inpatient or Observation E/M Services (HCPCS Codes GXXX1, GXXX2, and GXXX3): The College is extremely supportive of the Agency's proposal to accept the work RVU recommendations for the hospital inpatient or observation codes, nursing facility codes, home or residence visit codes, emergency department visits, and prolonged service codes. However, ACP has significant concerns regarding the Agency's prolonged services codes proposals. The College believes that having two different methodologies for reporting prolonged services in specific settings will create administrative burden, increases the potential for improper reporting, and is counter to the guiding principles of the CPT/RUC Workgroup on E/M.
 - ii. **Cognitive Assessment and Care Planning (CPT Code 99483):** The College supports CMS' proposal to increase CPT code 99483 from the current RVUs of 3.80 to 3.84 to account for the increase in physician time.
 - iii. Split (or Shared) Visits: The College is pleased that for CY23, CMS is proposing to delay the definitional changes to the split/shared visits policy finalized in CY22; however, this proposal does not resolve the concerns. The College recommends CMS rework its proposal to promote consistency across the E/M code family by transitioning to using either MDM or time to determine the substantive portion of the visit. We encourage CMS to work with specialty organizations to determine appropriate steps to facilitate the recommendation. ACP further encourages CMS to collaborate with the CPT/RUC Workgroup on E/M to address clarification and definitional requirements that would substantiate MDM in this context.

(E) Strategies for Improving Global Surgical Package Valuation

- i. In accordance with numerous studies, including the <u>RAND report</u>, the College believes that majority of the visits in the global period are not being furnished but are paid for, nonetheless. The College believes it is of foremost importance that CMS maintain integrity in the Medicare PFS and ensure patients receive high-quality care. However, we caution against the wholesale approach of eliminating the 90-day global periods in one fell swoop. ACP recommends an incremental approach to improving the global surgical package valuation, starting with the most egregious: 10-day global periods. The College also strongly recommends CMS' involvement via CPT-RUC and believes the collaboration with specialty societies will be integral to ensuring we appropriately compensate for *only* work that is being done and expenses *actually* incurred.
- (F) Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order

i. ACP is pleased that CMS has revised its policy to permit audiologists to furnish certain diagnostic tests. The College is confident that these revisions will broaden patient access to these services and remove the administrative burden associated with the requirement that physicians must approve audiology tests.

(G) Medicare Parts A and B Payment for Dental Services

i. ACP is pleased that the CY23 PFS proposed rule includes increases in facility fees for dental surgeries performed in hospital operating rooms. However, for reasons stated through this letter, ACP strongly cautions CMS against adding any such services that affect budget neutrality. The College also wishes to use this opportunity to point out that the (unfortunate) reality of these concerns only further underscores the need to address budget neutrality and the derivatives that constrain the collective efforts of medicine.

(H) Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

i. ACP is very pleased that CMS has taken steps to update Medicare coverage and payment policies to make it easier to get colorectal cancer screenings and help improve access to earlier treatment.

(I) Telehealth

- Telephone E/M Services; Requests to Add and Proposals to Remove Services to the Medicare Telehealth Services List: The College is pleased that several services are proposed to be added to the Medicare telehealth services list; however, we are deeply disappointed that audio-only E/M services (CPT codes 99441-99443) are set to be removed following expiration of the PHE and the 151-day provided for via legislation. ACP urges CMS to not further impede access due to a statutory landscape that should be appropriately revised, and we encourage CMS to collaborate with the CPT-RUC Telemedicine Office Visits Workgroup to assess available data and determine accurate coding and valuation for E/M office visits performed via audio-visual *and* audio-only modalities. ACP fully supports the continued coverage of audio-only E/M codes and via the CPT-RUC Workgroup, we are confident that CMS could address practice expense inputs and review data to determine what revisions may be necessary to ensure that compensation is adequate and the beneficiary population's access to audio-only services is preserved.
- ii. Emotional/behavior Assessment, Psychological, or Neuropsychological Testing and Evaluation Services: While ACP agrees there may be concern that some patients may not be able to be fully assessed via interactive audio-visual technology, the College feels the benefits outweigh the concerns. Emotional/behavior health is in crisis and providing additional ways to close the gap in this area in patient care is a move in the right direction.
- iii. **Proposed New G Codes to Replace Existing Prolonged Services CPT Codes:** Please see top recommendations for section (D)(i) above.
- iv. Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID-19: The College encourages CMS to collaborate with the CPT-RUC Telemedicine Office Visits Workgroup to ensure appropriate coding of visits performed via telehealth. While ACP believes use of a modifier and the appropriate POS code could inform the

Agency's tracking and inform future decision-making, we caution CMS against increasing administrative burden.

- v. **Expiration of PHE Flexibilities for Direct Supervision Requirements:** The College opposes the proposed policy to revert to synchronous direct supervision because this places an extra onus on the preceptor/supervisor to be in the same vicinity as the supervisee (the resident or fellow the physician is supervising). ACP strongly believes that direct supervision does not have to be synchronous and there is no reason to require synchronous direct supervision.
- Originating Site/Implementation of 2021 and 2022 Consolidated Appropriation Acts: vi. The College is very pleased that CMS is proposing to implement provisions of the 2021 and 2022 CAAs that allow a patient's home as an originating site for mental health telehealth services furnished on or after the end of the COVID-19 PHE. However, the College is disappointed that CMS did not broaden the scope of services for which geographic restrictions do not apply to include telehealth services furnished not only for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, but also all other telehealth services as approved at the time, effective for services furnished on or after the end of the PHE. The College continues to recommend that CMS permanently extend the policy to waive geographical and originating site restrictions after the conclusion of the PHE for all telehealth services. ACP strongly stands behind the continued coverage of audio-only services; when clinicians do not offer audio-only services, additional disparities in care are created and perpetuated. The College is disappointed that CMS will be implementing provisions of the 2021 and 2022 CAAs that establish a 6-month in person requirement for mental health telehealth services. While the College is pleased that the CAA will extend certain telehealth services for 151 days after the end of the PHE, ACP questions why these extensions would be limited to 151 days and would not be made permanent.

(J) Clinical Laboratory Fee Schedule: Proposal to Codify the Laboratory Specimen Collection Fee

- i. ACP does not believe the proposal to maintain the \$3 fee appropriately accounts for the cost of furnishing the service, nor the fact that costs have risen yet the collection fee has remained the same for several years. The College strongly urges CMS to revise its proposal to increase payments commensurate with the costs of performing the service.
- (K) Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) furnished by Opioid Treatment Programs (OTPs) Services
 - i. **Mobile Components Operated by OTPs:** ACP supports CMS' proposal to clarify that the geographic adjustment for medically reasonable and necessary Opioid Treatment Program (OTP) services provided via an OTP mobile unit will be treated as if they were delivered at a physical OTP facility.
 - Flexibilities for OTPs to Use Telecommunications for Initiation of Treatment with Buprenorphine: ACP supports maintaining flexibilities to allow audio-only initiation of buprenorphine treatment when audio-video capabilities are unavailable.
- (L) Electronic Prescribing of Controlled Substances (EPCS)
 - i. We do not object to CMS' proposal to modify this exception to be based on Prescription Drug Event (PDE) data from the current *evaluated* year instead of the *preceding* year to determine whether a prescriber qualifies for an exception based on the number of Part

D controlled substances claims. ACP is supportive of the alternative outlined for the CY 2023 year only, in which CMS would recognize a prescriber as a small prescriber for purposes of the exception if the prescriber had fewer than 100 Part D controlled substances prescriptions in 2022 or fewer than 100 Part D controlled substances prescriptions in 2023.

(M) Request for Information re: Potential Future EPCS Penalties

- i. ACP is very pleased that CMS is proposing to adjust the timeframe during which the Agency would issue non-compliance letters to non-compliant prescribers from the CY23 EPCS program implementation year (January 1, 2023, through December 31, 2023) to the CY24 year (January 1, 2024, through December 31, 2024). ACP continues to recommend CMS study the true costs and implications of the EPCS mandate on clinicians. ACP continues to recommend that a backup system, such as paper or telephone, should be established to accommodate systems going down or other technological barriers. The College believes state-level penalties are sufficient for encouraging EPCS adoption and compliance and is strongly opposed to imposing a secondary layer of penalties and enforcement on physicians who already face EPCS compliance requirements and enforcement at the state level. The College is also vigorously opposed to the notion of criminalizing noncompliance. Should CMS move forward with its proposals to penalize EPCS noncompliance, the College would not be opposed to the use of corrective action plans.
- (N) Request for Information re: Advancing to Digital Quality Measurement and the Use of FHIR(R) in Physician Quality Programs
 - i. While the College is generally supportive of FHIR and the goals underlying these proposals, ACP believes the Agency's proposal to fully transition to digital quality measurement (dQM) by 2025 is unachievable. The College emphasizes its previous recommendation to CMS to focus on one significant modification at a time. ACP believes that CMS and ONC's goal of achieving data interoperability would be much more successful if regulations like these were directed towards EHR vendors instead of physicians, and the College strongly encourages CMS to collaborate with stakeholders to greater understand the real-world circumstances that influence these proposed changes.

(O) Request for Information re: Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)

i. Despite the many important and necessary improvements that have been made in various drafts of TEFCA, the College believes that current efforts to improve interoperability, including advances in TEFCA, still do not adequately address the financial and technological burdens associated with these proposals. The College encourages the Agency to further collaborate with stakeholders to better understand which aspects of these interoperability issues are within physician and practice control, and which problems could be solved most effectively through vendor regulation. Additionally, the College once again urges CMS to consider the cost- and resource-related burdens of its proposals on small and independent practices.

(P) Traditional MIPS

i. Quality Performance: High Priority Measure

a. While the ACP is pleased with the prospect of expanding the definition of a high priority measure to include health equity-related measures, the College would appreciate greater specification on the guardrails of such a measure.

ii. Quality Performance: CAHPS for MIPS Survey

a. The College is encouraged by the proposed changes to the CAHPS for MIPS Survey measure which proposes to replace the "Asian language survey completion" case-mix factor with "language other than English spoken at home."

iii. Quality Performance: Scoring Changes

a. ACP agrees that using performance year benchmarks to score administrative claims measures would provide a more accurate reflection of physician performance. However, CMS should continue to use historical benchmark data for administrative claims measures that do not have performance year benchmarks.

iv. Quality Performance: Data Completeness

- a. ACP does not support the proposed data completeness criteria of 75 percent. While ACP understands that the intent of a higher data completeness threshold is to provide a more comprehensive view of performance, clinicians are still adjusting from the ongoing COVID-19 public health emergency (PHE).
- v. Quality Performance: Changes to the Internal Medicine Specialty Quality Measure Set a.See "Measures Proposed for Addition to the Measure Set" Table
- vi. Quality Performance: Measures Proposed for Removal from the Measure Set a.See "Measures Proposed for Removal from the Measure Set" Table

vii. Cost Performance Category: Measures and Scoring

a. ACP is supportive of setting the maximum cost improvement score at 1 percentage point out of 100 for the cost performance category beginning with the 2022 performance period. Additionally, the College encourages a delay in increasing the maximum in future years. This will allow clinicians further flexibility as they get accustomed to the cost measures and continue to navigate practicing throughout the ongoing COVID-19 pandemic.

viii. Improvement Activities

a. The College is pleased by the proposed changes to the IAs measure set and continues to be supportive of the streamlining of improvement activities and elimination of duplicative IAs.

ix. Promoting Interoperability

- a. ACP does not support the proposal to discontinue automatic reweighting for select healthcare professionals and encourages CMS to continue automatic reweighting for the duration of the PHE so as to not infer undue administrative burden.
- b. The College is pleased that CMS is proposing increased reporting flexibilities for those participating in MIPS at the APM entity level.
- c. ACP is disappointed in CMS' proposal to make the PDMP measure mandatory, however, appreciates the proposed expanded scope of the measure.

- x. Health Information Exchange Objective: Proposed Addition of an Alternative Measure for Enabling Exchange under TEFCA
 - **a.** The College is disappointed that this new alternative measure requires "all-ornothing" performance and fails to account for the significant expense to clinicians who wish to report. In the event that CMS finalizes the proposed addition, ACP would recommend the measure remain optional.

(Q) Public Health Reporting and Information Blocking

i. We remain concerned that understanding how these complex information blocking provisions and exceptions interact with and potentially impact public health reporting requirements will be challenging for our physician members, and we recommend postponing any additional requirements until staffing shortages have eased. The College also recommends that ONC, in coordination with other agencies, develop further guidance materials providing physicians with a baseline for what is required to comply with public health reporting requirements in the context of these important information blocking regulations. The College implores CMS to consider the recommendations and questions raised in a recent joint letter urging HHS to clarify penalties and other important aspects of information blocking regulations.

(R) Request for Information re: Patient Access to Health Information Measure

i. ACP encourages CMS partner with ONC to mandate vendors have a baseline standard of usability. The College would like to see more details from the Agency regarding how it intends to define "patients adding information to their record." The College encourages CMS to consider how these proposals, if implemented, could significantly add to administrative burden for physicians and their care teams and work with stakeholders to improve patient access without assigning clinicians more administrative responsibility.

