



September 13, 2021

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 Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

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) 2022 and beyond. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 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. We are 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 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**

- a. ACP is deeply concerned about the impact of this decreased conversion factor and recognizes that CMS is limited by current statute from addressing it directly. Therefore, ACP is urging Congress to stabilize the Medicare physician payment system and prevent Medicare cuts to physicians by including the following provisions in the FY 2022 budget reconciliation legislation. ACP strongly recommends that CMS carrier price code G2211 to allow carriers the discretion to reimburse for this added service until the congressional moratorium ends on December 31, 2024 when CMS can add it to the physician fee schedule.
- b. **Office Visits Included in Codes with a Surgical Global Period:** ACP strongly disagrees with the CMS proposal to bundle critical care visits into global surgery payment. The College believes that the Agency's policy implies that the clinician work for such vital service visits is not the same when performed in a surgical global period, which is an inaccurate position.
- c. **Teaching Physician Services and Primary Care Exception Flexibilities:** We continue to encourage CMS to maintain these modifications for a period after the PHE ends and until supervising physicians feel comfortable that they can control the spread of infection rates. This extension should last at least through the end of 2023 with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these supervision flexibilities. Therefore, ACP recommends that both time and MDM be allowed as options for selecting the appropriate level of visit.

B. **Telehealth**

- a. **Temporary Additions to the Medicare Telehealth Services List, and Codes Not Granted Category 3 Status:** We strongly recommend that Category 3 be made permanent as to provide for a more consistent and efficient on-ramp for new services to be added. Additionally, ACP strongly recommends CMS add codes 99441-99443 back to the Category 3 list and retain these services until at least the end of CY23.
- b. **New Originating Site:** ACP supports any efforts to expand 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. The College recommends that CMS permanently extend the policy to waive geographical and originating site restrictions after the conclusion of the PHE for *all* telehealth services. Additionally, the College does not support documenting a distinction between the telehealth and non-telehealth services in the patient's medical record and this should not be made a requirement.
- c. **Payment for Services Using Audio-Only Communication Technology:** ACP is extremely supportive of continuing to allow audio-only services. Therefore, the

College recommends that CMS maintain coverage of audio-only mental health visits even after the PHE is lifted. This extension should last at least through the end of 2023 with an option to extend it even further or consider making it permanent, based on the experience and learnings of patients and physicians who utilize these visits. This would require further study of the impact on access and the clinical effectiveness of audio-only services by the Agency. Additionally, because audio-only telehealth is an important component tool for physicians to improve health equity and patient access, it should not be limited to only patients seeking behavioral and mental health services. We are asking CMS to broaden the flexibility and continue to allow other evaluation and management (E/M) services to be provided using audio-only communication. Instead, ACP would support extending the use of audio-only technology for the services approved during the PHE at least through the end of 2023 with an option to extend it even further or consider making it permanent, based on the experience and learnings of patients and physicians who utilize these visits. The College also strongly recommends that CMS maintain pay parity between telephone E/M claims and in-person E/M visits and between all telehealth and in-person visits even after the PHE is lifted. This extension should last at least through the end of 2023 with an option to extend it even further or consider making it permanent, based on the experience and learnings of patients and physicians who utilize these visits.

- d. **Direct Supervision:** Based on the experience and learnings of patients and clinicians who are utilizing these supervision flexibilities, ACP believes that providing for a permanent flexibility in this space supports the expansion of telehealth services and protects frontline health care workers by allowing appropriate social distancing measures. Similarly, we believe that clinicians should feel empowered to supervise clinical staff virtually, at their discretion, regardless of whether there is a declared PHE.
- e. **Virtual Check-In Code:** ACP does not agree that the establishment of G2252 is the solution to providing an alternative to telephone E/M visits. Once again, rather than adopting a substitute, the College strongly recommends that CMS maintain pay parity between telephone E/M claims and in-person E/M visits and between all telehealth and in-person visits even after the PHE is lifted. This extension should last at least through the end of 2023 with an option to extend it even further, or consider making permanent, based on the experience and learnings of patients and physicians who are utilizing these visits.

C. Vaccine Administration Services

- a. ACP strongly encourages CMS to adopt the vaccine valuation recommendations for the new COVID-19 vaccines exactly as provided by the RUC.

- b. Further, the College strongly urges CMS to make coding and payment available for time spent by physicians providing counseling services to patients who are seeking to mitigate their risk for COVID-19 infection.

D. Updates to Physician Self-Referral Regulations under Stark Law

- a. The College is supportive of the positive steps to make the Stark Law more flexible, create exceptions that reduce the number of inadvertent or technical violations, and align the law with the industry shift from volume to value. Although we commend these efforts, we remain concerned that the frequent amendments to definitions will result in even greater regulatory burden to health care entities and clinicians.
- b. ACP recommends CMS collaborate with the appropriate entities to provide adequate lead time to compliance and less shock to those who must comply.
- c. The College is supportive of the Agency's efforts to provide health care entities and clinicians with clarifying guidance to its proposal. However, we are concerned that it remains unclear whether services performed by an employee but provided 'incident to' services personally performed by a physician would, in fact, qualify as the physicians' personally performed service. ACP recommends CMS provide further guidance in its final rule that speaks to this uncertainty more clearly.
- d. Considering the legal and regulatory complexities of the Stark Law, ACP is supportive of the intent behind CMS' proposals and subsequent clarifications.
- e. If finalized, the College strongly recommends CMS re-examine the ever-growing complexity of the statute, the likelihood its proposals will, in fact, lend greater clarity to the regulations, and continue to collaborate with health care entities and clinicians to better understand the downstream effects and burden of Stark regulations.

E. Requiring Certain Manufacturers to Report Drug Pricing Information for Part B, and Other Items

- a. ACP supports efforts to require manufacturers to provide CMS with regular and accurate average sales price information for drugs and biological products that are covered under Medicare Part B as a means to ensure accurate payment, and urges CMS to go further in requiring the reporting of additional price and cost information.

F. Electronic Prescribing of Controlled Substances (EPCS)

- a. ACP supports the use of electronic prescribing for controlled substances.
- b. Due to the burdens of the COVID-19 pandemic, ACP also supports the delay of implementation because 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.

G. Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging

- a. While the College recognizes that consultation of appropriate use criteria (AUC) for advanced diagnostic imaging tests is important, we believe that the denial of claims would impose significant disruption to physicians, hospitals and other health care clinicians and “provider” entities. We therefore urge the Centers for Medicare and Medicaid Services (CMS) to return claims that fail AUC claims processing edits rather than deny them.

H. Innovative Technology and Artificial Intelligence (AI) Request for Information

- a. The College applauds CMS for initiating a discussion on the use of AI and other innovative technologies. At the outset, the College wants to emphasize that we believe, due to its importance and implications, this RFI should be removed from the greater Proposed Rule and re-opened so as to allow more time to gather stakeholder feedback.
- b. Therefore, the College cautions against establishing precedent-setting payment policy based on limited experience and data. ACP welcomes the opportunity to engage in ongoing discussion of this technology and its impact on both direct and indirect practice expense.
- c. Today, expenses related to approved AI technology should be considered a direct expense. We further re-emphasize our strong recommendation that this topic be given its due time and attention by being separated from the broader Proposed Rule and re-opened as to provide more time for stakeholder input.

I. Advancing to Digital Quality Measurement and the Use of FHIR® in Physician Quality Programs – Request for Information

- a. While the College is generally supportive of FHIR we emphasize that small and independent practices that are dependent upon third-party vendors to enable this functionality are worried by these proposals.

J. MIPS Value Pathway (MVP)

- a. **MVP: Quality Measure Review:** The College supports the following measures that are included in the 4 MVPs that we reviewed. However, there are several measures that the ACP does not support. These are included in Appendix A, along with a rationale.
- b. **MVP: Patient Reported Outcome Measure Review:** The College reviewed PCPCM PROM in January 2021, and we do not support the use of this measure.
- c. **MVP: Population Health Measure Review:** The ACP generally supports measuring outcomes for patients at the group practice level or higher and supports the specific methodological changes proposed, particularly incorporating additional risk factors related to socioeconomic status and social risk factors, which has been a top advocacy priority of ACP’s for many years.
- d. **MVP: Cost Measure Review:** ACP does not support the TPCC (Total Per Capita Cost) cost measure that CMS has proposed to be included in 3 out of the 4 MVPs that we reviewed. The College strongly recommends that CMS invest in

developing cost metrics that would more accurately reflect the types of costs internists have an ability to influence, even if this focuses on a narrower scope.

K. PY 2022 MIPS Changes

- a. PY22 Reporting Exemptions Due to COVID-19:** ACP applauds CMS for continuing its MIPS extreme and uncontrollable circumstances exceptions for the 2022 performance year on a case-by-case basis.
- b. PY22 Scoring and PY21 Performance Feedback:** ACP opposes CMS' proposal to make MVP participation mandatory starting in PY2028. We strongly urge CMS to ensure that MVP participation is voluntary and that physicians, group practices, and subgroups maintain the option to participate in traditional MIPS. Also, while the ACP supports CMS allowing multi-specialty groups to create subgroups for MVP reporting, the College does not support CMS making it a requirement for 2025 performance year and beyond. Further, ACP does not support retiring "traditional" MIPS, nor do we think it is necessary.
- c. Quality Category: Data Completeness:** While ACP appreciates CMS maintaining the current data completeness threshold at 70 percent for the 2022 performance period, we strongly oppose increasing the threshold to 80 percent for the 2023 performance period.
- d. Quality Category: Quality Measure Scoring Changes:** The College appreciates the establishment of a five-point floor for new measures. However, we recommend that CMS consider an even higher floor, such as 7-points, to ensure that this incentive will be sufficient to encourage practices to take the risk of using these measures, which will then allow for greater understanding of their evidence-base and if they are appropriately attributed; ability to ensure patient-centeredness; and actionability, including necessary workflow changes or additional costs associated with implementation. ACP opposes the removal of the three-point floor for all measures whether they can be scored against a benchmark or not, as it will likely be an additional challenge on the practices that are already struggling with this pandemic. Physicians should continue to be incentivized for reporting on outcomes and high priority measures, as well as for end-to-end reporting.
- e. Promoting Interoperability (PI) Category:** This current proposal places the onus on the MIPS eligible clinician for something that is far out of their control.
- f. Cost Category:** 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.

L. APM Performance Pathway (APP)

- a.** ACP supports efforts to promote consistency across the QPP and to offer clinicians flexible reporting options, which reduces burden. We support the proposal that data could be reported at the clinician, group, or APM Entity level and that the highest available TIN/NPI level score would apply.