(S) MIPS Value Pathway (MVPs)

i. MVP Vision Overview

- a. ACP strongly supports the stated goals of MVPs to reduce reporting burden and complexity within MIPS while improving the accuracy and effectiveness of performance measurement, aligning with longstanding ACP priorities.
- b.ACP does not support making MVP participation mandatory starting in PY2028.

ii. MVPs and APM Participant Reporting Request for Information (from PR)

- a. The College agrees with many of the concerns expressed by CMS regarding the alignment between MVPs and APMs.
- b. The College encourages CMS to revisit such proposals for relevant APM options that may better facilitate transition from MVPs to APMs.
- c. The College urges CMS to review and consider implementing and /or incorporating the <u>Medical Neighborhood Model</u> (MNM) as an APM option for practices that participate in MVPs to transition into.

iii. MVP Development

a. ACP agrees that CMS should work with clinicians and specialty societies to develop and consider new MVPs.

b. The College believes it is crucial that other stakeholder feedback is sought, particularly from other clinicians not involved in the development of MVP as well as patients.

iv. MVP Maintenance Process and Engagement with Interested Parties

a. ACP approves of CMS's proposal to standardize the process for annual maintenance of MVPs.

v. Proposed Revisions to Previously Finalized MVPs

a. ACP supports CMS's modification to the Optimizing Chronic Disease Prevention (OCDM) MVP. See "Measures in Optimizing Chronic Disease Management MVP PFS 2023 Proposed Rule" Chart.

vi. Proposed New MVPs

- a. ACP applauds CMS's inclusion of the Promoting Wellness MVP.
- b. The College is pleased to see many of the changes that have been proposed by CMS with regards to measure additions and measure removals. See "Measures in Promoting Wellness MVP PFS 2023 Proposed Rule" Chart.

vii. MVP Reporting Requirements

a. ACP continues to highlight that changes to truly reinvent MIPS with MVPs, CMS must create synergy across the four performance categories and make adjustments to measures and metrics within the Promoting Interoperability and Cost Categories.

viii. Reporting MVPs and Team-Based Care

a. ACP continues to strongly oppose making sub-group reporting mandatory.

ix. Scoring MVP Performance

a. ACP supports applying the highest of scores reported.

(T) Medicare Shared Savings Program

i. Advance Investment Payments

a. While further thought may be warranted in the definition of high/low revenue ACOs as it impacts FQHCs/RHCs, this proposal seems to be a step in the right direction.

ii. Glide Path

a. ACP is encouraged by the proposal to allow ACOs inexperienced with downside risk up to seven years in one-sided risk before transitioning to two-sided risk.

iii. eCQM/MIPS CQMs and Health Equity Adjustment

- a. The College is pleased with the proposal to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the sunsetting of the CMS Web Interface reporting option.
- b. The College is encouraged to see a health equity adjustment but is critical of the eligibility criteria as eligibility is determined through the Area Deprivation Index (ADI) which may correctly identify some disadvantaged areas and improperly assess others.

(U) Advanced Alternative Payment Models

i. 5% APM Bonus

a. The College is disappointed to see that CMS has not proposed the extension of the 5% lump sum APM incentive payment.

b. ACP is calling on Congress to intervene to provide CMS with the statutory authority.

ii. **<u>QP Threshold</u>**

- a. ACP expresses disappointment that the QP threshold will not be frozen and is proposed to increase to 75 points for the 2023 performance year.
- b.For future performance thresholds, ACP suggests using the mean or median from 2021 performance year data when it becomes available.

iii. APM Incentive: Request for Information

- a. The College expresses agreement with many of the concerns mentioned regarding the expiration of the APM Incentive.
- b. The expiration of this incentive will significantly impact the entrance to and retention of APMs.
- c. The limited incentives currently available may not be enough to maintain participation once the APM incentive payment expires.

II. PFS Detailed Recommendations:

Regulatory Impact Analysis

Conversion Factor

CMS Proposed Policy: For CY23, the proposed conversion factor is \$33.08 (rounded), representing a decrease of \$1.53 (or roughly 4.5 percent), as compared to the CY22 conversion factor of \$34.61. This decrease is a result of budget neutrality adjustments, as required by law, as well as the required statutory update to the conversion factor for CY23 of zero percent and the expiration of the three percent increase to physician payments for CY22. The zero percent update is due to CMS' federal obligation to implement a zero percent conversion factor in FY23 and ensure payment rates for individual services do not significantly impact estimated Medicare spending. The expiration of the three percent increase was mandated by the Protecting Medicare and American Farmers from Sequester Cuts Act and was an attempt from Congress to temporarily boost physician reimbursement to mitigate the impact of pandemic-related expenses.

<u>Table 138</u> of the CY23 PFS proposed rule shows the payment impact of the policies contained in the proposed rule on PFS services, inclusive of the proposed impact to Internal Medicine physicians and its subspecialties. For the CY23 rulemaking cycle, the Agency has provided an additional impact table, <u>Table 139</u>, that includes a facility/non-facility breakout of payment changes.

ACP Comments: The College has significant concerns with the continued trend that is devaluing physician services. We continue to urge CMS to work with congressional leaders to recognize the cumulative impact that the proposed (and pending) cuts will have on our healthcare community and patients. For CY23, physicians could be faced with the following: a 1.5 percent cut due to the budget neutrality adjustment; expiration of the 3 percent positive adjustment to the CY22 conversion factor provided by the Protecting Medicare and American Farmers from Sequester Cuts Act; pending PAYGO sequestration cuts of 4 percent; and termination of the 2 percent sequestration moratorium. When combined, physicians face approximately a 10.5 percent cut to payment reduction, and this fails to

account for <u>decades of dis-investment</u> nor a nearly 10 percent inflation rate that has driven up costs for both physicians and their patients. The College has <u>warned</u> that these cuts are unsustainable and negatively impact the Medicare product, and as a result, we are quickly approaching a time where millions of beneficiaries could be without a dependable option for healthcare. ACP understands that CMS cannot unilaterally address these cuts and we call on Congress to reinstate the positive adjustment, waive the 4 percent PAYGO requirement, and make a significant time and monetary investment into ensuring that those who need care are able to receive it.

Though physicians are alarmed by the continued uncertainty regarding the conversion factor and the overall impact on reimbursement, we are also deeply concerned about the impact to patient access and health equity. An MGMA report conducted in 2019 found that over 67 percent of medical practices reported that Medicare payments would not cover the cost of delivering care to beneficiaries. Since its release, the healthcare community has endured a global pandemic and rising costs due to inflation, yet physician payments have continued to fall. These are all factors that contribute to the growing disparities in access to care and physician shortages. As a result, physicians are facing a crisis that has weighed heavily on their ability to accept new Medicare beneficiaries due to ever-decreasing reimbursement rates. The College urges CMS to seriously consider the impacts to patient access and ensure that Medicare remains a robust, dependable option for those who need it the most.

The College also urges CMS – and congressional leaders – to address the greater challenge of the longstanding issue of budget neutrality. The College recently joined over 100 organizations in expressing concerns about the proposed payment cuts and the overall financial instability of the PFS. Medicare reform is a long-term objective that should also include addressing shortfalls in MACRA and working with congressional leaders to safeguard the Medicare product, incentivize collaboration, and support health equity. To begin reversing the threat to access, support physician practices, and address the longterm instability in the Medicare PFS, the College strongly recommends CMS and Congress address the fundamental distortions in the process itself. ACP welcomes the opportunity to work alongside CMS to address both short- and long-term policy change.

Clinical Labor Pricing Update

CMS Proposed Policy: As discussed in the College's CY 2022 summary of the PFS final rule, in CY19, CMS updated the supply and equipment prices used for practice expense (PE) as part of a market-based pricing transition; CY22 was the final year of this four-year transition. At that time, however, the Agency did not propose to update the clinical labor pricing. Clinical labor rates were last updated for CY02. In our CY22 comments to the Agency, ACP raised concerns that the long delay created a significant disparity between CMS' clinical wage data and the market average for clinical labor. As a result, for CY22, the Agency finalized a multi-year transition to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates, thereby promoting payment stability from year-to-year. For CY23, the Agency is requesting feedback on the continued update to clinical labor pricing, as well as any data that will improve the accuracy of the final pricing.

ACP Comments: As discussed in our CY22 <u>comments</u> on the FFS final rule, **the College is pleased that CMS has implemented a four-year transition to update clinical labor pricing.** We are also pleased that CMS has continued with that update for CY23, to be completed in CY25. The College appreciates the Agency's intent to continue to examine its processes to increase transparency and consistency. This update is long overdue and most appropriate as wage rates are inadequate, do not reflect current labor rate information, and result in distortions in the allocation of direct PE. We remain encouraged that those physicians who rely primarily on clinical labor rather than supplies and equipment will receive relative increases that are commensurate with their true costs. ACP encourages CMS to partner with physician organizations to determine how to update the cost data more frequently and fairly compensate physicians for rising rates of clinical labor, including the impact of inflation and increased needs for clinical staff due to demand.

<u>Rebasing and Revising the Medicare Economic Index (MEI); Strategies for Updates to Practice Expense</u> <u>Data Collection and Methodology</u>.

CMS Proposed Policy: The PE inputs used in settings PFS rates, including both the development of PE RVUs and, historically, the relative shares among work, PE, and malpractice RVUs across the PFS, are central in developing accurate rates and maintaining appropriate relativity among PFS services and overall payment among the professionals and suppliers paid under the PFS. However, unlike other payment systems with cost reporting systems, PFS data inputs are primarily based on exogenous proprietary data, namely historical survey data, that is over a decade old. Each year, CMS continues to improve accuracy, predictability, and sustainability of updates to the PE valuation methodology. For CY23, the Agency is issuing a comment solicitation to better understand how to improve the collection of PE data inputs and refine the PE methodology. As discussed, last year CMS implemented a final transition year for supply and equipment pricing updates and started the first year of a four-year phase-in update to the clinical labor rates. However, the indirect PE data inputs remain tied to legacy information that is decades old.

To build on this progress, the Agency now believes indirect PE would also benefit from a refresh that implements similar standard and routine updates. Particularly, the Agency believes routine refreshes would reduce the likelihood of unpredictable shifts in payment, especially when such shifts could be driven by the age of data available rather than comprehensive information about changes in actual costs. Of the various PE data inputs, CMS believes that indirect PE data inputs, which reflect costs such as office rent, IT costs, and other non-clinical expenses, present the opportunity to build consistency, transparency, and predictability. As part of this effort, the Agency has contracted with the RAND Corporation to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates.

In the CY23 PFS proposed rule, CMS is signaling its intent to move to a standardized and routine approach to valuation of indirect PE. The Agency welcomes input on topics related, but not limited to, the following:

- Potential approaches to design, revision, and fielding of a PE survey that fosters transparency;
- Mechanisms to ensure that data collection and response sampling adequately represent physicians and non-physician practitioners across various practice ownership types, specialties, geographies, and affiliations;
- Alternatives that would result in more predictable results, increased efficiencies, and reduced burdens;

- Methods to adjust PE to avoid the unintended effects of undervaluing cognitive services due to low indirect PE; and
- Whether the Agency should stagger updates year-to-year for each update or establish "milestone" years at regular intervals during which all direct PE inputs would be updated in the same year.

Notably, the Agency additionally identified that market consolidation, shifts in workforce alignment, and the evolution of types of business entities predominant in health care markets all suggest significant transformation in the composition and proportions of PE required to furnish care. CMS states that ideally, PE data inputs and calculation methodology would better account for indirect/overhead costs, current trends in the delivery of health care, the use of machine learning technology and EHRs, and the cost differentials in independent versus facility-based practices. For these reasons, the Agency is seeking comment on current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations.

ACP Comments: ACP is encouraged by CMS' call for comment on updates to PE data collection and methodology. The data currently utilized for the MEI are profoundly outdated and physician practices across the country continue to be negatively impacted by inaccurate data and the need for allocations to reflect *true* costs. In resolving this discrepancy, the College strongly encourages CMS to collaborate with physician organizations, including both small and large physician practices. ACP further recommends that any updates be postponed until there has been an opportunity to examine *all* possible avenues and stakeholders have had a chance to perform a cost-benefit analysis for each.

As noted by CMS in the CY23 proposed rule, the AMA is currently involved in data collection efforts to develop a sampling method and a design methodology to collect practice cost data at the specialty level. To the extent that these efforts are an avenue for consideration, the College is supportive. **Given the financial and specialty-specific implications, ACP urges complete transparency and participation in these processes to ensure that we establish a system that accurately portrays practice expense.** Currently, the PFS data inputs are primarily based on exogenous proprietary data, namely historical data, that is over a decade old. The lack of any routine in collecting these inputs, particularly indirect costs, has led to a significant distortion that particularly harms internal medicine physicians, as well as their clinical staff and patients. The emergence of EHRs and current trends in the delivery of health care, as well as related healthcare business arrangements and cost differentials in independent versus facility-based practices, necessitate the Agency's move to a standardized, routine approach to indirect PE. Furthermore, since primary care has long been under-supported and costs have only increased over decades (including throughout the COVID-19 pandemic), ACP emphasizes that these shortcomings have only fueled the existing inequities and have harmed physicians in primary care and patients, too.