- b. Complex Patient Bonus:** As noted earlier, the College strongly recommends that CMS continue to support the reporting bonuses

M. Medicare Shared Savings Program (MSSP)

- a.** ACP encourages CMS to delay further these requirements and work collaboratively with the ACO, vendor, and medical community to resolve these barriers.

N. Advanced Alternative Payment Models (APMs)

- a.** ACP encourages CMS to work with the physician community to improve payment model design and implementation so that physicians are more willing to participate voluntarily in APMs. To further encourage APM participation, ACP also recommends that incentive payments for APM participation be extended beyond the MACRA 2024 deadline.

II. PFS Detailed Recommendations:

Regulatory Impact Analysis

CMS Proposal: For CY 2022, CMS has proposed a conversion factor of \$33.58 (\$33.5848). This represents a decrease of \$1.31 (or 3.75 percent) when compared to the 2021 conversion factor of \$34.89 (\$34.8931). The proposed decrease is based on several different factors. In CY 2021, Congress passed the Consolidated Appropriations Act of 2021 (CAA), which provided a 3.75 percent increase in the PFS conversion factor for CY21 only. This increase was intended to offset the 10.20 percent PFS conversion factor decrease CMS had finalized and was only funded for CY21. Congress will need to act to extend the update through CY22. The proposed decrease is also a result of the 0 percent update scheduled for the PFS in CY22, which was established by the Medicare Access and CHIP Reauthorization Act of 2015.

ACP Comments: ACP is deeply concerned about the impact of this decreased conversion factor and recognizes that CMS is limited by current statute from addressing it directly. Therefore, ACP is urging Congress to stabilize the Medicare physician payment system and prevent Medicare cuts to physicians by including the following provisions in the FY 2022 budget reconciliation legislation:

- Enact legislation that would prevent the 2 percent Medicare sequestration cut scheduled for January 1, 2022;
- Waive additional Medicare cuts of up to 4 percent that would be imposed on physicians at the end of this year through a federal law known as PAYGO, and;
- Approve an across-the-board 3.75 percent increase to ALL physician services to offset cuts that will be imposed due to the application of budget neutrality in the 2022 MPFS.

ACP is pleased that earlier this year the 117th Congress approved legislation, H.R. 1868, to delay the implementation of a 2 percent Medicare cut to physicians scheduled on April 1, 2021, that would have been triggered by a process known as sequestration, designed to reduce federal spending. We remain concerned that H.R. 1868 only delayed the 2 percent Medicare sequestration cut to physicians until January 1, 2022, and unless Congress acts before the end of this calendar year – this cut will be implemented. H.R. 1868 also failed to waive additional Medicare cuts that would be imposed on physicians through a federal law known as PAYGO – which would reduce Medicare payments to physicians by up to 4 percent at the end of this year. We also appreciate that at the end of last year, CMS finalized a Medicare Physician Fee Schedule (MPFS) final rule that provided an increase in payments for physicians' undervalued Evaluation and Management (E/M) services effective on Jan. 1, 2021. A significant portion of the work of internal medicine physicians is tied to E/M services (office-based visits with patients) that have long been undervalued in both Medicare and Medicaid. ACP fully supported the implementation of this increase in payment for E/M services, noting it was long overdue

and essential, but it only partially offsets the huge losses of revenue from the COVID-19 pandemic experienced by internal medicine specialists and other frontline physicians.

Federal law requires that any increases to physician services in the MPFS final rule (such as those applied to E/M services in the 2021 PFS) must be offset by an across-the-board budget neutral (BN) reduction to all services paid under the fee schedule, to keep overall spending budget neutral. The 2021 PFS rule would have imposed a substantial BN adjustment, with physicians providing undervalued E/M services seeing improvements, but these improvements were being significantly reduced by the BN adjustment – and those who do not bill for E/M were facing overall reductions in payment for other services in Medicare. ACP was pleased that at the end of last year, Congress passed legislation, H.R. 133, the Consolidated Appropriations Act of 2021, that included a provision providing for a temporary 3.75 percent increase to ALL services which has helped to mitigate a substantial portion of the cuts that were expected from budget neutrality while protecting the increased payments to frontline primary and comprehensive care physicians. All physician services will again be subject to reductions due to the application of budget neutrality in the 2022 PFS unless Congress steps in to stop it.

Further, CMS, in finalizing the Medicare Physician Fee Schedule (MPFS) final rule that provided an increase in payments for physicians' undervalued Evaluation and Management (E/M) services, also finalized an additional add-on code for complex visits, effective Jan. 1, 2021. This code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.*) was put on hold by the congressional action. **ACP strongly recommends that CMS carrier price code G2211 to allow carriers the discretion to reimburse for this added service until the congressional moratorium ends on December 31, 2024 when CMS can add it to the physician fee schedule.**

Refinements to "Split" or "Shared" E/M Visits

CMS Proposal: CMS has requested comments on developing additional policy for split (or shared) visits performed in a facility setting, including:

- *Qualifying Time:* CMS is seeking public comment on whether there should be a different listing of qualifying activities for determining total time and the substantive portion of split visits provided in emergency departments.
- *Same Group:* CMS is soliciting feedback on how "in the same group" should be defined as used in the proposed definition for split (or shared) visits. The Agency has considered several options, such as requiring that the physician and NPP must be in the same clinical specialty.
- *Medical Record Documentation:* To ensure program integrity and quality of care, CMS is proposing that documentation in the medical record must identify the two individual practitioners who performed the visit. The individual who performed the substantive

portion (and therefore bills the visit) would be required to sign and date the medical record.

- *Claim Identification:* CMS is proposing to create a modifier to describe split (or shared) visits and proposing to require that the modifier must be appended to claims for split (or shared) visits, whether the clinician or NPP bills for the visit.

ACP Comments: ACP strongly recommends CMS work with the CPT/RUC Workgroup on E/M to create a proposal to the CPT Editorial Panel to address the Agency’s areas for comment and to clarify the reporting in CPT Guidelines. It is important that physicians can focus on one consistent set of guidelines in reporting their services. The College also urges CMS not to require a modifier to be reported for split (or shared) visits. Requiring a modifier adds a level of administrative burden that the new E/M code structure and guidelines were designed to alleviate.

Critical Care Services

CMS Proposal: CMS proposes to adopt the CPT guidelines for the reporting of critical care services. The Agency also proposes that clinicians would no longer be able to report other E/M services on the same date as a critical care visit.

ACP Comments: ACP appreciates this push for consistency from CMS. However, we remain concerned about the proposal to no longer allow clinicians to report other E/M services on the same date as a critical care visit. Specifically, the College points out that this proposal is contrary to CPT specific instruction (*CPT 2021 Professional*, p. 31) which states, “Critical care and other E/M may be provided on the same patient on the same date by the same individual.” Considering such, we urge CMS to reconsider this proposal. Although it may not be a typical occurrence, there are instances where a patient may be seen on an inpatient floor, emergency department, or even a clinician office and then later require critical care services on the same date. These are all separate services and should be reported and paid for as such.

Office Visits Included in Codes with a Surgical Global Period

CMS Proposal: CMS proposes that critical care visits cannot be reported during the same time period as a procedure with a global surgical period. CMS is thus proposing to bundle critical care visits with procedure codes that have a global surgical period.

ACP Comments: **ACP strongly disagrees with the CMS proposal to bundle critical care visits into global surgery payment. The College believes that the Agency’s policy implies that the clinician work for such vital service visits is not the same when performed in a surgical global period, which is an inaccurate position.** Rather, ACP believes that critical care services, even when provided by others than the performing surgeon, should still be paid. If CMS’ proposed policy were implemented, it would incentivize elimination of the global surgical period codes and the billing for the work that is actually done, irrespective of whoever actually performs the service.

Teaching Physician Services and Primary Care Exception Flexibilities

CMS Proposal: CMS proposes that the time when the teaching physician was present can be included when determining the E/M visit level. However, for services furnished pursuant to the primary care exception, only MDM can be used to select the E/M visit level. CMS is seeking feedback on its assumption that MDM is a more accurate indicator of the appropriate level of the visit relative to time in the context of the primary care exception for services furnished by residents and billed by teaching physicians in primary care centers. CMS is also seeking comments on whether time is an accurate indicator of the complexity of the visit and how teaching physicians might select an office/outpatient E/M visit level using time when directing the care of a patient that is being furnished by a resident in the context of the primary care exception. After expiration of the PHE, office/outpatient levels 4-5 will no longer be included in the primary care exception.

ACP Comments: The College welcomes these proposals by the Agency that grant attending physicians and residents/fellows additional flexibilities that prioritize patient safety and meets them where they are. These important steps promote efficient patient care and allow physicians and supervisees to work together unencumbered by social distancing restrictions. **We continue to encourage CMS to maintain these modifications for a period after the PHE ends and until supervising physicians feel comfortable that they can control the spread of infection rates. This extension should last at least through the end of 2023 with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these supervision flexibilities.**

Further the College feels when directing the care of a patient that is being furnished by a resident in the context of the primary care exception, the time when the teaching physician was present via audio, video, or in-person should be included when determining the E/M visit level. There is no evidence that MDM is a more accurate indicator than time in selecting the appropriate level of the visit in the context of the primary care exception for services furnished by residents and billed by teaching physicians in primary care centers. Just as in a non-teaching setting, time spent by the teaching physician reviewing the chart, looking at images, discussing with consultants, etc. should all still count in determining the E/M visit level. **Therefore, ACP recommends that both time and MDM be allowed as options for selecting the appropriate level of visit.**

Telehealth

Temporary Additions to the Medicare Telehealth Services List, and Codes Not Granted Category 3 Status

CMS Proposal: In the CY21 PFS Final Rule, CMS created a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis following the end of the PHE. Category 3 describes those services that were added to the Medicare telehealth services

list during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under Categories 1 or 2. The CY21 Final Rule provided coverage through the end of the PHE for more than 100 services. Services that were temporarily added on an interim basis would not be continued after expiration of the PHE. In the Proposed Rule, CMS is proposing to retain all services added to the Medicare telehealth services list on a temporary, Category 3 basis, and that were maintained on that list in the CY21 Final Rule, until the end of CY 2023. The Agency believes this will allow additional time for stakeholders to collect, analyze, and submit data to support permanent inclusion on a Category 1 or 2 basis.