While ACP is supportive of the AMA's efforts, we request that adequate time is allowed for specialty societies to facilitate the requests of the survey. The financial implications of these decisions are enormous and significant efforts will need to be made to educate membership about the survey and its importance. Furthermore, since PE data, particularly indirect costs, are better known by the office staff than the physician, the AMA and specialty societies will need to ensure that the survey is geared towards the appropriate audience. As CMS points out, there must be representation of small and

independent practices, and this subset of the population is not equipped with the same resources as large health systems; that is, small and independent practices often have one administrative staff person as compared to large health systems that have a host of accountants and financial officers. The College also encourages the AMA to make sure that the language in the survey and the questions asked are easily understood and answerable by both audiences. Along with continued collaboration, the College strongly believes these recommendations retain integrity to the process, ensure adequate data inputs and representative samples, and guard against repeating mistakes of the past.

The College also warns against accelerating burnout and impacts to administrative burden. **We urge both CMS and the AMA to remain cognizant of the impact to physician practices, particularly those small and independent practices that provide care for the most vulnerable populations.** Should CMS continue with its proposal to update values via the MEI, the allocation to physician work could drop from 50.9 percent to 47.3 percent in order to account for the PE increase from 44.8 percent to 51.3 percent. If these shifts continue, what will be left of physician work in the MEI? Unfortunately, these are trends that have been evidenced over the past two decades and in conjunction with the COVID-19 pandemic, an aging population now faces a fleeting primary care workforce that is plagued by declining reimbursements. To re-emphasize, the College believes there is a need for these updates, irrespective of the approach, but we recommend that very close attention is paid to the burdensome and onerous tasks that may accompany these efforts, particularly if repeated on an ongoing basis. To inform these discussions, ACP recommends CMS engage with the healthcare community to balance the need with the burden.

Though the College is supportive of both the AMA and the Agency's intent, we are wary about the benefits of completing these updates in a zero-sum system. As previously discussed, the issues with budget neutrality and its impact on the conversion factor cannot be understated – and these dynamics present a significant drawback: an update in one area conditions a reduction in another. The College strongly believes that PE data inputs must be updated to account for growing costs and should dually account for inflation; however, ACP urges CMS and the AMA to account for how these updates lead to the devaluation of physician work. In moving forward with these proposals and forthcoming updates via rulemaking, the College strongly recommends CMS work with congressional leaders to address the fundamental challenges with the PFS system, incorporate specialty society input, and maintain transparency and open communication.

Potentially Misvalued Services Under the Physician Fee Schedule, and Valuation of Specific Codes

Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474)

CMS Proposed Policy: CMS has attempted to address the reduction in payment rates for the Part B preventive vaccine administration in the last three PFS rulemaking cycles. In this rule CMS is proposing two policy changes related to vaccine administration that could significantly alter the incentive structure for physician-administered vaccines. First, the Agency is proposing a shift in payments for vaccine administration based on stakeholder concerns that insufficient reimbursement is a barrier to administering routinely recommended adult vaccines. Second, CMS proposes a change to quality measures to incentivize adult vaccination and improve uptake, particularly given immunization rates

declined during the COVID-19 pandemic. Both proposals could have an impact on immunization rates for clinician-administered vaccines.

ACP Comments: ACP is pleased to see the proposal to include annual inflation-based adjustments to reimbursement rates, as well as accounting for geographic cost differences. The College agrees that this is a move in the right direction to address the reduction in payment rates for the Part B preventive vaccine administration. Additionally, the College is also very pleased that the higher fee for COVID-19 vaccines is continuing. As vaccine recommendations for boosters change, this will require additional time and resources to ensure patients are up to date. However, according to an Avalere <u>study</u> routine adult immunizations are down across all age groups, and the need to remove as many barriers to physicians recommending and administering vaccines as possible is still needed. The College continues to reiterate to CMS the importance of reimbursement for vaccine counseling, not just administration. ACP strongly urges the Agency to work with stakeholders in creating and reimbursing for vaccine counseling codes.

<u>Code Descriptor Changes for Annual Alcohol Misuse and Annual Depression Screenings (HCPCS Codes</u> <u>G0442 and G0444)</u>

CMS Proposed Policy: Over the past several years, the College has requested that CMS revise the code descriptors for HCPCS codes G0442 and G0444 to state, "up to 15 minutes", allowing physicians to efficiently furnish the service. As currently described, claims for the service are denied where records suggest that a full 15 minutes was not reached. In the CY23 PFS proposed rule, the Agency notes its belief that these screenings may not require a full 15 minutes to perform, so CMS is proposing to revise the descriptor to establish a lower time limit for both codes. Therefore, the proposed modification would read: HCPCS code G0442, "Annual alcohol misuse screening, 5 to 15 minutes", and for HCPCS code G0444, "Annual depression screening, 5 to 15 minutes."

ACP Comments: ACP is pleased that CMS is proposing to revise the code descriptors for HCPCS codes G0442 and G0444. The College believes these revisions will allow physicians to efficiently furnish the service in instances where the total time may not meet the full 15-minute threshold. For 2020, codes G0442 and G0444 have the following utilization rates based on AMA data: G0442 = 759,928 claims; G0444 = 1,939,323 claims. In 2020, there were 37,094,414 individuals enrolled in traditional Medicare, which means only 2 percent of the Medicare population received an alcohol screening and 5 percent received a depression screening. However, according to the <u>National Institute on Alcohol Abuse and Alcoholism</u>, and the <u>National Coverage Determination</u> which established the depression screening service, 25.8 percent of people ages 18 and older reported that they engaged in binge drinking in the past month and approximately 17 percent of persons older than 65 suffer from depression. These data suggest that these preventive services are severely underutilized relative to the percentage of the Medicare population likely to be eligible.

With such a desperate need, it is critical that CMS ensure access to these screenings and not impede physicians' ability to bill for the service or patients' ability to receive the same. For these reasons, the College supports the proposed modifications to G0442 and G0444 as part of an effort to allow physicians to efficiently furnish the service, absent minimum time requirements. ACP would further recommend that CMS take an additional look at whether G0442 and G0444 should be reevaluated to

ensure sufficient reimbursement that supports utilization and increasing need across the beneficiary population.

Chronic Pain Management and Treatment Bundles (HCPCS GYYY1 and GYYY2)

CMS Proposed Policy: In the CY22 PFS final rule, CMS discussed potential new policies for physicians treating patients with chronic pain. In this year's proposed rule, the Agency is proposing a new monthly bundled payment for management of patients with chronic pain, identified as codes GYYY1 and GYYY2.

ACP Comments: ACP agrees and supports the proposed revisions to the chronic pain management codes. The College believes it would be beneficial to allow separate payment for pain management and treatment services. We also understand that CMS is basing their definition of chronic pain similar to the way the CDC has defined chronic pain within its 2016 opioid prescribing Guideline: "Pain that typically lasts >3 months or past the time of normal tissue healing and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause." The College would recommend that CMS consider defining chronic pain as "persistent or recurrent pain lasting longer than one month.

Behavioral Health Services

CMS Proposed Policy: In an effort to improve access to behavioral health services, CMS is proposing to allow licensed professional counselors, marriage and family therapists, and other types of behavioral health practitioners to provide behavioral health services under general (rather than direct) supervision. The Agency is also proposing to create a new behavioral health integration service category, allowing payment for clinical psychologists and licensed clinical social workers who provide integrated behavioral health services as part of a patient's primary care team.

ACP Comments: The College is deeply supportive of CMS' efforts to improve access to behavioral health services. ACP also appreciates the Agency's support for multiple evidence-based models of integrated care, as it allows flexibility to support the behavioral health needs of the community. ACP supports reimbursing general BHI services when a CP or LCSW is a focal point of care integration under the direct supervision of the primary care physician. These needs are particularly prevalent in underserved communities. In these instances, internal medicine physicians are frequently involved in the management of behavioral symptoms and work closely with their psychiatry, neurology, and family medicine colleagues, as well as licensed professional counselors, marriage and family therapists, and other types of behavioral health practitioners. To the extent that CMS' proposals facilitate access to mental and behavioral health treatment, support health equity, and provide physicians the tools needed to meet the mental and behavioral health needs of diverse communities, the College supports the Agency's proposals.

Evaluation and Management (E/M) Visits, including Valuation and Split (or Shared) Visits

<u>E/M Visits, including Hospital Inpatient and Observation (CPT Codes 99221-99236); Hospital and</u> <u>Observation Discharge Day Management (CPT Codes 99217, 99238, and 99239); and Valuation of</u> <u>Prolonged Inpatient or Observation E/M Services (HCPCS Codes GXXX1, GXXX2, and GXXX3)</u> **CMS Proposed Policy:** CMS is proposing to adopt most of the CPT- and RUC-recommended changes to several E/M code families, including hospital inpatient; hospital observation visits; consultations; and services in the emergency department, nursing facility, home, and residence. These proposals are part of the ongoing updates to E/M visits, like those finalized in the CY21 PFS final rule for office/outpatient E/M visit coding and documentation.

ACP Comments: The College is extremely supportive of the Agency's proposal to accept the work RVU recommendations for the hospital inpatient or observation codes, nursing facility codes, home or residence visit codes, emergency department visits, and prolonged service codes. ACP was heavily involved in the development of these recommendations via the CPT-RUC process. If finalized, the College strongly believes that these revisions will lead to a significant reduction of administrative burden given the streamlined descriptors. Furthermore, these revisions will allow for better recognition of the resources involved in these visits, and hospital-based specialties like those within internal medicine may see a much-needed increase compared to prior years. For these reasons, ACP recommends CMS finalize the proposals for all the E/M visits.

However, ACP has significant concerns regarding the prolonged services codes. As proposed, CMS will create three new G codes (GXXX1, GXXX2, and GXXX3) to describe prolonged services for hospital, nursing facility, and home visits, since the Agency believes the CPT reporting guidelines for prolonged service 993X0 will lead to duplicative payment and confusion regarding total time spent per patient. For CY23, CMS also proposes to make CPT codes 99358 and 99359 invalid for Medicare purposes as the Agency asserts it would cause confusion and invite duplicative billing. In response to the CY21 PFS final rule, the College <u>expressed concerns</u> that CMS' decision to not adopt the CPT revisions exactly as recommended would upend the work done by the CPT Editorial Panel and the RUC to clarify the code descriptor for 99417. Rather than doing so, CMS finalized policy for non-payment of 99417 with a substitution to report G2212 (*Prolonged service office or other outpatient*) instead.

The College is concerned that CMS' CY23 proposals for prolonged E/M services create the same issues. Having two different methodologies for reporting prolonged services in specific settings creates administrative burden, increases the potential for improper reporting, and is counter to the guiding principles of the CPT/RUC Workgroup on E/M. The CPT/RUC Workgroup on E/M set out with a goal to create a consistent set of guidelines and the Agency's proposal is antithetical to that objective. Given the Agency's decision to decline to cover 993X0 and make 99358 and 99359 invalid for Medicare purposes, ACP is also concerned that other private health insurers may follow this action. Should other payers follow, their decision, coupled with the fact that many private insurers may decline to cover G codes, means that physicians may go uncompensated for prolonged services provided to patients. Therefore, to ensure consistency, the College strongly encourages CMS to adopt and finalize the CPT revisions for the prolonged inpatient or observation E/M services exactly as recommended.

Cognitive Assessment and Care Planning (CPT Code 99483)

ACP Comments: In February 2021, the CPT Editorial Panel revised CPT code 99483 to replace "50 minutes" from its descriptor with a revised time value determined by the RUC survey to align with the principles underlying the office/outpatient E/M CPT codes. For 2023, the descriptor time will be 60 minutes typical time instead of 50 minutes. Due to the increase in the valuation for office/outpatient E/M visits, CMS finalized in 2021 an increase to the value, from 3.44 to 3.80 work RVUs. In the CY23 PFS

proposed rule, the Agency is deciding not to propose the RUC-recommended work RVU of 3.50 because it believes this service is appropriately valued more highly than the analogous office/outpatient E/M visit code, CPT code 99205. In the interest of supporting access to this service, CMS is instead proposing an increase from the current 3.80 to 3.84 to account for the increase in physician time with use of a total time ratio. The College supports this proposal to increase CPT code 99483 from the current work RVUs of 3.80 to 3.84. ACP believes this increase more appropriately accounts for the increase in physician time spent and we appreciate CMS' intent to compensate that time accordingly.

Split (or Shared) Visits

CMS Proposed Policy: For CY23, CMS is proposing to delay the split (or shared) visits policy finalized in CY22 for the definition of substantive portion until January 1, 2024. Rather than the substantive portion being defined as more than half of the total time, the substantive portion of a visit may be met by any of the following elements:

- 1. History;
- 2. Performing a physical exam;
- 3. Medical decision making; or
- 4. Spending more than half of the total time.

The Agency notes that this delay is a direct result of ongoing concerns from the College and other stakeholders that relate to practice patterns, as well as possible adjustments needed to the practice's internal processes or information systems to track visits based on time, rather than MDM. Although proposing a delay in the transition, CMS continues to believe it is appropriate to define the substantive portion of a split (or shared) service as more than half of the total time. This proposal, however, is intended to allow for the changes in the coding and payment policies for inpatient or observation E/M visits to take effect for CY23 and allows for a one-year transition for physicians and other practitioners to get accustomed to the new changes and adopt their workflow in practice.

ACP Comments: In response to the CY22 FFS final rule, ACP and nearly twenty other organizations <u>expressed concerns</u> regarding CMS' policies on split/shared E/M visits. Based on CMS' policy that the substantive portion would be defined only as more than 50 percent of the total time spent, we cautioned against the implications for physician-advanced practitioner (AP) reimbursement plans, as well as the detrimental impact on the care delivery model and the patient experience. Therefore, we urged CMS to discontinue its policy and not move forward with the transition set to take effect in 2023.

The College is pleased that for CY23, CMS is proposing to delay the definitional changes to the split/shared visits policy finalized in CY22. However, it is important to note that this does not resolve the concerns that we outlined previously. Additionally, allowing only one year to educate the physician and AP community is a lofty task. ACP strongly <u>supports</u> collaboration between primary care, specialty care, and AP teams to improve care coordination, clinical outcomes, patient and clinician satisfaction, and costs. In realizing the value of team-based care, we believe CMS should recognize the physician contributions and appropriately compensate the time it takes to supervise and furnish these services. For these reasons, the College recommends CMS rework its proposal.

To promote consistency across the E/M code family, ACP recommends that CMS transition to using either MDM or time to determine the substantive portion of the visit. This alternative would align with the 2021 office and outpatient (O/O) E/M changes as well as forthcoming changes to the inpatient code

family. ACP further recommends that when the physician participates and meaningfully contributes to the MDM, even if the physician does not perform the MDM in its entirety, or when the physician meets the time threshold, then the criteria for performing the substantive portion of the visit will have been met. ACP believes this would better account for the physician's contributions in collaborating with the AP, particularly when involved in cases with greater complexity. The alternative also encourages APs to work to the top of their license, consulting with the physician when the situation is particularly difficult. In these situations, the physician is performing the key component of the visit and has meaningfully contributed, though not necessarily spending more than half of the total time. If CMS were to finalize its policy as proposed, however, the physician's work would be discounted when their expertise was sought due to increased patient complexity.

The MDM components to support the billing of the split/shared visit should also align with the key elements finalized with the 2021 O/O visits. MDM, provided by the physician, is what determines the plan of care. The College understands CMS' concerns regarding auditability of the complexity in split/shared visits, but we believe an attestation requirement could sufficiently resolve these concerns and supports the Agency's goal of maintaining integrity. Simultaneously, the concept of collaborative practice is preserved and the negative downstream impact on the patient experience is removed. **Should CMS move forward with attestation statements, however, the College cautions against doing so in a way that adds onto the already-existing burdens to physicians.** We encourage CMS to work with specialty organizations to determine appropriate steps to facilitate the recommendation. **ACP further encourages CMS to collaborate with the CPT/RUC Workgroup on E/M to address clarification and definitional requirements that would substantiate MDM in this context.**

Strategies for Improving Global Surgical Package Valuation

ACP Comments: There is no question that as currently described, the global surgical packages are creating significant distortions in the Medicare PFS. In accordance with numerous studies, including the RAND report, the College believes that majority of the visits in the global period are not being furnished but are paid for, nonetheless. Over the past several years, the Office of the Inspector General (OIG) has also <u>questioned</u> whether these visits are being performed, and CMS has gone so far as proposing to eliminate the global periods in the CY21 PFS final rule. These efforts were impeded by legislative actions via MACRA in 2015, and as a result, the distortions are unresolved.

The College believes it is of foremost importance that CMS maintain integrity in the Medicare PFS and ensure patients receive high-quality care. When post-operative visits are paid for despite their not occurring, this challenges the integrity of the system and leaves patients without having received follow-up care. This also impacts professional credibility, transparency, accountability, reliability, and sustainability. Though the College believes the lack of performance of the post-operative visits in the global periods is incredibly problematic, we caution against the wholesale approach of eliminating the 90-day global periods in one fell swoop. There are varying implications to this approach, and we would be remiss to not mention the challenge of addressing the consequences to medical malpractice, physician work, and practice expense.

For these reasons, **ACP recommends an incremental approach to improving the global surgical package** valuation, starting with the most egregious: 10-day global periods. As evidenced by the RAND report, only 4 percent of all expected reporters were observed to have performed the post-operative visits; for 90-day global periods, 39 percent were observed. Even when the definition of "post-operative care" was expanded to address concerns about potential underreporting (i.e., the sensitivity analysis), the patterns were similar to what was observed in the main analysis (10-day global periods = 7 percent; 90-day global periods = 43 percent). These findings support the College's recommendation that CMS should start the updates with the 10-day periods, which will also prove more manageable.

Beginning with the 10-day global period will additionally allow CMS and stakeholders to examine all the challenges regarding the possible separate reporting of E/M codes, as well as the relevant impact to practice expense and physician work. It would further permit time for the specialties to begin doing a self-examination of the 90-day global periods and figuring out how to address the potential overvaluation via the CPT-RUC process. ACP strongly recommends CMS' involvement via CPT-RUC and believes the collaboration with specialty societies will be integral to ensuring we appropriately compensate for only work that is being done and expenses actually incurred. In considering these comments, the College welcomes the opportunity to discuss further with CMS representatives.

Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order

ACP Comments: In the CY97 PFS final rule, CMS established its long-standing policy that all diagnostic tests, including audiology tests, must be ordered by the physician. In the CY98 PFS final rule, the Agency clarified that *only* the physician can approve routine hearing evaluations and since audiologists were not authorized, they were unable to meet the order requirement for these services. In response to stakeholder feedback, CMS is now proposing to revise its policy by removing the order requirement under certain circumstances for certain audiology order services furnished by an audiologist.

ACP is pleased that CMS has revised its policy to permit audiologists to furnish certain diagnostic tests. The College is confident that these revisions will broaden patient access to these services and remove the administrative burden associated with the requirement that physicians must approve audiology tests. Through our <u>Patients Before Paperwork</u> initiative, ACP has strived to reduce administrative complexities and eliminate unessential tasks that detract from patient care and contribute to physician burnout. We believe the elimination of the order requirement will enable greater access and help mitigate ongoing concerns of physician burnout from unnecessary tasks.

Medicare Parts A and B Payment for Dental Services

ACP Comments: ACP is pleased that the CY23 PFS proposed rule includes increases in facility fees for dental surgeries performed in hospital operating rooms. The College believes this policy will increase access to dental rehabilitation surgery for patients who need extensive dental procedures performed in operating rooms. Medicare payment for dental services has long lagged the extensive needs of adult patient access, and these limitations in access have been exacerbated by the COVID-19 pandemic. However, for reasons stated throughout this letter, ACP strongly cautions CMS against adding any such services that affect budget neutrality. It is our hope that improving access to these services would not negatively impact existing Part B payment rates. The College also wishes to use this opportunity to point out that the (unfortunate) reality of these concerns only further underscores the need to address budget neutrality and the derivatives that constrain the collective efforts of medicine.

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

ACP Comments: In CY19, the last year for which incidence data are available, colorectal cancer accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States. Rural communities and communities of color are especially impacted by the incidence of colorectal cancer. Given its prevalence and negative impacts as a result of health inequities, in 2021, the United States Preventive Services Taskforce and the CDC issued a recommendation that adults who do not have signs or symptoms of colorectal cancer and who are at average risk begin screening at age 45 instead of the previous recommendation of age 50. Accordingly, in the CY23 PFS proposed rule, CMS is proposing to modify coverage of certain colorectal cancer screening tests to begin when the individual is age 45 or older. The Agency is also proposing to expand the definition of colorectal cancer screening tests to include follow-on screening colonoscopy after a Medicare-covered non-invasive stool-based screening returns a positive result.

ACP is very pleased that CMS has taken steps to update Medicare coverage and payment policies to make it easier to get colorectal cancer screenings and help improve access to earlier treatment. The College believes these proposals will significantly expand access to quality care and improve health outcomes through prevention, early detection, more effective treatment, and reduced mortality. We are also confident that these proposals will directly advance health equity by promoting access and removing barriers for cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of colorectal cancer.

Telehealth

<u>Telephone E/M Services; Requests to Add and Proposals to Remove Services to the Medicare Telehealth</u> <u>Services List</u>

ACP Comments: ACP is pleased that CMS has continued to recognize the value of telehealth services. Though the COVID-19 pandemic has wreaked havoc on the nation, the provision of services via telehealth has emerged as a silver lining for both physicians and patients. The College is pleased that several services are proposed to be added to the Medicare telehealth services list; however, we are deeply disappointed that audio-only E/M services (CPT codes 99441-99443) are set to be removed following expiration of the PHE and the 151-day provided for via legislation.

As telehealth has emerged as an upside, numerous studies and reports demonstrate that access to audio-only services is imperative to providing access to care for patients in rural, underserved, and urban areas. This modality has extended care to the most vulnerable patients, often for the first time, and physicians and patients across the country support audio-only care for varied reasons. Patients with significant impairments and limited resources often have little to no access to transportation nor audio-visual platforms, and the physician's ability to provide services via audio-only allows greater opportunities for care and maximizes use of the physician and patient time. The proposed removal also detrimentally impacts health equity as <u>studies</u> demonstrate patients in older age groups and those who are Black are more likely to use audio-only telehealth as compared with audio-visual. To remove audio-only E/M codes from coverage is to leave millions of beneficiaries without any resolve.

The College understands that CMS believes it does not have the statutory authority to waive the audiovisual standard that informs the permissible use of telehealth. We also understand the Agency's belief that by their nature, audio-only services cannot meet the requirement that the service be analogous to in-person care by being a substitute for face-to-face care. However, older age groups, the Black population, and beneficiaries in rural communities are already faced with significant hurdles in accessing healthcare, for a variety of reasons. **ACP urges CMS to not further impede access due to a statutory landscape that should be appropriately revised.** In realizing the continued coverage of audio-only E/M services, **ACP also encourages CMS to collaborate with the CPT-RUC Telemedicine Office Visits Workgroup to assess available data and determine accurate coding and valuation for E/M office visits performed via audio-visual** *and* **audio-only modalities.**

For reasons of retaining and improving patient access, supporting health equity, and providing appropriate compensation, ACP fully supports the continued coverage of audio-only E/M codes. The College also encourages CMS to empower physicians as the key decision-maker in determining which services could and should be performed via audio-only versus audio-visual. This discretion should rest with the physician and CMS should trust their clinical decision-making rather than remove coverage altogether. In determining appropriate valuation, ACP is cognizant of the concept that furnishing a service via audio-only may not require the same resource inputs as audio-visual or face-to-face services. However, if there is too big a delta between audio-only and audio-visual or face-to-face care, then audio-only will not be utilized and patients will be without the benefits. To address these factors, the College encourages CMS to engage with the CPT-RUC process to address practice expense inputs and review data to determine what revisions may be necessary to ensure that compensation is adequate and the beneficiary population's access to audio-only services is preserved.

Emotional/behavior Assessment, Psychological, or Neuropsychological Testing and Evaluation Services **ACP Comments:** CMS received several requests to add emotional/behavior, psychological, or neuropsychological testing and evaluation services, including those described by CPT codes 97151-97158, to the Medicare Telehealth Services List permanently on a Category 2 basis. These services are currently on the Medicare Telehealth Services List temporarily for the duration of the PHE. In considering this request, the Agency is proposing to include these services for temporary inclusion on a Category 3 basis. These services were not originally included on a Category 3 basis after the initial assessment, but CMS noted there is likely to be a clinical benefit when furnished via telehealth, so they meet the criteria for temporary inclusion. **While ACP agrees there may be concern that some patients may not be able to be fully assessed via interactive audio-visual technology, the College feels the benefits outweigh the concerns. Emotional/behavior health is in crisis and providing additional ways to close the gap in this area in patient care is a move in the right direction.**

Proposed New G Codes to Replace Existing Prolonged Services CPT Codes

ACP Comments: For comments in this letter, please see *E/M Visits, including Hospital Inpatient and Observation (CPT Codes 99221-99236); Hospital and Observation Discharge Day Management (CPT Codes 99217, 99238, and 99239); and Prolonged Inpatient or Observation E/M Services (HCPCS Codes GXXX1, GXXX2, and GXXX3).*

Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID-19

ACP Comments: As discussed earlier, the AMA has formed a joint CPT-RUC Telemedicine Office Visits Workgroup, which will assess available data and ascertain the appropriate next steps to determine accurate coding and valuation, including the use of modifiers, for E/M office visits performed via audiovisual and audio-only modalities. The College encourages CMS to collaborate with this Workgroup to ensure appropriate coding of visits performed via telehealth. While ACP believes use of a modifier and the appropriate POS code could inform the Agency's tracking and inform future decision-making, we caution CMS against increasing administrative burden. For additional comments in this letter, please see_Telephone E/M Services; Requests to Add and Proposals to Remove Services to the Medicare Telehealth Services List. We look forward to working with CMS to provide appropriate flexibility and ensure revisions to the E/M code family align with collective efforts to reduce burden.