ACP Comments: ACP supports CMS' proposal to retain all services added to the Medicare telehealth services list on a temporary, Category 3 basis until the end of CY23. While the College appreciates and supports this extension, **we strongly recommend that Category 3 be made permanent as to provide for a more consistent and efficient on-ramp for new services to be added. Additionally, ACP strongly recommends CMS add codes 99441-99443 back to the Category 3 list and retain these services until at least the end of CY23.** Recommendations regarding audio-only services are discussed in greater detail in sections to follow.

New Originating Site

CMS Proposal: CMS is broadening the scope of services for which the geographic restrictions do not apply and for which the patient's home is a permissible geographic originating site to include telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE. CMS is additionally proposing to amend its regulations to conform with the statutory change of the CAA (2021) to include rural emergency hospitals as telehealth originating sites beginning in CY23. In order to implement the new requirement, CMS is proposing that, as a condition of payment, the billing clinician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the six-month period before the date of the mental health telehealth service. The Agency is also proposing that this distinction between the telehealth and non-telehealth services must be documented in the patient's medical record. CMS is seeking comment on whether the required in-person, non-telehealth service could also be furnished by another clinician or practitioner of the same specialty and same subspecialty within the same group as the clinician or practitioner who furnishes the telehealth service.

ACP Comments: ACP supports any efforts to expand 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. Even before the pandemic, mental health professionals were and are limited, and the need for mental health and substance use treatment is growing exponentially. The pandemic and fear of seeking in-person care has exacerbated this issue.

While it would be preferred that a beneficiary be known to the primary care clinician, setting an arbitrary requirement that they be seen in-person within 6 months before the telehealth visit may not be feasible in an area with a shortage of mental health professionals, nor even be necessary if the clinician and beneficiary have an established relationship. Whether the mental health service is provided using audio-video or audio-only should be most appropriately determined by the clinician(s) providing the service based on patient needs, preferences, personal and technological capabilities, and clinical appropriateness. In addition, it should also not matter if the clinicians or practitioners are in the same group or not if they are providing different services for different diagnoses for the patient – if they are in communication with each other regarding the patient’s care and treatment.

ACP also supports broadening the scope of services for which the geographic restrictions do not apply, and for which the patient’s home is a permissible originating site, 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 recommends that CMS permanently extend the policy to waive geographical and originating site restrictions after the conclusion of the PHE for *all* telehealth services.**

Additionally, the College does not support documenting a distinction between the telehealth and non-telehealth services in the patient’s medical record and this should not be made a requirement. Medicare has the modifier 95 “synchronous telemedicine service rendered via a real-time audio and video telecommunications system” in place to identify telehealth services and the 02-place of service code. Requiring additional documentation in the patient medical record would only place an additional documentation burden on the clinician.

Payment for Services Using Audio-Only Communication Technology

CMS Proposal: CMS is proposing to revise its definition of “telecommunications system” to permit use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home. In support of its proposal, CMS cites the possible negative impact on access to care if a sudden discontinuation were allowed, as well as its belief that mental health services are distinct from most other services on the telehealth list in that they do not necessarily require visualization of the patient to fulfill the full scope of service elements.

The Agency is also seeking comment on what, if any, additional documentation should be required in the medical record to support the clinical appropriateness of providing audio-only telehealth services for mental health. Additional documentation could include information about the patient’s level of risk and any other guardrails that are appropriate to demonstrate clinical appropriateness and minimize program integrity and patient safety concerns. For purposes of the proposed audio-only mental health services exception, CMS is seeking comment on whether it should exclude certain higher-level services, such as level 4 or 5 E/M visit codes, when furnished alongside add-on codes for psychotherapy.

ACP Comments: ACP is extremely supportive of continuing to allow audio-only services. **Therefore, the College recommends that CMS maintain coverage of audio-only mental health visits even after the PHE is lifted. This extension should last at least through the end of 2023 with an option to extend it even further or consider making it permanent, based on the experience and learnings of patients and physicians who utilize these visits. This would require further study of the impact on access and the clinical effectiveness of audio-only services by the Agency.** Since the beginning of the COVID-19 pandemic, we have repeatedly called attention to the need for patients to access care by phone.

Additionally, because audio-only telehealth is an important component tool for physicians to improve health equity and patient access, it should not be limited to only patients seeking behavioral and mental health services. We are asking CMS to broaden the flexibility and continue to allow other evaluation and management (E/M) services to be provided using audio-only communication. Although in-person care is preferred over audio-video care, which in turn is preferred over audio-only care, there are too many situations when audio-only care is the only option for patients. As parts of the country struggle with broadband connectivity and smartphone capabilities to support video visits, particularly in rural and economically-disadvantaged communities—and some patients remain uncomfortable with video visit technology—ACP encourages CMS to allow telephone E/M services to support these communities in their efforts to care for patients. The patient’s personal clinician is able to make the professional determination on when the use of audio-only technology is appropriate and when the patient needs to come into the office or to a location that has audio-video technology available (when getting to the office for an in-person visit is not possible). In addition, these changes have greatly aided clinicians who have had to make up for lost revenue and still provide accessible and appropriate care to patients. Further, by excluding higher-level services, such as level 4 or 5 E/M visit codes, CMS is adding burden to both the clinician and, therefore, the patient. **Instead, ACP would support extending the use of audio-only technology for the services approved during the PHE at least through the end of 2023 with an option to extend it even further or consider making it permanent, based on the experience and learnings of patients and physicians who utilize these visits.**

The College also strongly recommends that CMS maintain pay parity between telephone E/M claims and in-person E/M visits and between all telehealth and in-person visits even after the PHE is lifted. This extension should last at least through the end of 2023 with an option to extend it even further or consider making it permanent, based on the experience and learnings of patients and physicians who utilize these visits. Furthermore, ACP encourages CMS to place trust in clinicians regarding their ability to assess the appropriateness of an audio-only visit. The College believes CMS’ intent to treat audio-only and in-person visits as wholly separate and distinct is misguided. It would be inappropriate to treat documentation requirements for audio-only services and in-person visits differently as they are, indeed, not different.

Patients have become accustomed to and appreciate telehealth/telephone visits, and many appreciate the flexibility these visits provide. The transition from in-person visits to the greater use of telehealth and telephone visits during this PHE has provided patients a safe option of receiving equivalent or nearly equivalent care to what they otherwise would receive in an in-person setting. Internists are skillfully adapting to gathering necessary information via telehealth that they would have gathered during an in-person visit. The use of telehealth has allowed physicians to visit patients virtually in their homes, allowing in some cases for certain unexpected improvements in care, as the clinician may better be able to identify the impact of social determinants on a patient's health. It is imperative that physicians and payers have an opportunity to evaluate the impact of these changes and adapt before moving forward.

Direct Supervision

CMS Proposal: In its March 2020 Interim Final Rule with Comment (IFC), CMS changed the definition of "direct supervision" during the PHE to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY21 Final Rule, CMS finalized continuation of this policy through the end of the calendar year in which the PHE ends or December 31, 2021. CMS is seeking comment on whether this flexibility should be continued or potentially be made permanent. The Agency is also seeking comment on:

- The extent to which the flexibility to meet the immediate availability requirement through the use of real-time, audio/video technology is being used during the PHE, and whether clinicians and practitioners anticipate relying on this flexibility after the PHE;
- The possibility of permanently allowing immediate availability through virtual presence for only a subset of services due to potential concerns over patient safety; and
- Requiring a service level modifier, if this flexibility were made permanent, to identify when the requirements for direct supervision were met using two-way, audio/video communications technology.

ACP Comments: ACP was pleased to see CMS respond to the needs of clinicians by extending the flexibility to continue to provide direct supervision via interactive audio/video technology through the end of 2021. **Based on the experience and learnings of patients and clinicians who are utilizing these supervision flexibilities, ACP believes that providing for a permanent flexibility in this space supports the expansion of telehealth services and protects frontline health care workers by allowing appropriate social distancing measures. Similarly, we believe that clinicians should feel empowered to supervise clinical staff virtually, at their discretion, regardless of whether there is a declared PHE.** ACP would be supportive of the use of a service level modifier if it does not add additional burden to the patient or physician. The use of a service level modifier could prove useful in tracking the experience and learnings of patients and physicians who utilize these services. The College looks forward to continued work with CMS to provide flexibility in this regard as we learn more about the impact of the COVID-19 pandemic.

Virtual Check-In Code

CMS Proposal: In the CY21 Final Rule, CMS established on an interim basis HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion*) for an extended virtual check-in. This code could be furnished using any form of synchronous communication technology, including audio-only. In that rule, the Agency finalized a direct crosswalk to CPT code 99442 and established a payment rate of 0.50 work RVUs. In the Proposed Rule, CMS is proposing to permanently adopt coding and payment for CY22, HCPCS code G2252 as described in the CY21 Final Rule.

ACP Comments: ACP does not agree that the establishment of G2252 is the solution to providing an alternative to telephone E/M visits.

Alternatively, CMS should work to expand coding options for telephone E/M services using CPT or G-codes. As the College has noted previously, telephone E/M services are not just a longer virtual check-in service; they are an E/M service. Therefore, ACP strongly disagrees with CMS' conflation of virtual check-ins, of any duration, with audio-only (telephone) E/M, as they are completely different. Patients without access to telehealth need options that provide reliable, remote means to communicate with their physician, even following the end of the PHE.

Additionally, while ACP does not support the use of G2252 as a replacement for telephone E/M visits, it should be noted that the cross-walk G2252 to the current value of 99442 is significantly flawed. The physician work RVUs associated with G2252 and 99442 (work RVU: 0.50) are considerably lower than the value of 99442 established by CMS through interim final rulemaking for the duration of the PHE. During the PHE, CMS has established a work RVU for 99442 that is cross-walked to the value of 99213 (work RVU: 1.30). Use of G2252 would provide considerably less resources to physicians to enable them to provide effective care for their patients. This may lead to many physicians deciding against using G2252, despite CMS' best intentions. **Once again, rather than adopting a substitute, the College strongly recommends that CMS maintain pay parity between telephone E/M claims and in-person E/M visits and between all telehealth and in-person visits even after the PHE is lifted. This extension should last at least through the end of 2023 with an option to extend it even further, or consider making permanent, based on the experience and learnings of patients and physicians who are utilizing these visits.** The College looks forward to working with CMS and the CPT Editorial Panel to ensure that coding and payment options for these services are made widely available.

Vaccine Administration Services

CMS Proposal: Due to the PHE and ongoing interest in payment rates for vaccine administration, CMS is requesting comment to obtain information on the costs involved in furnishing preventive vaccines, with the goal to inform the development of more accurate rates for these services. Specifically, CMS is seeking comment on:

- The different types of health care clinicians (and providers) who furnish vaccines and how those clinicians (and providers) changed since the start of the pandemic;
- How the costs of furnishing flu, pneumococcal, and hepatitis B vaccines compare to the costs of furnishing COVID-19 vaccines, and how costs may vary for different types of clinicians (and providers); and
- How the COVID-19 PHE may have impacted costs and whether clinicians (and providers) envision these costs to continue.

CMS is additionally seeking feedback on its proposed policy to pay \$35 add-on for certain vulnerable beneficiaries when they receive a COVID-19 vaccine at home. The Agency is interested in input on what qualifies as the “home” and how it can balance ensuring program integrity with beneficiary access.

ACP Comments: ACP strongly encourages CMS to adopt the vaccine valuation recommendations for the new COVID-19 vaccines exactly as provided by the RUC. On July 30, 2021, the CPT Editorial Panel created new code 0003A to describe the immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS[1] CoV-2) (Coronavirus disease [COVID-19]) vaccine for the Pfizer-BioNTech third dose. Most recently, on August 16, 2021, the CPT Editorial Panel created new code 0013A to describe the immunization administration injection for COVID-19 vaccine for the Moderna third dose.

In August 2021, the RUC reviewed CPT codes 0003A and 0013A. The RUC recommends a work RVU of 0.20 for CPT codes 0003A and 0013A, the same as the first and second dose COVID-19 immunization administration codes.

Further, the College strongly urges CMS to make coding and payment available for time spent by physicians providing counseling services to patients who are seeking to mitigate their risk for COVID-19 infection. Specifically, ACP encourages CMS to make payment and coverage available for CPT code 99401 (Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes), wRVU 0.48. The College believes that this code adequately describes the resources and physician work involved in providing counseling and risk factor reduction services to patients with inquiries about COVID-19. We encourage CMS to temporarily make payment available for this code through at least December 31, 2023, and waive the face-to-face requirement associated with this service. COVID 19 vaccines have been available since December of 2020 and physicians have been receiving inquiries from their patients and providing significant counseling and risk factor reduction services to patients who are concerned about the COVID-

19 vaccines prior to that time. ACP further urges CMS to make payment for CPT code 99401 retroactive for physicians that have provided this service until January 1, 2021.

ACP supports the \$35 add-on for vulnerable beneficiaries to receive a COVID-19 vaccine at home, which would include a private home, nursing home, assisted living facility, group home, or other congregate setting. The key is that the beneficiary is at high risk for COVID-19 due to age, living situation, or risk status due to chronic or acute illness as deemed appropriate by the beneficiary's personal physician or healthcare professional.

Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance

CMS Proposal: CMS is proposing to add a travel allowance for a lab technician to collect a specimen from homebound and/or non-hospital patients. The Agency is proposing to allow these travel logs to be documented using electronic or paper means. The payment for travel allowance is set to expire once the PHE ends. Additionally, this proposal would also allow labs to perform COVID-19 diagnostic testing to these patients.

ACP Comments: ACP supports improved access to COVID-19 diagnostic testing for homebound and non-hospital patients. Paying a travel allowance and allowing flexibility in the format for travel logs provides additional incentive for labs and other entities to provide testing to those who have difficulty obtaining such testing.

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

CMS Proposal: CMS is proposing several modifications to this section. Specifically, CMS is proposing:

- Geographic adjustments to the non-drug component of the OUD bundled payment (including take-home opioid antagonist medication [Naloxone]);
- Payments for medications delivered, administered, or dispensed to a beneficiary as part of an adjustment to the bundled payment are to be considered a duplicative payment if Part B or D also separately paid for the same medication to the same beneficiary on the same day;
- A new G-Code and payment for a new, higher dose nasal spray Naloxone product; and
- To revise the regulations to allow OTPs to continue to furnish therapy and counseling using audio-only communication technology when audio/video is not available to the beneficiary or the beneficiary has not consented to use. After the PHE ends, OTPs would be required to use the -95 modifier to the counseling and therapy add-on code (G2080).

ACP Comments: ACP supports extending access to audio-only consultations, whether due to no audio-video capabilities or by patient preference.

Updates to Physician Self-Referral Regulations under Stark Law

CMS Proposal: CMS recently made several changes to the Stark Law regulations, which were effective January 19, 2021. Among the changes finalized, the Agency revised the definition of “indirect compensation arrangement” which added a second condition related to the compensation under review for the compensation to potentially implicate the Stark Law. In the CY22 Proposed Rule, CMS is backtracking this definition. Specifically, CMS is revising the definition to make clear it only applies if the compensation arrangement closest to the clinician involves compensation for that clinician’s (or clinician’s immediate family members’) *personally performed services*. All other arrangements would be analyzed under essentially the same definition that was in effect prior to January 19, 2021.

ACP Comments: ACP greatly appreciates CMS’ attempts to lessen the complexities of the Stark Law. **The College is supportive of the positive steps to make the Stark Law more flexible, create exceptions that reduce the number of inadvertent or technical violations, and align the law with the industry shift from volume to value. Although we commend these efforts, we remain concerned that the frequent amendments to definitions will result in even greater regulatory burden to health care entities and clinicians.** For example, the Proposed Rule would amend the definition of “indirect compensation arrangement” (ICA). While we understand CMS’ intent, just this year (in January 2021) the Stark Sprint Regulations¹ introduced a new ICA definition. With only seven months between these two acts, and the certainty of downstream burden to clinicians, the College cautions CMS against continuing the practice to structurally amend definitions that are critical to the application of the regulations. In this instance, the proposed ICA definition multiplies the number of variables and introduces new, defined terms into the analysis. Surely, this will confound the host of designated health care entities and clinicians required to comply. Moving forward, **ACP recommends CMS collaborate with the appropriate entities to provide adequate lead time to compliance and less shock to those who must comply.**

To guide the application of the new ICA definition, CMS also proposed regulatory text clarifying when services will be considered *personally performed*:

Services that are personally performed by a physician... do not include services that are performed by any person other than the physician... including, but not limited to, the referring physician’s... employees, independent contractors, group practice members, or persons supervised by the physician...

The College is supportive of the Agency’s efforts to provide health care entities and clinicians with clarifying guidance to its proposal. However, **we are concerned that it remains unclear whether services performed by an employee but provided ‘incident to’ services personally performed by a physician would, in fact, qualify as the physicians’ personally performed**

¹ [Stark Sprint Regulations, 85 FR 77492.](#)

service. ACP recommends CMS provide further guidance in its final rule that speaks to this uncertainty more clearly.

Considering the legal and regulatory complexities of the Stark Law, **ACP is supportive of the intent behind CMS' proposals and subsequent clarifications.** Echoing our previous concerns about the 'turn-around-time' for compliance, though, we also note the burdens resulting from the proposed compliance timeline. The comment period for the Proposed Rule ends September 13, 2021. The PFS final rule, then, will likely go into effect January 1, 2022. Consequently, it would be prudent to consider both the current and proposed ICA definitions in determining whether an arrangement is appropriate under Stark. This is a tall task, especially for small and independent clinicians who do not retain large legal and compliance departments. **If finalized, the College strongly recommends CMS re-examine the ever-growing complexity of the statute, the likelihood its proposals will, in fact, lend greater clarity to the regulations, and continue to collaborate with health care entities and clinicians to better understand the downstream effects and burden of Stark regulations.**

Requiring Certain Manufacturers to Report Drug Pricing Information for Part B, and Other Items

CMS Proposal: CMS is proposing to implement the reporting requirements of Section 401 of the CAA (2021). Section 401 established a requirement that manufacturers without Medicaid drug rebate agreements report quarterly average sales price (ASP) information beginning in January 2022 for drugs and biologics paid for by Part B. A civil monetary penalty of \$10,000 per price misrepresentation per day will be issued for the failure to report.

ACP Comments: **ACP supports efforts to require manufacturers to provide CMS with regular and accurate average sales price information for drugs and biological products that are covered under Medicare Part B as a means to ensure accurate payment, and urges CMS to go further in requiring the reporting of additional price and cost information.** While manufacturers are required to report information on average sales prices for some Medicare Part B drugs to CMS quarterly, the true price of the drug remains unclear as the reported ASP includes discounts, rebates, and other payments and differs from the list price. [ACP supports](#) transparency in the pricing, cost, and comparative value of all pharmaceutical products and believes that manufacturers should disclose actual material and production costs to regulators, as well as research and development costs contributing to a drug's pricing. Additionally, [the College supports](#) methods to align payment for prescription drugs administered in-office in a way that would reduce incentives to prescribe higher-priced drugs when lower-cost and similarly effective drugs are available.

Electronic Prescribing of Controlled Substances (EPCS)

CMS Proposal: Based on the consideration of challenges brought on by the COVID-19 pandemic, CMS is proposing to extend the compliance date for EPCS requirements until January

1, 2023. The Agency is also proposing to further extend the compliance date for Part D controlled substance prescriptions written for beneficiaries in long-term care facilities until January 1, 2025, due to the unique circumstances of these clinicians. As a means of enforcement, CMS proposes that its compliance actions in CY 2023 would consist of sending letters to prescribers that the Agency believes are violating the EPCS requirement. The Agency notes it will consider whether further compliance actions will be necessary in future rulemaking.

ACP Comments: Where the practice is, in fact, less burdensome for both patients and clinicians, **ACP supports the use of electronic prescribing for controlled substances.** We caution, though, that it is not always true that e-prescribing of controlled substances is *actually* less burdensome. 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 encourages CMS to study the true costs and implications of this mandate on clinicians.

Due to the burdens of the COVID-19 pandemic, ACP also supports the delay of implementation because 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. Additionally, rural areas face their own challenges. In some rural parts of states, the system does not operate consistently due to limited broadband availability or reliability and there is no manual back-up system in place. Therefore, ACP strongly recommends that a backup system, such as paper or telephone, should be established in order to accommodate for systems going down or other technological barriers. In finalizing its proposals, CMS should pay close attention to the real, true conditions in practice and the downstream implications of its policies – especially to small, independent practices, particularly in rural areas.

Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging

CMS Proposal: In the CY22 Proposed Rule, CMS proposes to delay the effective date for the penalty period until January 1, 2023, or January of the year following the end of the PHE, whichever is later. CMS believes this delayed implementation is a proper acknowledgment of the impact of the COVID-19 pandemic and the time required to implement any operational changes to its claim processing and prepare for the upcoming penalty phase.