Expiration of PHE Flexibilities for Direct Supervision Requirements

ACP Comments: The College is pleased that CMS is considering making the direct supervision flexibility permanent. In the College's response to the CY22 final rule, ACP advocated for making the direct supervision flexibility permanent based on our belief that doing so would support the expansion of telehealth services and protect frontline health care workers by allowing for appropriate social distancing measures. In our comments, we stated that the College believes that clinicians should feel empowered to supervise clinical staff virtually, at their discretion, regardless of whether there is a PHE.

The College is concerned, however, that the expiration of the direct supervision requirement means that supervision will be required to happen synchronously. The College opposes such a requirement because this places an extra onus on the preceptor/supervisor to be in the same vicinity as the supervisee (i.e., the resident or fellow the physician is supervising). ACP strongly believes that direct supervision does not have to be synchronous and there is no reason to require synchronous direct supervision.

Originating Site/Implementation of 2021 and 2022 Consolidated Appropriation Acts

ACP Comments: The College is very pleased that CMS is proposing to implement provisions of the 2021 and 2022 CAAs that allow a patient's home as an originating site for mental health telehealth services furnished on or after the end of the COVID-19 PHE. ACP has been a proponent of expanding access to mental and behavioral health services, including allowing beneficiaries to access services from home, or if the technology is not available at home, from a rural health clinic or hospital. However, the College is disappointed that CMS did not broaden the scope of services for which geographic restrictions do not apply to include telehealth services furnished *not only* for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, but also all other telehealth services as approved at the time, effective for services furnished on or after the end of the PHE. The College continues to recommend that CMS permanently extend the policy to waive geographical and originating site restrictions after the conclusion of the PHE for *all* telehealth services.

ACP is extremely supportive of CMS expanding audio-only communications technology for mental health telehealth services. ACP continues to believe that because audio-only telehealth services are an important tool for physicians to improve health equity and patient access, and as such, it should not be limited to only patients seeking behavioral and mental health services. HHS itself acknowledges the <u>benefits</u> of audio-only telehealth for addressing health care gaps and inequities. The role of audio-only telehealth in expanding access to care and reducing care disparities among minorities has also been

widely documented in the literature.¹ ACP strongly stands behind the continued coverage of audioonly services; when clinicians do not offer audio-only services, additional disparities in care are created and perpetuated.

The College is also disappointed that CMS will be implementing provisions of the 2021 and 2022 CAAs that establish a 6-month in person requirement for mental health telehealth services. The College believes that there are many positive aspects of both phone and video visits that benefit patients (i.e., access to other family members, transportation issues, the ability to check medications, etc.) and sees no solid rationale or clinical application for requiring a physician to see a patient in person for a mental health exam. This requirement is not based on medical necessity, and the College is opposed to imposing regulations that do not improve patient safety or outcomes. This policy would additionally hamper many psychiatrists who care for patients outside of their locality from continuing to care for many of their patients, unless the in-person visit could be local for the patient and conducted in partnership with a primary care physician. If CMS' imposition of this requirement is based on fraud and abuse concerns for audio-only visits, the Agency should consider the many informatics solutions that could be implemented to eliminate such concerns.

While the College is pleased that the CAA will extend certain telehealth services for 151 days after the end of the PHE, ACP questions why these extensions would be limited to 151 days and would not be made permanent. If these services can be effectively delivered via telehealth for 151 days after the end of the PHE, there appears to be no reason why they cannot be effectively delivered via telehealth thereafter, for the long term. Therefore, we question the arbitrary 151-day limit to coverage of these services and urge CMS to continue to work with Congress and stakeholders to cover these services permanently.

Clinical Laboratory Fee Schedule: Proposal to Codify the Laboratory Specimen Collection Fee Policy

¹ Uscher-Pines L, Sousa J, Jones M, et al. Telehealth Use Among Safety-Net Organizations in California During the COVID-19 Pandemic. *JAMA*. 2021;325(11):1106–1107. doi:10.1001/jama.2021.0282; Hirsch Q, Davis S, Stanford M, et al. Beyond Broadband: Equity, Access, And The Benefits Of Audio-Only Telehealth, *Health Affairs Blog*, September 20, 2021, https://www.healthaffairs.org/do/10.1377/forefront.20210916.819969; Uscher-Pines L, Schulson L. Rethinking The Impact Of Audio-Only Visits On Health Equity, *Health Affairs Forefront*, December 17, 2021. https://www.healthaffairs.org/do/10.1377/forefront.20211215.549778; Health Resources and Services Administration, 2022 National Telehealth Conference Summary Report, May 2022,

https://www.hrsa.gov/sites/default/files/hrsa/rural-health/topics/chsd-national-telehealth-summary-report.pdf; Payán DD, Frehn JL, Garcia L, Tierney AA, Rodriguez HP. Telemedicine implementation and use in community health centers during COVID-19: Clinic personnel and patient perspectives. *SSM - Qualitative Research in Health*. 2022;2. https://doi.org/10.1016/j.ssmqr.2022.100054; AMA, 2021 Telehealth Survey Report, https://www.amaassn.org/system/files/telehealth-survey-report.pdf; Samson L, Tarazi W, Turrini G, Sheingold S. Medicare Beneficiaries' Use of Telehealth in 2020: Trends by Beneficiary Characteristics and Location (Issue Brief No. HP-2021- 27). Office of the Assistant Secretary for Planning and Evaluation, Office of Health Policy, December 2021, https://aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealthreport.pdf; Chu R, Peters, C, De Lew N, Sommers B. State Medicaid Telehealth Policies Before and During the COVID-19 Public Health Emergency (Issue Brief No. HP-2021-17). Office of the Assistant Secretary for Planning and Evaluation, Office of Health Policy, July 2021, https://www.aspe.hhs.gov/sites/default/files/2021-07/medicaidtelehealth-brief.pdf.

ACP Comments: In the CY23 PFS proposed rule, CMS is proposing to codify and clarify various laboratory specimen collection fee polices. The Agency is also soliciting comments on the proposal to maintain the \$3 nominal specimen collection fee amount, including how this amount could be updated. We are appreciative of these efforts to engage with the healthcare community, but the College is concerned that the \$3 nominal fee does not cover the true costs in collecting the sample. While we understand that CMS is statutorily required to pay a "nominal fee to cover the *appropriate* costs", **ACP does not believe the proposal to maintain the \$3 fee appropriately accounts for the cost of furnishing the service, nor the fact that costs have risen yet the collection fee has remained the same for several years. In light of this, the College strongly urges CMS to revise its proposal to increase payments commensurate with the costs of performing the service.** In doing so, ACP encourages CMS to work with healthcare organizations to inform the recommended increases.

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

Mobile Components Operated by OTPs

ACP Comments: Over the last two decades, nearly 500,000 people died from an opioid overdose in the United States. From 2019 to 2020, the number of drug overdoses increased by 31 percent. The increase in drug overdose rates was particularly high for Black and American Indian/Alaska Native populations, who also report difficulty accessing evidence-based substance use disorder treatment. Rural populations also experience substance use disorder treatment barriers. Mobile substance use disorder treatment programs may help improve access to methadone, buprenorphine, and other medication-assisted treatment among underserved populations, including people who are homeless and residents of rural areas. ACP supports CMS' proposal to clarify that the geographic adjustment for medically reasonable and necessary OTP services provided via an OTP mobile unit will be treated as if they were delivered at a physical OTP facility.

Flexibilities for OTPs to Use Telecommunications for Initiation of Treatment with Buprenorphine **ACP Comments:** The COVID-19 pandemic <u>amplified the need</u> for remote substance use disorder treatment options to ensure continuity of care. Flexible prescribing policies issued by the <u>Drug</u> <u>Enforcement Agency</u> and the Substance Abuse and Mental Health Services Administration have helped to provide <u>continuous access to treatment</u> when in-person visits are not possible. In-person buprenorphine treatment may be difficult for the <u>millions of people</u> who do not live close to a buprenorphine-waived prescriber. **ACP supports maintaining flexibilities to allow audio-only initiation of buprenorphine treatment when audio-visual capabilities are unavailable.**

Electronic Prescribing of Controlled Substances (EPCS)

ACP Comments: The College is supportive of the Small Prescriber Exception, having long been concerned that many small and independent physician practices are not in the position to cover the costs and acquire the necessary resources for technical or system upgrades required to incorporate EPCS into their existing EHRs. We do not object to CMS' proposal to modify this exception to be based on Prescription Drug Event (PDE) data from the current *evaluated* year instead of the *preceding* year to determine whether a prescriber qualifies for an exception based on the number of Part D

controlled substances claims. This would allow the Small Prescriber Exception to align with all other exceptions described in the CY22 PFS final rule, which are evaluated based on data from the same year to which the exception is applied, providing consistency for practices.

ACP is also supportive of the alternative outlined for the CY23 year only, in which CMS would recognize a prescriber as a small prescriber for purposes of the exception if the prescriber had fewer than 100 Part D controlled substances prescriptions in 2022 or fewer than 100 Part D controlled substances prescriptions in 2023. While the College understands CMS' reasoning that it would be simpler to have a single set of exceptions for the program versus different rules for different years, the College believes this alternative is accommodating to small practices, considering some prescribers are expecting CMS to use the CY22 PDE data to assess whether the exception applies for purposes of CY23 EPCS compliance (as was outlined in the CY22 PFS).

Request for Information re: Potential Future EPCS Penalties

ACP Comments: ACP is very pleased that CMS is proposing to adjust the timeframe during which the Agency would issue non-compliance letters to non-compliant prescribers from the CY23 EPCS program implementation year (January 1, 2023, through December 31, 2023) to the CY24 year (January 1, 2024, through December 31, 2024). Many clinician practices have not had time to implement the necessary technology and/or are struggling with the costs or other challenges associated with this technology. For example, criticism has been leveled against the costs of two-factor authentication that some third-party vendors are passing onto the practices. Also, since e-prescribing adds an unfunded mandate whereby participating clinicians must pay an annual fee to use—and there are broadband issues for some clinicians—e-prescribing is often an additional burden. For these reasons, ACP continues to recommend CMS study the true costs and implications of this mandate on clinicians. In the meantime, the College welcomes this extension for issuing non-compliance letters.

We remain concerned, however, on the effect of the EPCS requirement for small, independent, and/or rural practices. These under-resourced practices face distinct challenges. For example, in addition to the financial burden of implementing EPCS technology, in some rural parts of states, the EPCS system does not operate consistently due to limited broadband availability or reliability, and there is no manual back-up system in place. Therefore, **ACP continues to recommend that a backup system, such as paper or telephone, should be established to accommodate systems going down or other technological barriers.** In looking forward to January 1, 2025, CMS should pay close attention to the real, true conditions in practice and the downstream implications of its policies—especially to small, independent practices and those in rural areas—and be willing to extend the date of compliance actions in further rulemaking if it is determined that a significant percentage of small, rural, or independent practices are still facing implementation barriers.

Furthermore, we remind CMS that physicians in states where EPCS is required face a wide array of penalties related to their medical license depending on whether they use EPCS. **The College believes these penalties are sufficient for encouraging EPCS adoption and compliance, and we are strongly opposed to imposing a secondary layer of penalties and enforcement on physicians who already face EPCS compliance requirements and enforcement at the state level.**

The College is also vigorously opposed to the notion of criminalizing noncompliance. ACP sees no need to involve the Drug Enforcement Agency in enforcing EPCS compliance. Noncompliance with EPCS requirements can be rooted in a wide range of innocuous issues related to infrastructure, expense, health IT/EHR functionality, and EHR vendors, and these have nothing to do with the fraud, waste, or abuse that CMS seeks to thwart via the proposed penalties. Should CMS move forward with its proposals to penalize EPCS noncompliance, the College would not be opposed to the use of corrective action plans. The College believes that corrective action plans have the benefit of allowing the Agency to understand why a physician or practice is not using EPCS and assuaging the Agency's concerns that reasons for noncompliance are somehow nefarious or that noncompliant prescribers are "bad actors." Furthermore, ACP is opposed to the notion of identifying/naming noncompliant prescribers on any website. Doing so may actually contribute to fraud and abuse by enabling fraudsters to seek care and treatment from physicians who would be publicly singled out for writing paper prescriptions for controlled substances.

Request for Information re: Advancing to Digital Quality Measurement and the Use of FHIR[®] in Physician Quality Programs

ACP Comments: The College commends CMS for working collaboratively with the Office of the National Coordinator (ONC) on their work to improve interoperability and promoting the adoption of Fast Healthcare Interoperability Resource[®] (FHIR) standards and standards-based Application Programming Interfaces (APIs). While the College is generally supportive of FHIR and the goals underlying these proposals, ACP believes the Agency's proposal to fully transition to digital quality measurement (dQM) by 2025 is unachievable. The resources needed to implement this transition are significant, even for large health care systems, and essentially non-existent for small and independent practices. Additionally, the financial burden on practices, especially small and independent practices, would be enormous, as it would be the responsibility of individual health systems or practices to enable these capabilities, rendering them cost-prohibitive for many. As healthcare becomes more digital overall, ACP believes it is crucial for federal agencies, health societies, EHR vendors, and other stakeholders to work together to understand and mitigate the costs of implementing these innovations for small and independent practices.

For these reasons, **the College emphasizes its previous recommendation to CMS to focus on one significant modification at a time.** Progress on many other fronts is necessary before quality measures can function in a truly digital way. In addition to building data collection systems and adapting to new data structure and storage mechanisms, dQMs will also require changes to workflow to which busy physicians and practices will need time to adjust. This, taken in conjunction with the many proposed modifications to the Quality Payment Program (QPP) regarding the inclusion of MIPS Value Pathways (MVPs) as a starting point to transition to APMs remains untenable. We also note that it would be particularly challenging for independent practice physicians and solo practitioners to keep up with these changes given their slower adoption of EHRs as compared to practices that exist within large healthcare systems. Therefore, the College continues to ask CMS to focus on one significant modification at a time and supports the transition to MVPs being the priority given that their development is further along than dQMs and because they are more comprehensive of a change. The College is also concerned that CMS' proposed approaches to advancing the use of standardized data, achieving FHIR-based electronic clinical quality measures (eCQM) reporting, and framing around defining data standards and exchange mechanisms for FHIR-based dQMs are misdirected. While ACP agrees that the standardization of vocabulary and terminology within EHRs is needed, the College does not agree that physicians have control over the vocabulary and/or terminology in their EHRs. ACP encourages the Agency to consider partnering with ONC and requiring EHR vendors to update and standardize their language and maintain consistency between different systems, instead of misguidedly placing the responsibility of this change on physicians and their care teams. The College insists that any potential regulations require vendors to make those mandated changes available to practices free of charge, so that the functionality does not become a component of another "package" of upgrades for which vendors upcharge. ACP believes that CMS and ONC's goal of achieving data interoperability would be much more successful if regulations like these were directed towards EHR vendors instead of physicians, and the College strongly encourages CMS to collaborate with stakeholders to greater understand the real-world circumstances that influence these proposed changes.

Request for Information re: Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)

ACP Comments: ACP supports CMS and ONC's continued partnership and commitment to developing the policies, procedures, and technical framework to facilitate secure, seamless, and sustainable health information exchange to improve care across the entire care continuum. Effective, practical, and secure interoperability is crucial to improving the patient experience and the patient-physician relationship, reducing burden on physicians, and in turn, improving the quality of care.

Despite the many important and necessary improvements that have been made in various drafts of TEFCA, the College believes that current efforts to improve interoperability, including advances in TEFCA, still do not adequately address the financial and technological burdens associated with these proposals. Implementing TEFCA would be an expensive, time-intensive undertaking for even a large health system, and it would be close to impossible for small or independent practices. TEFCA implementation will be financially prohibitive for smaller health systems and practices, because in order to join TEFCA, a practice must join a Health Information Exchange (HIE), and HIE memberships are unreasonably expensive. As with several other proposals in this rule, ACP supports CMS' underlying intent and goals. However, the College encourages the Agency to further collaborate with stakeholders to better understand which aspects of these interoperability issues are within physician and practice control, and which problems could be solved most effectively through vendor regulation. Additionally, the College once again urges CMS to consider the cost- and resource-related burdens of its proposals on small and independent practices.

Updates and Modifications to the Quality Payment Program

Traditional MIPS

Quality Performance Category *Quality Performance: High Priority Measure* ACP Comments: While ACP is pleased with the prospect of expanding the definition of a "high priority" measure to include health equity-related measures, the College would appreciate greater specification on the guardrails of this measure.

Quality Performance: CAHPS for MIPS Survey

ACP Comments: The College is encouraged by the proposed changes to the CAHPS for MIPS Survey measure, which proposes to replace the "Asian language survey completion" case-mix factor with "language other than English spoken at home." This may allow for greater accuracy in capturing language preference. ACP is also pleased to see the proposal to create a shorter CAHPS for MIPS Survey measure which would be more easily utilized by specialty groups. The College has consistently articulated the need for greater opportunity and ease of access for specialists in both MIPS MVPs and APMs. ACP is hopeful that this adjustment is indicative of CMS' continued commitment to provide greater onramps for specialists into value-based payment agreements.

Quality Performance: Scoring Changes

ACP Comments: ACP agrees that using performance year benchmarks to score administrative claims measures would provide a more accurate reflection of physician performance. However, CMS should continue to use historical benchmark data for administrative claims measures that do not have performance year benchmarks.

Quality Performance: Data Completeness

ACP Comment: ACP opposes increasing the proposed data completeness criteria from 70 to 75 percent. While we understand that the intent of a higher data completeness threshold is to provide a more comprehensive view of performance, clinicians are still recovering from the ongoing COVID-19 PHE. 70 percent of all data should be sufficient to provide an accurate representation of clinician performance. A higher data completeness threshold would add more reporting burden to clinicians and divert attention from patient care. ACP urges CMS to maintain the data completeness at 70 percent.

Quality Performance: Changes to the Internal Medicine Specialty Quality Measure Set

CMS has proposed several changes to the Internal Medicine Specialty Measure Set. **ACP's comments** are reflective of the ACP Performance Measurement Committee (PMC) review and the data submitted to the Measure Applications Partnerships (MAP) for the 2022 Measures Under Consideration (MUC).

Quality Measure #	Quality Measure Name	Quality Measure –Description	ACP Comments
176	Tuberculosis Screening Prior to First Course Biologic Therapy	If a patient has been newly prescribed a biologic disease modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12- month period.	ACP supports the adoption of this measure. Biologic Disease-Modifying Anti-Rheumatic (DMARD) therapy can reactivate latent tuberculosis, leading to significant morbidity and even mortality. Administrative data suggests that over 1 in 4 individuals with RA receive biologic DMARDs. Over 1.3 million individuals in the United States have RA; therefore, this measure is expected to impact over

Measures Proposed for Addition to the Measure Set:

Quality Measure #	Quality Measure Name	Quality Measure –Description	ACP Comments
			300,000 Americans with RA. This should only be applicable to physicians who are managing and providing medical therapy for RA. Most often, this measure will apply to rheumatologists, but primary care physicians may also manage RA.
476	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	ACP plans to review this measure but is unable to provide a comment at this time.
TBD	Screening for Social Drivers of Health	Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	ACP agrees that this measure is highly important and would fill a large gap in health care equity. Understanding the environmental difficulties patients face in obtaining care is crucial. ACP urges CMS to delay adoption of this measure until reliability and validity testing data for the performance measure has been completed to ensure the measure is methodologically sound before using this measure in a reimbursement program. Additionally, there are concerns with implementation of this measure at the individual clinician and clinician group levels. This measure is more feasibly implemented at the health plan level, as shared patient information in the health plan reduces the burden on both the patient and the clinician. SDOH measures should only be implemented after adequate resources and tools have been provided to the clinicians and groups, to be able to address those needs once they are identified. This measure should be aligned with other federal efforts to collect such data (e.g., using Z-codes).

Quality	Quality	Quality Measure –Description	ACP Comments	
Measure #	Measure Name			
			ACP would also like to see the measure revised to require the AHC HRSN and other validated instruments.	
TBD	Kidney Health Evaluation	Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.	ACP agrees that this measure fills a gap in care and provides a more comprehensive assessment of kidney health. The measure is supported by a strong evidence base and was tested at the individual and clinician group levels. Though there isn't complete agreement on the benefits of testing for patients on ACE/ARB, ACP believes that monitoring of kidney health is very important to confirm correct dosages of medications and evaluation of the progression of CKD.	
TBD	Adult Immunization Status	Percentage of members 19 years of age and older who are up-to date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	ACP believes that this measure provides an inclusive assessment of adult vaccination status. The evidence base for this measure is strong. However, there are concerns with feasibility at the individual clinician and clinician group attribution levels, as patients do not always go to the same physician to receive all required vaccinations. Additionally, this measure was developed, tested and endorsed at the health plan level, and for this reason, the MAP did not support this measure for use at the individual clinician and clinician group levels. Health plans have ready access to the information required for the measure.	

Quality Parformanca: Magguras Prop	osed for Removal from the Measure Set:
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Quality	Quality	Quality Measure –	ACP Review Date	ACP Review – Rationale
Measure #	Measure Name	Description		
Q110	Preventive Care and Screening: Influenza Immunization	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	November 19, 2017	ACP does not support the removal of Q110 from the Internal Medicine set unless the Adult Immunization Status measure is finalized for adoption. This measure aligns with the clinical recommendations on influenza vaccination from

Quality	Quality	Quality Measure –	ACP Review Date	ACP Review – Rationale
Measure #	Measure Name	Description		the Centers for Disease Control and Preventions (CDC) Advisory Committee. While we support this measure, we suggest developers consider revising the specifications to include exclusion criteria for patient, medical, and system reasons for vaccination not given. Additionally, we note that the measure is nearly topped out with a narrow opportunity for improvement. Developers should include updated performance data in the NQF submission materials for re-endorsement. Lastly, we note that EHR information blocking could prevent the transmission of immunization information between competing
Q111	Pneumococcal Vaccination Status for Older Adults	Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine.	November 19, 2017	electronic systems. ACP supports the removal of this measure from the Internal Medicine measure set. 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.
Q119	Diabetes: Medical Attention	The percentage of patients 18-75 years of age with diabetes who had a nephropathy	November 2018	ACP <u>does not support the</u> <u>removal</u> of this measure from the Internal Medicine measure set unless the

Quality Measure #	Quality Measure Name	Quality Measure – Description	ACP Review Date	ACP Review – Rationale
Quality Measure #	Quality Measure Name For Nephropathy	Quality Measure – Description screening test or evidence of nephropathy during the measurement period.	ACP Review Date	proposed Kidney Health Evaluation measure is finalized for adoption.ACP supports this measure because the opportunity for improvement is well documented, developers cite 2018 clinical recommendations of the American Diabetes Association on "Standards of Medical Care in Diabetes" to form the basis of the measure, the numerator and denominator are well defined, the denominator
				includes well specified and clinically appropriate exceptions to eligibility for the measure, and measurement is repeatable and precise.

Cost Performance Category: Measures and Scoring

ACP Comment: Beginning with the 2022 performance period, CMS is proposing to establish a maximum cost improvement score of 1 percentage point out of 100 percentage points available for the cost performance category starting with the CY22 performance period. As CMS did not establish a maximum improvement score in prior rulemaking, the College agrees that this proposal would clarify the improvement scoring policy. ACP is supportive of setting the maximum cost improvement score at 1 percentage point out of 100 for the cost performance category beginning with the 2022 performance period. Additionally, the College encourages a delay in increasing the maximum in future years. This will allow clinicians further flexibility as they get accustomed to the cost measures and continue to navigate practicing throughout the ongoing COVID-19 pandemic. As stated in our <u>comments</u> on the CY22 PFS Final Rule, ACP continues to have specific concerns, including attributing costs at the group practice level or higher, not attributing the same costs to multiple clinicians/groups, and risk adjusting for social determinants of health.

Improvement Activities

ACP Comments: The College is pleased with the Agency's proposal to establish two new criteria for nominating new Improvement Activities (IAs) to limit duplication of other IAs in the inventory and drive improvements that go beyond standard clinical practices. ACP continues to be supportive of the streamlining of improvement activities and elimination of duplicative IAs. We encourage CMS to continue to develop and adopt more IAs that encourage participation in activities intended to improve patient care during the COVID-19 PHE and beyond.

Promoting Interoperability/Query of Prescription Drug Monitoring Program (PDMP) Measure

ACP Comments: ACP does not support the proposal to discontinue automatic reweighting for select healthcare professionals and encourages CMS to continue automatic reweighting for the duration of the PHE in an effort to not create undue administrative burden. The College is also pleased that CMS is proposing increased reporting flexibilities for those participating in MIPS at the APM entity level. This would allow APM entities to choose between reporting PI data at the individual, group, and APM entity level.

ACP is additionally disappointed in CMS' proposal to make the PDMP measure mandatory, however, the College appreciates the proposed expanded scope of the measure (inclusion of not only Schedule II but also Schedules II and IV drugs). The College continues to raise concern over the administrative burden consequences which would be exacerbated by this requirement. While ACP is accepting of this measure as an option, we do not support the mandatory requirement of this measure.

<u>Health Information Exchange Objective: Proposed Addition of an Alternative Measure for Enabling</u> <u>Exchange under TEFCA</u>

ACP Comments: The College is supportive of the Trusted Exchange Framework and Common Agreement's (TEFCA) underlying principles, and we appreciate some of CMS' changes to this proposed measure as compared to the HIE Bi-Directional Exchange measure from the MPFS/QPP CY21 Proposed Rule. To meet the HIE Bi-Directional Exchange measure, MIPS-eligible clinicians must attest to the following statements:

- Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy.
- Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.