CMS is seeking comment on whether it is more appropriate to deny or return claims that fail AUC claims processing edits during this period. Specifically, CMS is considering whether claims that do not pass the AUC claims processing edits, and therefore will not be paid, should be initially returned to the health care clinician so they can be corrected and resubmitted, or should be denied so they can be appealed. CMS also requests comment on whether the penalty phase should begin first with returning claims and then transition to denying claims after a

period of time. The Agency hopes this feedback will help it better understand which pathway would be most appropriate once the AUC program is fully implemented

ACP Comments: While the College recognizes that consultation of appropriate use criteria (AUC) for advanced diagnostic imaging tests is important, we believe that the denial of claims would impose significant disruption to physicians, hospitals and other health care clinicians and “provider” entities. **We therefore urge the Centers for Medicare and Medicaid Services (CMS) to return claims that fail AUC claims processing edits rather than deny them.**

Additionally, CMS should continue voluntary participation in the AUC Program. Voluntary participation should not require consultation of AUC using a CMS qualified Clinical Decision Support Mechanism (CDSM), nor should Medicare reimbursement be contingent upon documentation of consultation on the furnishing clinician’s claim. Physicians and other health care “providers” are unprepared for another significant regulatory requirement. ACP, while committed to educating physicians about Medicare policies and mandates, has prioritized our investment in education and training for successful participation in Medicare’s Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). Preparing physicians for a Medicare AUC Program that requires use of a qualified CDSM and claims documentation will divert important resources and attention away from meaningful quality improvement—particularly while we are in the midst of the ongoing COVID-19 pandemic.

Innovative Technology and Artificial Intelligence (AI) Request for Information

CMS Proposal: CMS is soliciting public comment to better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. In the Proposed Rule, CMS posed several questions regarding coverage of AI and other innovative technologies.

ACP Comments: The College applauds CMS for initiating a discussion on the use of AI and other innovative technologies. **At the outset, the College wants to emphasize that we believe, due to its importance and implications, this RFI should be removed from the greater Proposed Rule and re-opened so as to allow more time to gather stakeholder feedback.** By way of preliminary comments, however, the College offers the following for CMS consideration.

The rapid growth of digital technologies and their role in clinical care has the potential to improve patient care and outcomes. However, at present, these technologies are far from widespread or typical. Present experience with these applications is insufficient to draw conclusions that may have an impact across the payment schedule. **Therefore, the College cautions against establishing precedent-setting payment policy based on limited experience and data. ACP welcomes the opportunity to engage in ongoing discussion of this technology and its impact on both direct and indirect practice expense.**

ACP is additionally concerned that these technologies are most challenging for small and independent practices because they are dependent on third parties to implement. These third parties can be costly.

- *To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work?*

The College believes it is too early to make determinations regarding the impact of augmented intelligence/machine learning on physician work. These technologies are expanding in clinical use, but until they become more commonplace, making determinations across the Medicare physician fee schedule is not possible. While ACP does acknowledge that impacts on work are possible, this will vary across the services to which AI is applied and the role AI plays in the clinical encounter. For instance, AI applications may provide varied clinical contributions from assistive to augmentative to autonomous, each of which will have a different effect on physician work for both the primary care physician or other Qualified Healthcare Professional (QHP).

Additionally, ACP does not agree with the terminology of “substitutes or supplements” for physician work. Rather, we believe the contribution to clinical work depends on the level of autonomy of the application. For example, assistive technology may provide additional clinical data points, contributing to the overall evaluation of the patient. This could lessen or increase physician work, depending on the clinical situation to which the application is used. An assistive technology could potentially broaden the patient population for whom a certain diagnostic service is applicable or increase the number of potential diagnoses the physician would need to consider. An autonomous technology, on the other hand, may have different impacts on physician work.

- *How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries? For example, if a new software algorithm or AI technology for a diagnostic test result in a reduction in the amount of time that a practitioner spends reviewing and interpreting the results of a diagnostic test that previously did not involve such software algorithm or AI technology, and if the software algorithm or AI could be considered in part a substitute for at least some physician work, it may follow that the intensity of the service decreases. It is also possible that a software algorithm for a diagnostic test that is supplementing other tests to establish a diagnosis or treatment pathway for a particular condition could result in an increase in the amount of time that a practitioner spends explaining the test to a patient and then reviewing the results.*

The College strongly believes it is too early in the diffusion of these technologies to make broad determinations. In one instance, it may seem that an AI application

performing clinical tasks or making clinical decisions lessens the quantity of physician work. In another, this additional software acquired information may prompt additional physician tasks. For instance, integrating the determinations of the AI algorithm into the broader clinical presentation requires careful consideration. There may be instances where the new data is contradictory or inconsistent with other clinical data or the physician's clinical intuition, increasing the intensity of decision making. As CMS acknowledges above, there may be additional work in explaining to the patient that a digital application is being used and the way the application operates. It is possible that the total time may decrease at the same time as the intensity increases, thereby maintaining or increasing the total work involved.

- *How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI? For example, it is possible that services that involve software algorithms and/or AI may allow a practitioner to furnish care more efficiently to more Medicare beneficiaries, potentially increasing access to care. Additionally, to what extent have services that involve innovative technology such as software algorithms and/or AI affected access to Medicare-covered services in rural and/or underserved areas, or for beneficiaries that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions, frailty, etc.) in obtaining health care?*

Digital technology, including AI, has the potential to increase access to care. For example, the COVID-19 PHE demonstrated the benefits of telemedicine and remote patient monitoring. Software and AI driven algorithms stand to provide similar benefit through expanded access.

These technologies also have the potential to improve access to medical care in rural and underserved areas. However, it is important to consider that these technologies may involve patient (consumer) expense, such as for access to broadband internet service—or they may even be out of a patient's reach if broadband service is not even provided in their area. Where such access is limited, there is the potential to create or exacerbate health disparities across populations. Health care is not the only area where digital/broadband access is important to quality of life. To that end, ACP believes broader public policy is necessary to enable rural and underserved areas to experience the full potential benefit of digital technologies, such as AI.

- *Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? For example, increased access to services to detect diabetic retinopathy such as the service described*

by CPT code 92229 could eventually lead to fewer beneficiaries losing their vision. Because CPT code 92229 can be furnished in a primary care practice's office and may not require the specialized services of an ophthalmologist, more beneficiaries could have access to a test, including those who live in areas with fewer ophthalmologists. Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?

Software algorithms and AI stand to improve health care disparities as the diabetic retinopathy example demonstrates. The potential to worsen or widen health disparities also exists. These technologies require specific hardware, software, smartphone/laptop access, and broad band capability. Each of which involves expenses which may extend beyond the control of the furnishing physician. Therefore, more far-reaching policies outside the Medicare physician fee schedule may be necessary to strengthen equitable access across the United States.

The potential for bias in machine-learning algorithms is well-described in the data science literature and a legitimate concern. Guardrails to ensure that bias does not lead to compromised patient care is necessary as regulations around software as a medical device evolve.

CMS asks several important questions in the Proposed Rule about AI. ACP notes that these questions, in summary, are best answered by noting that in the current environment each AI technology should be considered on a case-by-case basis. **Today, expenses related to approved AI technology should be considered a direct expense. We further re-emphasize our strong recommendation that this topic be given its due time and attention by being separated from the broader Proposed Rule and re-opened as to provide more time for stakeholder input.**

Advancing to Digital Quality Measurement and the Use of FHIR® in Physician Quality Programs – Request for Information

CMS Proposal: The Proposed Rule includes a RFI to collect information on planning and transitioning CMS programs to complete digital measurement by 2025. Maintaining alignment with the Department of Health and Human Services (HHS) Health Quality Roadmap, CMS is approaching priorities and initiatives with other entities, like the ONC (i.e., 21st Century Cures Act), to promote data interoperability and access. The RFI seeks comments on the following:

- CMS adoption of FHIR® to reduce the collection and analysis burden imposed by current electronic quality measures. Under the HL7 framework, quality data reporting programs

would utilize a standardized data collection structure and single terminology to collect electronic measure data.

- Enhancement of the definition of dQM so that it contains language regarding proposed software that processes digital data to determine measure scores.
- Redesign quality measures as “self-contained tools” that dQM software incorporates end-to-end measure calculation solutions.
- Alignment of quality measure reporting programs across federal and state agencies and other sectors via the adoption of a dQM portfolio.

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 we emphasize that small and independent practices that are dependent upon third-party vendors to enable this functionality are worried by these proposals.** If a third-party vendor refuses to turn on the functionality, those practices will fail. This is the same issue seen in the quality measures and elsewhere. ACP is concerned that CMS is failing to consider small or independent practices and their capabilities when writing its proposals in these spaces, and strongly encourages CMS to collaborate with stakeholders to greater understand the real-world circumstances.

The College recommends CMS consider issuing an Interim Final Rule (IFR) with an additional 30- or 60-day comment period prior to finalizing any recommendation for the use of FHIR. This will allow CMS to review public feedback and make final determinations on the readiness of FHIR® Release versions.

Health Equity Initiative

CMS Proposal: CMS makes several proposals to advance health equity, consistent with President Biden’s recent Executive Order 13985. The 2022 Proposed Rule includes a RFI asking for feedback on the Agency’s efforts to collect additional data to identify and respond to health disparities in its 32 programs and policies. The Agency notes several strategies it has considered, including clinician and/or public-facing reports on MIPS quality measures stratified by dual-eligible status, race, and other factors. CMS is also seeking comment on ways the Agency can increase the collection of demographic and social risk data, including the collection of a “minimum set” of demographic elements (e.g., race, ethnicity, language, disability status) that could be used for a variety of tracking and quality measurement purposes. The Agency is considering using EHRs as a data collection mechanism.

ACP Comments: ACP is encouraged to see CMS interest in advancing health equity for people with Medicare while protecting individual privacy. Access to health equity data may enable a more comprehensive assessment of health equity and support initiatives to close the equity

gap. However, it is important that any CMS designed data collection is performed in a way that would not place an undue burden on physicians or their practices.

Quality Payment Program (QPP)

CMS Proposal: For Performance Year (PY) 2021, there are two exceptions that may be applied for: extreme and uncontrollable circumstances, and the MIPS Promoting Interoperability (PI) application. Both exceptions require an application be received by December 31, 2021, as they are not automatic.

CMS is proposing to extend CMS web interface as a collection type for quality reporting into the 2022/2023 PYs.

ACP Comments: The ACP supports CMS extending the web interface reporting into 2022/2023 performance years. As we noted in last year's comments, with the additional challenges that the practices are navigating due to the COVID-19 PHE, now is not the right time to enact major changes to MIPS reporting such as eliminating a reporting mechanism.