In particular, ACP is pleased to see TEFCA's structure support information exchange through connections at different levels, inclusive of entities such as health information networks, care practices, hospitals, public health agencies, and Individual Access Services (IAS) "providers." The College is also appreciative that the Enabling Exchange Under TEFCA measure would not require a MIPS-eligible clinician to assess whether they participate in an HIE that meets the attributes of attestation Statement 2, though an issue remains due to Statement 1, for which a MIPS-eligible physician would still have to assess whether their practice's situation meets the attributes of attestation.

In addition to our concerns regarding the burden TEFCA implementation will place on small and independent practices, the College is concerned with details of the Agency's proposal to add an additional measure through which a MIPS-eligible clinician could earn credit for the Health Information Exchange (HIE) Objective. Similar to ACP's objections regarding the HIE Bi-Directional Exchange measure as an optional alternative in our <u>October 2020 comment letter</u> on the MPFS/QPP CY21 Proposed Rule, **the College is disappointed that this new alternative measure requires "all-or-nothing" performance**

and fails to account for the significant expense to clinicians who wish to report. This measure also fails to account for the clinical relevance and value at the point of care, as there is no value in querying for data all the time. Additionally, CMS' proposed attestations assume clinicians know if their hospital or healthcare system is a signatory to a Framework Agreement, and whether the entity is in good standing. Most physicians are not aware of their health system's implementation of TEFCA, and this would put the clinician in a position of having to defer to others with this knowledge – an unnecessary and onerous task that increases burden.

Generally, ACP supports CMS' focus on interoperability and patient access to data, as well as its intention to give clinicians greater flexibility while reducing their burdens and exchanging information safely. Participating in TEFCA comes at substantial cost to practices, which limits access to this proposed measure and disadvantages rural clinicians and small practices during a period of great challenges due to severe nationwide staffing shortages and the ongoing COVID-19 pandemic. In the event that CMS finalizes the proposed addition, ACP would recommend the measure remain optional.

Public Health Reporting and Information Blocking

ACP Comments: The College is supportive of the Department of Health and Human Services' (HHS) efforts, through coordination across the various agencies, including the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare and Medicaid Services (CMS), to improve interoperability of and patient access to electronic health information, and we agree these efforts are integral to improving patient-centered, value-based health care. The College is appreciative of ONC's ongoing educational and resource development efforts for clinicians focused on information blocking, including the recently released information blocking frequently asked question (FAQ) that highlights important points about public health reporting and information blocking. However, we remain concerned that understanding how these complex information blocking provisions and exceptions interact with and potentially impact public health reporting requirements will be challenging for our physician members, and we recommend postponing any additional requirements until staffing shortages have eased. The College also recommends that ONC, in coordination with other agencies, develop further guidance materials providing physicians with a baseline for what is required to comply with public health reporting requirements in the context of these important information blocking regulations. This additional guidance and/or educational resources should include real-world scenarios and/or use cases, as well as examples of the types of documentation needed should physicians be subject to an information blocking claim or investigation specifically regarding public health reporting.

The College is also very concerned that the penalties for information blocking have not been made clear. In the absence of further details regarding penalties, it is difficult for physicians to understand the ramifications of information blocking violations. **The College implores CMS to consider the recommendations and questions raised in a recent joint letter urging HHS to clarify penalties and other important aspects of information blocking regulations.**

Request for Information re: Patient Access to Health Information Measure

ACP Comments: ACP is appreciative and supportive of CMS' belief in the importance of taking a patientcentered approach to health information access and related efforts to move towards a system in which patients have immediate access to their electronic health information and can be assured that their health information will follow them as they move throughout the health care system. However, the College has serious concerns about the existing digital divide in this nation, which were not addressed within this RFI. Most patient portals are English-only, leaving most non-English speakers with no way of navigating their own health information. Vendors do not want to translate information due to liability concerns, meaning that if practices or health systems want to offer portals in other languages, the cost and onus is on them. This makes offering a translation service cost-prohibitive to a lot of small and under-resourced practices – further increasing the digital divide. To achieve the stated goal of better, more equitable patient access to their health information, **ACP encourages CMS partner with ONC to mandate vendors have a baseline standard of usability**, as what most impacts patient portal usage is the intuitiveness and user-friendliness of the portal itself.

The College would like to see more details from the Agency regarding how it intends to define "patients adding information to their record." Information gathered from patient-completed pre-exam questionnaires and screenings being incorporated into a patient's health record in a structured way could potentially be quite valuable, for example, however ACP strongly objects to the idea of patients being able to directly edit their health information via a portal. Any information added by a patient to their health record would eventually have to be validated by their physician, because the physician is the person ultimately responsible for the content of the patient's health record. The College encourages CMS to consider how these proposals, if implemented, could significantly add to administrative burden for physicians and their care teams and work with stakeholders to improve patient access without assigning clinicians more administrative responsibility.

MIPS Value Pathway (MVPs)

MVP Vision Overview

ACP Comments: ACP strongly supports the stated goals of MVPs to reduce reporting burden and complexity within MIPS while improving the accuracy and effectiveness of performance measurement, aligning with longstanding ACP priorities. For MVPs to achieve these goals, CMS must fully commit to burden reduction by reducing the overall number of metrics and awarding credit across multiple performance categories for innovations that touch both.

While ACP views MVPs as a tool to help clinicians to transition to Advanced Alternative Payment Models APMs, we have concerns about CMS stated intent to fully transition to MVPs as the only MIPS reporting option. We understand that CMS has not indicated a specific time frame for this transition. However, in last year's proposed rule, the **ACP expressed that we do not support making MVP participation mandatory starting in PY2028.** While ACP supports the MVP concept and would like it to move forward, we believe it is important to get it right. MVPs represent a critical juncture in the evolution of MIPS and the larger QPP. They offer a unique opportunity to critically evaluate the shortcomings of MIPS and devise meaningful, long-lasting solutions to make the program more effective and workable for years to come. However, MVPs must include 1) truly creating more synergy between the performance categories; 2) revamping the Promoting Interoperability Category; and 3) improving cost measurement.

MVPs and APM Participant Reporting Request for Information (from PR)

ACP Comments: The College agrees with many of the concerns expressed by CMS regarding the alignment between MVPs and APMs. If MVPs are going to continue to be poised as an onramp to value-based payment, there must be APMs for those participating in MVPs to transition into. The College agrees that there is a significant gap in the availability of 2022-2024 APMs available for specialty practitioners. While CMS currently has a process in place for interested parties to submit APM proposals, the materialization of these proposals has not occurred. The College encourages CMS to revisit such proposals for relevant APM options that may better facilitate transition from MVPs to APMs. We appreciate the expression of CMS of a need to identify the best coordination and alignment between MVPs and APMs and encourage CMS to consult impacted parties for such information and to explore a broader definition of value in such considerations. The College urges CMS to review and consider implementing and /or incorporating the Medical Neighborhood Model (MNM) as an APM option for practices that participate in MVPs to transition into.

Furthermore, ACP shares the belief that MVPs could serve a role in furthering specialty measurement. The College also echos CMS' emphasis on the integral role of primary care measurement within MIPS.

MVP Development

ACP is pleased to see that CMS has proposed a more structured process around the development and maintenance of MVPs. Specific comments are included below.

ACP Comments: ACP agrees that CMS should work with clinicians and specialty societies to develop and consider new MVPs. However, it is also crucial that other stakeholder feedback is sought, particularly from other clinicians not involved in the development of the MVP as well as patients. ACP supports the 30-day comment period and believes this to be a beneficial added step to the development process. We would also suggest that the feedback be shared with the developer to allow the developer to consider the feedback and further refine the MVP as proposed with the maintenance process.

MVP Maintenance Process and Engagement with Interested Parties

ACP Comments: ACP approves of CMS's proposal to standardize the process for annual maintenance of MVPs. We strongly support CMS's recommendation that the feedback received be shared with the MVP developer to allow for potential modifications. We sincerely appreciate CMS' ongoing efforts to seek our *feedback* and consider it as you continue to improve the MVPs. We look forward to continuing productive conversations and collaboration.

Proposed Revisions to Previously Finalized MVPs

ACP Comments: While ACP did not support either of the measure options to survey patient experience, we support CMS's modification to the Optimizing Chronic Disease Prevention (OCDM) MVP. We believe that having only one patient experience option is not tenable. Many physicians and groups are already collecting CAHPS surveys and adjusting their workflow to add this new patient experience measure is overly burdensome. Additionally, during its review of measures, ACP identified fewer concerns with quality measure Q321: CAHPS for MIPS Clinician/Group Survey than the current measure included in the MVP [i.e., Q438: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)]. While we have some concerns with Q321, we support it being added as an option within the Optimizing Chronic Disease MVP and would prefer it over Q438. We sincerely appreciate CMS' ongoing efforts to seek our feedback for the OCDM and considering it as you

continue to improve the MVP. ACP looks forward to continuing productive conversations and collaboration.

Measures in Optimizing Chronic Disease Management MVP PFS 2023 Proposed Rule

Type of ACP Support

Summary: 10 measures

- ACP support: 5
- ACP does not support; uncertain validity: 4
- ACP does not support; invalid: 1

Quality Measure	Type of ACP Support	ACP Rationale
• Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy	Support, Valid	ACP supports QPP 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.
• Q047: Advance Care Plan	Do not Support, Uncertain Validity	ACP does not support QPP 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.
• Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment	Support, Valid	ACP supports QPP 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.
 Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) 	Support, Valid	ACP supports MIPS measure ID# 118 (NQF ID# 0066): "Coronary Artery Disease: Angiotensin Converter Enzyme-Inhibitor (ACE-I) or Angiotensin Receptor Blocker (ARB) Therapy—Diabetes or LVSD (LVEF <40%)" because implementation will likely promote appropriate use of ACE-I and ARB therapy in patients who are diagnosed with CAD, the developer cites clinical recommendations of the American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Physicians (ACP) for the "Management of Stable Ischemic Heart Disease" to form the basis of the measure, the measure specifications are well-defined, and data collection is feasible and burden is acceptable for clinicians report this measure. While we support this measure, we note that the measure is close to being topped out. Performance data suggests that 81% of clinicians who reported this measure in 2014 adhere to the interventions described in the specifications.

• Q119: Diabetes: Medical Attention for Nephropathy	Support, Valid	ACP supports MIPS measure ID# 119 (NQF ID# 0062): "Diabetes: Medical Attention for Nephropathy" because the opportunity for improvement is well documented, developers cite 2018 clinical recommendations of the American Diabetes Association on "Standards of Medical Care in Diabetes" to form the basis of the measure, the numerator and denominator are well defined, the denominator includes well specified and clinically appropriate exceptions to eligibility for the measure, and measurement is repeatable and precise.
• Q236: Controlling High Blood Pressure	Do not Support, Uncertain Validity	ACP does not support "NQF#0018/MIPS Quality#236 - Controlling High Blood Pressure" for application at the proposed levels of attribution: Individual Clinician, Group/Practice, Health Plan, and Integrated Delivery System, because of uncertain validity. The PMC believes that this measure has high impact and there is ample evidence to demonstrate that treating patients towards an appropriate blood pressure goal results in decreased heart attacks and strokes. However, the committee has concerns with the strict BP control across the whole patient population, especially for older patients. The committee feels that the measure denominator age range should either be 18-60 years or there should be different BP targets for stratified age groups. Based on AAFP/ACP guidelines, the PMC does not believe that less than 140 is ideal for every hypertensive patient across all age groups. Moreover, the committee thinks that by assessing the most recent BP from the measurement period, the measure deviates from actual practice. Physicians managing hypertension usually rely on a series of BP readings to make a diagnosis or a treatment decision. To make the measure more meaningful, the measure developers need to consider altering that component, and allow the use of either the median or the mode BP during the measurement period. The committee also believes that the numerator should allow the inclusion of home BP readings that are reviewed and entered in the EHR by the patient's clinical team, and that the specifications need to add some additional clarification on what digital transmission of remote BP entails. The committee feels that the measure should allow risk adjustment to include clinical, demographic, and social risks in the calculations, particularly to consider for physicians treating a

		higher proportion of marginalized patient populations.
• Q321: CAHPS for MIPS Clinician/Group Survey	Do not Support, Uncertain Validity	ACP does not support QPP 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).
• Q398: Optimal Asthma Control	Do not Support, Uncertain Validity	ACP does not support QPP 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.
• Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Support, Valid	ACP supports QPP 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 non-adherent patients.
 · Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO- PM) 	Do not Support, Not Valid	ACP does not support NQF 3568: "Person-Centered Primary Care Measure PRO-PM (PCPCM PRO-PM)" for application at the actual/intended level of analysis: "Individual Clinician" or "Group Practice" because it lacks validity. The ACP had concerns regarding whether the measure would lead to improvements in care and a lack of evidence to indicate as much. There were also some problems regarding the face validity of the instrument and the feasibility and burden to implement this in a general internal medicine practice.