MIPS Value Pathway (MVP)

CMS Proposal: CMS is proposing to begin the MVP program in CY 2023 to provide time for MIPS-eligible clinicians to familiarize themselves with MVPs and begin preparing their practices (e.g., system updates). For the CY23 PY, CMS proposes seven MVPs (Rheumatology, Stroke Care and Prevention, Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia).

As an example of the MVP most applicable to internists, MVP for Optimizing Chronic Disease Management beginning in PY 2023 is proposed as follows:

Quality Measures

- Q006: Coronary Artery Disease: Antiplatelet Therapy
- Q107: Adult Major Depressive Disorder: Suicide Risk Assessment
- Q118: Coronary Arter Disease: Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)
- Q119: Diabetes: Medical Attention for Nephropathy
- Q236: Controlling High Blood Pressure
- Q398: Optimal Asthma Control
- Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease
- Q047: Advanced Care Plan
- TBD: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure

Improvement Activities

- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_21: Improved practices that disseminate appropriate self-management materials
- IA_CC_13: Practice improvements for bilateral exchange of patient information
- IA_AHE_3: Promote use of Patient-Reported Outcome Tools
- IA_BE_20: Implementation of condition-specific chronic disease self-management support programs
- IA_BE_22: Improved practices that engage patients pre-visit
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_CC_14: Practice improvements that engage community resources to support patient health goals
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_PCMH: Implementation of Patient-Centered Medical Home model
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes

Cost

The Total Per Capita Cost is proposed to be the measure that aligns with this MVP, as there are no current episode-based measures. The two new proposed episode-based measures, diabetes and asthma/COPD, could be applicable in future rulemaking.

Promoting Interoperability

CMS Proposal: The scoring methodology for Promoting Interoperability (PI) in MVPs will be the same as in traditional MIPS, except for subgroups, which will be scored based on their affiliated group's PI score. As in traditional MIPS, the scoring of the PI category recognizes the importance of using CEHRT to support quality improvement, patient engagement, and interoperability.

ACP Comments: ACP believes that MVP pathway could be a step in the right direction if we include measures that are methodologically sound and evidence-based addressing clinical areas of importance. It is also critically important that MVPs move toward a wholesale departure from traditional MIPS in order to offer a true onramp for practices to Alternative Payment Models.

The ACP has been working closely with CMS in developing MVPs such as the Optimizing Chronic Disease Management MVP. The College's original Chronic Disease Management MVP [submission](#) was provided to CMS in February 2020 (as well as a proposal for a Preventive Care MVP). Over the course of the past year and a half, CMS has worked on this concept and ultimately proposed what is in this current rule. Upon review of the latest CMS draft of this MVP, out of the 9 quality measures that CMS has proposed to include, the ACP supports 5, and does not support 4, as listed below.

The ACP supports these 5 measures:

- Coronary Artery Disease (CAD): Antiplatelet Therapy
- Adult Major Depressive Disorder (MDD): Suicide Risk Assessment
- "Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor
- Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)"
- Diabetes: Medical Attention for Nephropathy
- Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

The ACP does NOT support these 4 measures:

- Controlling High Blood Pressure
- Optimal Asthma Control
- Advanced Care Plan
- Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (The reasons for not supporting these measures are included later).

Further, as outlined in our [letter](#) following CMS' MVP Town Hall in January 2021, ACP believes that changes to truly reinvent MVPs, CMS must:

- Create synergy across the four performance categories. To do so, we must stop thinking of each category as siloed and 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.

MVP: Quality Measure Review

The ACP reviewed the quality measures under four MVPs (Optimizing Chronic Disease Management MVP, Advancing Care for Heart Disease MVP, Coordinating Stroke Care to

Promote Prevention and Cultivate Positive Outcomes MVP, Advancing Rheumatology Patient Care MVP), that are related the Internal Medicine.

The College supports the following measures that are included in the 4 MVPs that we reviewed:

Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy

Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Q118: "Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor

Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)"

Q119: Diabetes: Medical Attention for Nephropathy

Q176: Tuberculosis Screening Prior to First Course Biologic Therapy

Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Q178: Rheumatoid Arthritis (RA): Functional Status Assessment

Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

However, there are several measures that the ACP does not support. These are included in Appendix A, along with a rationale.

MVP: Patient Reported Outcome Measure Review

ACP also reviewed the measures proposed for addition to the MIPS program and noted a new measure, titled Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PROM). This measure has been proposed to be included in an MVP and the internal medicine specialty measure set.

The College reviewed PCPCM PROM in January 2021, and we do not support the use of this measure. While ACP is supportive of PRO-PMs that are methodologically sound, and evidence based to assess, promote, and reward patient-centered care, we believe that this measure does not meet those criteria and there is a need to see additional data before it is ready for implementation. More specifically, ACP has concerns that this measure was poorly specified and does not have data to show that it would lead to improvements in care or clinical outcomes. The measure includes all patients who have completed the survey without any exclusions or risk adjustment, and hence this would result in a non-representative sample. Also, while the measure intends to establish a benchmark for good, comprehensive

primary care, the evidence that this measure will lead to improved outcomes and is actionable at the level of the individual clinician or group, was not presented. There are no articles cited to support the actions that can be done to improve the scores on individual items. The vast majority of these interventions are at the system level. While the developer presents quite a bit of information regarding the validity and reliability of the PCPCM instrument, ACP had a number of concerns regarding the face validity of the instrument. For example, one of the questions, “The care I get takes into account knowledge of my family,” might not apply if you are visiting the physician for a sore throat. In addition, the answers to many of the questions would be dependent on a patient’s health status. There is some question as to how this measure would work in a clinical practice when there are multiple issues to focus on during a patient visit; therefore, ACP is not certain it would apply to internal medicine.

MVP: Population Health Measure Review

The ACP also reviewed the two-population health measure that are being proposed to be included in the foundational layer of the MVPs:

- Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups (finalized in CY 2021 final rule)
- Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (proposed)

The ACP generally supports measuring outcomes for patients at the group practice level or higher and supports the specific methodological changes proposed, particularly incorporating additional risk factors related to socioeconomic status and social risk factors, which has been a top advocacy priority of ACP’s for many years.

While the ACP has not yet formally reviewed the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups, we have reviewed NQF 1789: Hospital Wide All Cause Readmission Measure, and we support it, at the level of the hospital.

The ACP has not yet reviewed the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions measure.

MVP: Cost Measure Review

ACP does not support the TPCC (Total Per Capita Cost) cost measure that CMS has proposed to be included in 3 out of the 4 MVPs that we reviewed. The ACP strongly supports the development of cost measures targeted to specific specialties, patient populations, and conditions and believes the measures should be attributed at the group practice level or higher. The current use of one-size-fits-all cost metrics fails to account for varying abilities to control certain costs. While every clinician plays an important role in controlling costs, their ability to influence costs at different points in the process can vary widely. It is ineffective to

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

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

PY 2022 MIPS Changes

PY22 Reporting Exemptions Due to COVID-19

CMS Proposal: In response to the COVID-19 PHE, CMS is granting hardship exemptions on a case-by-case basis. If a clinician submits a hardship exemption application and the application is approved, they will not be eligible for a bonus or potentially face a penalty based on their MIPS performance in 2021.

ACP Comment: ACP applauds CMS for continuing its MIPS extreme and uncontrollable circumstances exceptions for the 2022 performance year on a case-by-case basis. This critical policy will provide physician practices with needed assurance to continue diverting all necessary resources toward treating patients and bringing about an end to the COVID-19 PHE. We commend CMS for making this important and necessary change.

PY22 Scoring and PY21 Performance Feedback

CMS Proposal: CMS is proposing to sunset traditional MIPS at the end of the 2027 performance and data submission periods and move to using only MVPs. The Agency notes that MIPS has been criticized as being expensive and time consuming, with low positive payment adjustments as a reward, and an uncertainty regarding its impact on patient care. At the same time,

however, CMS raises concern about the proposal to sunset traditional MIPS because MVPs remain untested, and it is unclear whether there will be MVP options for all participants.

CMS is statutorily required to weight the cost and quality performance categories equally, beginning with PY22. For PY22, the proposed MIPS performance category weights are summarized below (compared to PY 2021):

Performance Category	PY 2021 Weight	PY 2022 Proposed Weight	Percent Change
Quality	40%	30%	-10%
Cost	20%	30%	+10%
Promoting Interoperability	25%	25%	0%
Improvement Activities	15%	15%	0%

ACP Comment: ACP opposes CMS’ proposal to make MVP participation mandatory starting in PY2028. While ACP supports the MVP concept and would like it to move forward as soon as possible, we believe it is important to get it right. MVPs represent a critical juncture in the evolution of MIPS and the larger QPP. It offers 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. As discussed in our [letter](#) responding to the January 2021 Town Hall, ACP strongly believes that MVPs must be a wholesale departure from traditional MIPS—they must include 1) truly creating more synergy between the performance categories; 2) revamping the Promoting Interoperability Category; and 3) improving cost measurement.

We strongly urge CMS to ensure that MVP participation is voluntary and that physicians, group practices, and subgroups maintain the option to participate in traditional MIPS. Also, while the ACP supports CMS allowing multi-specialty groups to create subgroups for MVP reporting, the College does not support CMS making it a requirement for 2025 performance year and beyond. We urge CMS to delay this requirement so that we can see how the multi-specialty groups are managing the MVPs. CMS should allow some more time for the multi-specialty groups to figure out how to operationalize MVPs, before making any such mandatory requirements. **Further, ACP does not support retiring "traditional" MIPS, nor do we think it is necessary.** As those with the clinical expertise and understanding of their unique patient populations, it is critical that clinicians have the option choose which MVPs are most relevant to their specialty and unique patient populations. Another important advantage to physician selection of MVPs is that it would help to avoid potential downstream complications or delays

that could arise from sub-group reporting if CMS prospectively assigns or requires use of MVPs that are in existence by 2028. In terms of ensuring clinicians choose “appropriate MVPs,” this is just one of the many reasons why robust minimum reliability and case minimums are so important. If the MVP achieves its goals of reducing reporting burden, being more clinically relevant, etc., physicians will want to move to MVPs. That said, under no circumstances should CMS retire traditional MIPS before: 1) a comprehensive menu of MVPs are available to accommodate all specialties, practice sizes, and geographic locations; and 2) only a small minority of clinicians are still in MIPS.

We urge CMS to reconsider the threshold of at least 75 points, in 2022 PY, for the avoidance of MIPS penalty. The increase of the same from 60 in PY-2021 to 75 in PY-2022 is quite high, considering the burden that the healthcare systems are already under, during the pandemic. The threshold should remain at 15.01-59.99 given the current PHE. We also would ask that CMS slowly phase this in over several years, rather than instituting a significant increase from one year to the next.

ACP was surprised and disappointed in CMS’ decision to reverse its proposal to make a temporary exception to use performance year data to set 2021 benchmarks due to COVID-19. While there may be a sufficient quantity of 2019 data with which to make benchmark calculations, the pandemic’s untold impact on patient attribution, risk adjustment, and all aspects of performance measurement render comparing pre-pandemic data to 2021 impractical. ACP generally supports prospective performance benchmarks for all the reasons CMS provides in the rule. However, we believe the unique challenges physicians are facing this year and its inevitable impact on performance far outweigh the advantages of using prospective benchmarks in this unique case. We urge CMS to reconsider a temporary exception to use 2019 performance year data to set 2021 quality measure benchmarks.

Quality Category

There are currently 206 quality measures available for the 2021 performance period. CMS is proposing a total of 195 quality measures for the 2022 performance period.

ACP Comment: [ACP continues to recommend](#) that CMS ensure that all measures used by the program are patient-centered, actionable, appropriately attributed, and evidence-based measures. More specifically, ACP calls for all measures that are relevant to internal medicine be recommended by ACP’s [Performance Measurement Committee](#) (PMC). The ACP’s Performance Measure Reviews can be found at: <https://www.acponline.org/clinical-information/performance-measures>.

We reviewed the Internal Medicine Quality Measures Set and noticed that Quality#391: Follow-Up After Hospitalization for Mental Illness (FUH) is included in the set. The ACP does not support the measure at either the clinician or group levels, finding the measure not valid. The ACP supports this measure at the health plan level, finding the measure valid. While the ACP agrees with the importance of the measure, there is concern with access to ambulatory mental

health in the community, particularly rural communities, and therefore do not support it at the clinician or group levels. Additionally, this measure has not been tested at the level of the clinician or group and therefore more data are needed to apply it to any clinician or group, regardless of the specialty. It would be appropriate to apply it at the level of the health plan and may incentivize health plans to support efforts to increase the supply of mental health providers in communities. This is a measure that would be applicable to mental health practitioners but not internists and the ACP recommends removing it from the internal medicine specialty set for MIPS.

We also reviewed the new Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) that is being proposed to be added to the Internal Medicine Set, and we do not support that measure. The ACP's rationale for not supporting the measure is included under our review of MVP quality measures, as it is also proposed to be included in the Optimizing Chronic Disease Management MVP.

Among the measures that are being proposed to be removed from the Internal Medicine Set, we support the removal of these measures:

- Falls: Risk Assessment
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented
- Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier
- Pain Brought Under Control Within 48 Hours

However, we urge CMS to reconsider the removal of the following two measures because the ACP believes that these measures are valid for internal medicine:

- I. Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

The ACP supports QPP measure 050: "Urinary Incontinence: Plan of care for UI in Women Aged 65 Years and Older" because a performance gap exists, treatments exist to create meaningful improvements in clinical outcomes/quality of life, and the benefits of reducing the patient disease burden outweigh the clinician measurement burden.

- II. Medication Management for People with Asthma

The ACP supports QPP measure 444: "Medication Management for People with Asthma" because implementation may promote patient adherence to prescribed controller medication therapy and a 50% medication compliance rate is an achievable threshold. Clinicians are well aware of medication adherence issues in patients with asthma and underuse of controller medication therapy is clearly a problem.

Regarding the proposal of adding the SARS-CoV-2 Vaccination by Clinicians measure in the future, ACP appreciates the goal. However, measuring at the level of the individual clinician or

group doesn't seem appropriate without additional details on evidence/testing. Additionally, it seems most suitable at higher levels of measurement.

Quality Category: Data Completeness

CMS is proposing to maintain the current data completeness threshold at 70 percent for the 2022 performance period with a proposal to increase the data completeness threshold to 80 percent for the 2023 performance period. This means that to meet the current and CY21 proposed data completeness criteria, a clinician must report performance data (performance met or not met, or denominator exceptions) for at least 70 percent of the denominator eligible encounters.

ACP Comment: While ACP appreciates CMS maintaining the current data completeness threshold at 70 percent for the 2022 performance period, we strongly oppose increasing the threshold to 80 percent for the 2023 performance period. Data completeness requirements have a direct and significant impact on physician burden and pull directly from practice resources that could be used toward direct patient care—particularly at a time when practices are likely to still be recovering from the impact of the COVID-19 pandemic, which is continuing to surge across the country. This change would disproportionately negatively impact small practices and clinicians reporting individually, who average around significantly lower scores than medium and large practices reporting as a group. While ACP understands it is important to capture sufficient claims data to ensure an accurate indicator of performance for scoring purposes, 70 percent of all claims data over the course of a full year reporting period is already a substantial hurdle and provides more than sufficient data to capture an accurate snapshot of performance. CMS should first demonstrate why the data it receives at the 70 percent level is insufficient, how raising the minimum threshold would meaningfully improve the accuracy of quality data being captured, and how that positively impacts patient care. Without this, it appears as though MIPS is more focused on collecting data than leveraging data to improve patient care. Moreover, CMS should not propose this change at the same time it is asking practices to take on reporting of MVPs and shifting to digital quality measures.

Quality Category: Quality Measure Scoring Changes

Beginning with the 2022 performance period, CMS is proposing the following changes to quality measure scoring to align with proposals for scoring MVPs:

- Establish a five-point floor for the first three performance periods for new measures.

ACP Comment: The College appreciates the establishment of a five-point floor for new measures. However, we recommend that CMS consider an even higher floor, such as 7-points, to ensure that this incentive will be sufficient to encourage practices to take the risk

of using these measures, which will then allow for greater understanding of their evidence-base and if they are appropriately attributed; ability to ensure patient-centeredness; and actionability, including necessary workflow changes or additional costs associated with implementation.

- Remove the three-point floor for measures that can be scored against a benchmark.
- These measures would receive one to 10 points.
- (Note: This proposal would not apply to new measures in the first two performance periods available for reporting).
- Remove the three-point floor for measures without a benchmark (except small practices of 15 or fewer clinicians).
- These measures would receive zero points.
- Small practices would continue to earn three points.
- (Note: This proposal would not apply to new measures in the first two performance periods available for reporting. This proposal would not apply to administrative claims measures. Measures calculated from administrative claims are excluded from scoring if the case minimum is not met).

ACP Comment: ACP opposes the removal of the three-point floor for all measures whether they can be scored against a benchmark or not, as it will likely be an additional challenge on the practices that are already struggling with this pandemic. We request CMS reconsider this proposal. ACP appreciate the flexibilities that have been provided on this to date and we do believe that all measures should have clear, transparent, and prospective benchmarks in order to provide practices a predictable, transparent target for which to aim. However, should CMS decide to remove these point floors, we are strongly supportive of maintaining the point floors for new measures for the reasons outlined above and also for small practices, who continue to struggle with successful participation in the program.

- Remove bonus points for reporting additional outcome and high priority measures, beyond the one required.
- Remove bonus points for measures that meet end-to-end electronic reporting criteria.

ACP Comment: Physicians should continue to be incentivized for reporting on outcomes and high priority measures, as well as for end-to-end reporting. Taking on either or both of these tasks is significantly challenging and can be quite costly for practices, particularly as they are still in the midst of dealing with the COVID-19 pandemic. They need to have every opportunity to succeed, particularly if they are expected to begin preparing for MVPs down the line.

ACP is pleased that CMS increased previously established scoring flexibility by:

1. Expanding the list of reasons that a quality measure may be impacted during the performance period. For 2022, CMS is further proposing to expand the list of reasons that a quality measure may be impacted to include errors included in the measure specifications as finalized as cause to suppress or truncate a measure.

These errors include, but are not limited to:

- Changes to the active status of codes;
- The inadvertent omission of codes; and
- The inclusion of inactive or inaccurate codes.

Promoting Interoperability (PI) Category

CMS is proposing to make several modifications to the PI category. Specifically, CMS is proposing:

- To apply automatic reweighting to clinical social workers and small practices – particularly, reweighting clinical social workers and small practices to zero if they do not report the category, and redistributing its weight to another category or categories;
- To make modifications to the Public Health and Clinical Data Exchange objective to require MIPS-eligible clinicians to report on Immunization Registry Reporting and Electronic Case Reporting;
- Beginning in PY22, MIPS-eligible clinicians would receive 10 points for reporting “yes” to the required measures Immunization Registry Reporting and Electronic Case Reporting (unless a qualified exception applies);
- To add a requirement in the Provide Patients Electronic Access to Their Health Information measure to require patient health information remain available to the patient to access indefinitely;
 - A new measure where clinicians must attest to conducting an annual assessment of the High Priority Guide of the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides);
 - Require that clinicians make patient health information available indefinitely starting with encounters on or after January 1, 2016; and
 - To modify the Prevention of Information Blocking attestation statements to distinguish this from separate information blocking policies under the Office of the National Coordinator for Health Information Technology (ONC) requirements established in the 21st Century Cures Act.

CMS is seeking comment on all the proposals included in this subsection. Particularly, CMS is seeking comments on their intention to align additional PI performance category objectives with approaches utilizing HL7 Fast Healthcare Interoperability Resources (FHIR®) standard Release-4 based API functionality, specifically targeting the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. CMS is interested in public comments on how these two program objectives could be furthered through the use of FHIR®-based API solutions. The Agency is interested in the following questions:

- To what degree are stakeholders currently using or interested in using APIs to exchange information in support of the numerator/denominator measures under the HIE objective?
 - What revisions to the measures under the HIE objective should CMS explore to facilitate use of standards-based APIs in health IT modules certified under the 2015 Edition Cures Update?
 - How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures?
 - What are promoting FHIR®-based approaches to public health reporting use cases that the ONC and CMS should explore for potential future consideration as part of the PI performance category and the ONC Health IT Certification Program?
 - To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting?
3. What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches?
 4. What potential policy and program changes in CMS and other HHS programs could reduce health care clinician and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?

ACP Comment: Regarding the Promoting Interoperability (PI) Category, while we appreciate CMS' intent with the proposal to require immunization registry reporting to ensure that data are collected in a uniform way, we believe this is more a function of local and state agencies and object to it being a required measure under the "Public Health and Clinical Data Exchange" objective of the Promoting Interoperability category within MIPS. **This current proposal places the onus on the MIPS eligible clinician for something that is far out of their control.** We strongly agree, though, that the collection of this information is crucial.