Proposed New MVPs

ACP Comments: ACP applauds CMS's inclusion of the Promoting Wellness MVP. This MVP provides another option that is strongly tied to the daily practice of general internal medicine physicians and has been adapted from one of the MVPs submitted by ACP in February 2020.

Overall, we are pleased to see many of the changes that have been proposed by CMS with regards to measure additions and measure removals. Of the 14 quality measures proposed, ACP's prior review indicates support for eight of them, does not support four of them with uncertain validity, and has found one of them to be invalid. While ACP hasn't reviewed the Adult Immunization Status formally, we have provided our comments on that measure in the MIPS section and in the table below.

The table below includes ACP's level of support as well as our rationale for the quality measures included in the Promoting Wellness MVP.

Quality Measure	Level of ACP Support	ACP Rationale
• Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age	Support, Valid	ACP supports QPP 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.
• Q112: Breast Cancer Screening	Support, Valid	ACP supports QPP measure 112. Current evidence supports the measure. The specification allows for screening done in the last 27 months of the performance year which helps in the implementation of this measure. The measure exclusions are proper; however, they can be challenging to document in the patient's medical record. There are some concerns related to patient attribution to clinicians at the individual physician level, as well as feasibility concerns with outside imaging reports being entered in a patient's medical record to signify that the screening was completed. However, as more

		organizations move towards team-based care, these issues should be minimal in the future.
• Q113: Colorectal Cancer Screening	Support, Valid	ACP supports QPP measure 113. Colorectal cancer screening is an important clinical area. It is critical to improve access to evidence-based tests to make a meaningful clinical impact. These evidence-based tests should be clearly identified as not all tests have validity to support their use as stand-alone screening tests. The ACP recommends modifying the numerator to include only the types of tests that qualify as colorectal cancer screening, consistent with current guidelines. It would also be beneficial to extend the numerator time interval for performing the colonoscopy from nine years to ten years to ensure the exam is ordered and performed adequately.
• Q309: Cervical Cancer Screening	Support, Valid	ACP supports QPP measure 309. ACP believes that the Cervical Cancer Screening is an important measure, given its ability to impact disease prevention. Current evidence supports this measure, and it does not increase clinician burden or have any feasibility issues. The measure specifications need clarity; the ACP recommends revising the specifications for better interpretation of the age appropriate screening tests. To avoid unnecessary screening, the ACP encourages the development of an overuse measure.
• Q310: Chlamydia Screening for Women	Support, Valid	ACP supports QPP measure 310 because it aligns with recommendations from the United States Preventive Services Task Force and the Centers for Disease Control and Prevention (CDC) and evidence supports screening in primary care as feasible and effective.
• Q400: One-Time Screening for Hepatitis C Virus (HCV) for all Patients	Support, Valid	 ACP supports QPP 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.
• Q475: HIV Screening	Do not Support, Uncertain Validity	ACP does not support MIPS measure ID# 475 (NQF ID# 3067): "HIV Infection Screening" because of uncertain validity. To the extent the intent of this measure is to standardize HIV screening, thereby increasing early diagnosis and reducing the stigma of testing, including some measure of "ever tested" seems like a reasonable first step. However, we note several implementation and methodological flaws that reduce the measure's ability to lead to measurable and meaningful improvements in clinical outcomes. First, while evidence suggests the benefit of screening for HIV in all adults on clinical outcomes is high, the patient's consent to testing is often beyond the clinician's control. Second, poor interoperability across EHRs poses a significant burden on clinicians who report this measure. Additionally, clinicians may encounter confidentiality barriers to retrieving patient sensitive information around test results. If clinicians are unable to retrieve previous results, they may feel inclined to order additional tests. Second, the specifications should include exclusion criteria for patient refusal, patients who are diagnosed with limited life expectancy, and patients who are already infected with HIV. Finally, developers not cite any evidence to form the basis of the annual screening frequency described in the denominator specifications. Data are far better for the frequent screening of high-risk patient. 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 with limited benefit of screening. Additionally, one-time screening in low- risk patients has mixed data on effectiveness and is highly dependent on the assumptions about the underlying prevalence. For example, two major papers on the topic conclude that the cost- effectiveness is >\$100,000 per QALY.
• TBD: Adult Immunization Status: This MIPS quality measure ensures patients are assessed for and/or receive the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines, as recommended.	Not Reviewed	While this measure has not been formally reviewed, ACP believes that this measure provides an inclusive assessment of adult vaccination status. The evidence base for this measure is strong. However, there are concerns with feasibility at the individual clinician and clinician group attribution levels, as patients do not always go to the same physician to receive all required vaccinations. Additionally, this measure was

• Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan	Do not Support, Uncertain Validity	developed, tested and endorsed at the health plan level, and for this reason, the MAP did not support this measure for use at the individual clinician and clinician group levels. Health plans have ready access to the information required for the measure. ACP does not support QPP 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/m ² . It is burdensome for clinicians to design a follow-up plan for patients with a BMI measurement between 25-30 kg/m ² 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.
• Q134: Preventive Care and Screening: Screening for Depression and Follow- Up Plan	Do not Support, Uncertain Validity	ACP does not support QPP measure 134: "Preventive Care & Screening: Screening for Clinical Depression and Follow-Up." 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.
• Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	Support, Valid	ACP supports QPP 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)
• Q321: CAHPS for MIPS Clinician/Group Survey	Do not Support, Uncertain Validity	ACP does not support QPP 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).
• Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	Support, Valid	ACP supports QPP 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".
• Q483: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO- PM)	Do not Support, Not Valid	ACP does not support NQF 3568: "Person-Centered Primary Care Measure PRO-PM (PCPCM PRO-PM)" for application at the actual/intended level of analysis: "Individual Clinician" or "Group Practice" because it lacks validity. The ACP had concerns regarding whether the measure would lead to improvements in care and a lack of evidence to indicate as much. There were also some problems regarding the face validity of the instrument and the feasibility and burden to implement this in a general internal medicine practice.

While the College is generally supportive, ACP is not in full agreement with CMS' proposals regarding the quality measures included in the two MVPs, however, many of the changes that are incorporated resonate with <u>comments</u> we have made in the past.

MVP Reporting Requirements

ACP Comments: ACP continues to highlight that changes to truly reinvent MIPS with MVPs, CMS must:

- Create synergy across the four performance categories. To do so, each category must not be seen as siloed. It is especially important to look for opportunities to leverage existing data to satisfy requirements for multiple categories, when relevant and appropriate.
- For the PI Category, ACP supports a menu of attestation-based measures similar to the Improvement Activities category that would more accurately reflect the many innovative ways practices are already leveraging emerging innovative Health Information Technology (IT) to improve patient care.
- For the Cost Category, CMS must lead the charge in developing new metrics that are more actionable and targeted to specific specialties, patient populations, and conditions. We implore CMS to lead the charge in this development rather than relying on individual stakeholders to do so.

Reporting MVPs and Team-Based Care

ACP Comments: ACP continues to strongly oppose making sub-group reporting mandatory. Doing so would represent a huge increase in reporting burden, particularly for large multispecialty practices. ACP appreciates CMS' desire to dispense performance data and feedback at more targeted levels, but notes that while providing data and performance insights at individual clinician or sub-group levels is possible and can be helpful for quality improvement, scoring and posting for public purposes should be done at the group practice level. As part of ACP's <u>New Vision for U.S. healthcare</u>, ACP recommends moving toward a limited set of patient-centered, actionable, appropriately attributed, and evidence-based measures for public reporting and payment purposes, while supporting the use of additional clinically meaningful measures for internal quality improvement purposes. This reinforces clinical care teams, which ACP strongly supports.

Scoring MVP Performance

ACP Comments: ACP supports applying the highest of scores reported. This encourages participation and minimizes errors that could arise during subgroup selection or assignment. There is precedent with facility-based scoring. ACP supports physicians being able to select MVP reporting when submitting MIPS data at the end of a performance period (as opposed to midway through the performance year). This approach provides more time to make the decision and better accounts for NPI/TIN changes during the performance year, which far outweigh any drawbacks. In general, flexibility in reporting is critical to reducing burden while increasing clinical relevance and patient-centeredness.

Medicare Shared Savings Program

Advance Investment Payments

ACP Comments: Due to plateaued participation in MSSP and advocacy aimed at providing greater opportunities to ACOs serving underserved populations, CMS has proposed a substantial number of changes to the incentive structure of MSSP. One such promising proposal is aimed at low revenue ACOs inexperienced with performance-based risk. While further thought may be warranted in the definition of high/low revenue ACOs as it impacts FQHCs/RHCs, this proposal seems to be a step in the right direction. Offering a one-time fixed payment provides a unique opportunity for certain ACOs to enter into accountable care agreements. The College is pleased to see the application of lessons learned from prior APMs applied to permanent programing.

<u>Glide Path</u>

ACP Comments: ACP is encouraged by the proposal to allow ACOs inexperienced with downside risk up to seven years in one-sided risk before transitioning to two-sided risk. The College agrees that the quick transition into downside risk may deter participation and that these proposals may encourage participation by those in small, rural, and/or otherwise underserved communities.

eCQM/MIPS CQMs and Health Equity Adjustment

ACP Comments: The College is pleased with the proposal to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the sunsetting of the CMS Web Interface reporting option. Additionally, the College is encouraged to see a health equity adjustment which would upwardly adjust an ACO's quality performance score, to reward ACOs that report all-payer eCQMs/MIPS CQMs, that are high performing on quality, and serve a high proportion of underserved beneficiaries. The college is critical of the eligibility criteria as eligibility is determined through the Area Deprivation Index (ADI) which may correctly identify some disadvantaged areas and improperly assess others. In ACP's paper *Reforming Physician Payments to Achieve Greater Equity and Value in Health Care*, the College emphasizes the importance of greater testing of assessments of Social Determinates of Health (SDOH) such as ADI and recommends broad implementation "by Medicare and other payers in ways that minimize unnecessary administrative burden on physicians and staff". Although this may only impact a small percentage of program participants; it is a step in the right direction and may have the potential to support health equity in the MSSP.

Advanced Alternative Payment Models

5% APM Bonus

ACP Comments: The College is disappointed to see that CMS has not proposed the extension of the 5% lump sum APM incentive payment. In our comments in response to the APM RFI below, we express our concern that the expiration of this incentive will have significant impacts with participation. While the ACP understands the Agency's lack of statutory authority to change this on their own, **the College is calling on Congress to intervene to provide CMS with the statutory authority.**

QP Threshold

ACP Comments: CMS proposes to use the mean of the final scores for all MIPS eligible clinicians for the CY 2019 MIPS payment year, which is 75 points (rounded from 74.65 points) for the 2023 MIPS performance year. Therefore, beginning with 2023 performance year, QP thresholds would increase to 75 percent for the payment threshold and 50 percent for the patient count. Though the ACP understands that CMS is statutorily obligated to use the mean or median for the performance threshold, **the College expresses disappointment that the QP threshold will not be frozen and is proposed to increase to 75 points for the 2023 performance year**. The Regulatory Impact Analysis (RIA) indicates that while some clinicians opted out of MIPS in 2019, it is the best performance thresholds, ACP suggests using the mean or median from 2021 performance year data when it becomes available. The 2019 performance year mean may be too high, as many clinicians are still recovering from the COVID-19 PHE. Using 2021 performance year data may provide a more accurate representation of how clinician performance has been affected.

APM Incentive: Request for Information

ACP Comments: The College expresses agreement with many of the concerns mentioned regarding the expiration of the APM Incentive. The expiration of this incentive will significantly impact the entrance to and retention of APMs. Many practices seek an alternative to traditional MIPS which allows for greater coordination of patient care without disproportionate administrative burden added and without the subjection to MIPS reporting requirements and payment adjustments. Without this incentive, many practices will struggle to cover the improved care that participation in APMs intends to provide patients.

Particularly for specialty practices, the greater options for reporting within MIPS coupled with the lack of requirement for attainment of QP status may draw some participants out of APMs. The limited incentives of (1) continuation of receiving any financial incentive payments available under the APM(s) in which they participate, (2) the future prospect of being paid under the PFS in the payment year using a higher QP conversion factor (0.75 percent rather than 0.25 percent) beginning in payment year 2026, and (3) lack of subjection to MIPS reporting requirements or payment adjustments, may not be enough to maintain participation once the APM incentive payment expires.

Conclusion

Thank you for this opportunity to comment on CMS' Notice of Proposed Rulemaking regarding changes to the Physician Fee Schedule, Quality Payment Program, and other federal programs for CY23 and beyond. ACP is confident these recommended changes would improve the strength of these proposals and help promote access to affordable care for Medicare patients, while supporting physicians in their

ability to deliver innovative care and protecting the integrity of the Medicare trust funds. The College appreciates the opportunity to offer our feedback and looks forward to continuing to work with the Agency to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Ph.D., Director, Regulatory Affairs for the American College of Physicians, at <u>boutland@acponline.org</u> or (202) 261-4544 with comments or questions about the content of this letter.