Furthermore, there are a number of things that will need to be in place before quality measures can function in a truly digital way and, as such, the timeline to move to fully digital quality measures by 2025 is far too aggressive. In addition to building data collection systems and

adapting to new data structure and storage mechanisms, digital quality measures will also require changes to workflow that busy physicians and practices will need time to adjust to. This, taken in conjunction with the many proposed modifications to the Quality Payment Program (QPP) regarding the inclusion of MVPs as a starting point to transition to APMs seems untenable. Therefore, we ask CMS to focus on one significant modification at a time and would support the transition to MVPs being the priority given that their development is further along than digital quality measures and because they are more comprehensive of a change.

We are also concerned with physician burnout and believe that moving this too quickly will lead to that outcome. Given that EHRs and performance measure reporting are cited as internists greatest source of administrative burden, we recommend a phased approach to combining these two elements into one. We additionally 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 health care systems.

Improvement Activities (IA) Category

There is currently no existing policy to remove activities outside of the rulemaking process. CMS is proposing that in the case of an IA for which there is a reason to believe that the continued collection raises possible patient safety concerns or is obsolete, the Agency would promptly suspend the IA and immediately notify clinicians and the public through the usual communication channels, such as listservs and Web postings. CMS would then propose to remove or modify the IA as appropriate in the next rulemaking cycle.

Further, CMS is proposing two new criteria for nominating new IAs:

- Shouldn't duplicate other IAs in the inventory.
- Should drive improvements that go beyond standard clinical practices.

CMS also proposes that new IAs must, at minimum, meet all of the following eight criteria, consisting of the two proposed criteria above and these six existing criteria:

- Relevance to an existing IAs subcategory (or a proposed new subcategory).
- Importance of an activity toward achieving improved beneficiary health outcomes.
- Feasible to implement, recognizing importance in minimizing burden, including, to the extent possible, for small practices, practices in rural areas, or in areas designated as geographic Health Professional Shortage Areas by the Health Resources and Services Administration (HRSA).
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes.

- Can be linked to existing and related MIPS quality, promoting interoperability, and cost measures, as applicable and feasible.
- CMS is able to validate the activity.

Finally, the Agency is proposing six optional factors that they may use to consider nominated activities (made up of previously finalized criteria):

- Alignment with patient-centered medical homes.
 - Support for the patient’s family or personal caregiver.
- Responds to a PHE as determined by the Secretary.
- Addresses improvements in practice to reduce health care disparities.
- Focus on meaningful actions from the person and family’s point of view.
- Representative of activities that multiple individual MIPS-eligible clinicians or groups could perform (i.e., primary care, specialty care).

ACP Comment: For the new criteria, ACP agrees that any new Improvement Activities (IAs) should not be duplicative of existing options. For any IAs that specify programs or resources, organizations should have the opportunity to have their resources listed as an approved option that meets the criteria for that IA.

However, ACP is concerned that the criteria of driving improvements that go beyond standard clinical practices might be a bit lofty. If there are gaps in standard clinical practice that need improvement, those should be supported. Particularly for members in niche specialties or particularly high risk or vulnerable populations. ACP believes the weighting system for IAs is sufficient to help clinicians prioritize high weight activities that go beyond standard clinical practice.

The College is happy to see improvements that address disparities listed, as well as engagement of patient families/caregivers.

Cost Category

CMS is proposing to add five newly developed episode-based cost measures into the MIPS cost performance category beginning with the CY22 performance period.

Two procedural measures: Melanoma Resection, Colon and Rectal Resection

One acute inpatient measure: Sepsis

Two chronic condition measures: Diabetes, Asthma/Chronic Obstructive Pulmonary Disease [COPD]

Within the Cost Measure Development Process, all cost measures are developed by CMS’ measure development contractor. In addition to the current process, CMS is proposing a process of external cost measure development and a call for cost measures beginning in CY2022 for earliest adoption into the MIPS program by the 2024 performance period.

ACP Comment: 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. ACP supports counting telehealth services toward the calculation of existing cost measures, but reiterates the importance of issuing appropriate guidance and making necessary changes to accommodate instances where the quality action cannot be completed during the telehealth and add-on telehealth modifiers for eCQMs.

All measures should be held to transparent, consistent standards for statistical reliability, actionable impact on patient outcomes, and clinical evidence base. CMS' current average minimum reliability of 0.4 for episode-based cost measures is insufficient. Increasing case minimums improves measurement accuracy. While this may result in fewer clinicians being counted, this is preferable to clinicians having their payments adjusted based on measures of questionable validity. ACP believes measurement at the group practice or clinical team level is most appropriate for public reporting and payment purposes, while supporting the use of additional metrics for internal quality improvement efforts. Approval from an independent body such as the National Quality Forum should be mandatory, not optional, prior to finalizing any future MIPS measures. We also implore CMS to make MIPS measure development more transparent and user-friendly.

Over the past several years, ACP's Performance Measurement Committee (PMC) has reviewed hundreds of MIPS measures based on detailed evaluation criteria and found a good proportion to be invalid as currently designed. ACP cannot support the inclusion of invalid measures, either in traditional MIPS or MVPs. That said, while ACP appreciates CMS' attempt to improve the accuracy of MIPS performance measurement by removing measures it identifies as having validity, accuracy, or clinical concerns, we are concerned that CMS' pace of measure removal may leave certain specialties with an insufficient number of measures to report. We urge CMS whenever possible to make technical improvements to measures, as opposed to removing them. In many cases, ACP's PMC offers [specific suggestions](#) to remediate technical issues with individual measures. We encourage CMS to review our analyses in detail and welcome opportunities to discuss our specific concerns.

APM Performance Pathway (APP)

CMS Proposal: CMS is proposing to allow MIPS-eligible clinicians to report the APP as a subgroup beginning with the 2023 PY.

Currently, MIPS APM participants can report the APP as an individual, a group, or APM Entity. CMS is proposing to add subgroups as a participation option for reporting the APP beginning with the 2023 PY.

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

ACP believes having some selection of measures is critical to quality measurement that is accurate and clinically relevant and appropriate for a range of specialties and patient populations. Additionally, while ACP appreciates an effort to create overlap with required measures for various APMs such as the Comprehensive Primary Care Plus Program, these six measures are not universally required across all APMs. Accordingly, the APP would constitute an additional reporting burden beyond existing quality reporting requirements for various APMs, which each have their own distinct quality reporting requirements. While ACP appreciates the important goal of streamlining duplicative reporting, trying to fit all APMs into a one-size-fits all box of reporting has the opposite effect by stacking additional quality reporting requirements on top of existing quality reporting requirements that are specific to each APM. ACP additionally has several technical concerns with the measures proposed for inclusion and does not support them as proposed.

Complex Patient Bonus

CMS Proposal: Provided that a MIPS-eligible clinician, group, virtual group, or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year using the following formula:

Average hierarchical condition category (HCC) risk score + (the ratio of your dual eligible patients x 5)

The complex patient bonus cannot exceed 5.0 points, except for the 2020 MIPS performance year/2022 payment year when CMS doubled the bonus to 10 points. Because of the concerns of the direct and indirect effects of the COVID-19 PHE, CMS is proposing to continue doubling the complex patient bonus for the 2021 MIPS performance year/2023 MIPS payment year. These bonus points (capped at 10-points) would be added to the final score.

CMS is also proposing to revise the complex patient bonus beginning with the 2022 MIPS performance year/2024 MIPS payment year by:

- Limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual proportion).

- Updating the formula to standardize the distribution of two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients.
- Increasing the bonus to a maximum of 10.0 points.

ACP Comments: As noted earlier, the College strongly recommends that CMS continue to support the reporting bonuses. The bonus for reporting the high-priority measures and end-to-end electronic is a significant incentive for physicians and groups that report these measures and through this method. This often requires a change in workflow and should be rewarded. CMS has said that they want physicians and groups to report on high priority measures and noted a focus on digital measures and yet removing these bonuses seems contrary to those goals.

Medicare Shared Savings Program (MSSP)

CMS Proposal: Shared Savings Program ACOs may currently report the CMS Web Interface measures for PY 2021 only. Per prior rulemaking, beginning in performance year 2022, the CMS Web Interface would be removed as a collection type, moving ACOs to report quality data via the new Clinical Quality Measures collection type. However, CMS is proposing to extend the CMS Web Interface as a collection type for the Quality Payment Program for Shared Savings Program ACOs reporting under the APP by continuing to make the CMS Web Interface available for PYs 2022 and 2023.

CMS is proposing that for PY 2022, ACOs would either report the 10 CMS Web Interface measures or the three eQMs/MIPS CQMs. Under the APP, all ACOs would administer the CAHPS for MIPS Survey and be scored on two administrative claims-based measures (calculated by CMS).

ACP Comment: While ACP appreciates phasing out the Web Interface as a reporting option, ACP has strong reservations about the alignment of ACO and MIPS quality standards. Furthermore, ACP is concerned about the feasibility of reporting eCQM and all-payer data starting in 2023 because it not practicable. Because ACOs often include a variety of EHRs, which provide patient-level data, versus QRDA III files which provide de-identified aggregate data, there are both technical and operational challenges making it difficult if not impossible to aggregate data or report eCQMs at the ACO level. **ACP encourages CMS to delay further these requirements and work collaboratively with the ACO, vendor, and medical community to resolve these barriers.**

The College wishes to underscore the importance of making appropriate adjustments to future MSSP quality measure benchmarks, financial benchmarks, patient attribution, and risk adjustment methodologies to account for the impact of COVID-19. This includes adjusting how performance years 2020 and 2021 will be weighted toward future financial benchmarks, and

adjusting regional/national ratios to account for ACOs in COVID-19 “hot spots.” We urge CMS to adjust patient attribution calculations. We also urge CMS to remove or (at minimum) increase the current three percent cap on risk score increases over an ACO’s five-year participation agreement period, particularly in the wake of the COVID-19 PHE. We implore CMS to engage stakeholders and ACO participants in these discussions.

ACP strongly encourages CMS to extend certain beneficial scoring exceptions, including the 3-point floor for measures that meet case minimum, data completeness, and benchmark scoring requirements, and the 1-point floor (3 points for small practices) for measures that meet data completeness requirements but do not have a benchmark or fail to meet case minimums. We believe that these policies offer practices a reasonable backstop for unpredictable performance and encourages program participation by offering practices some reward for making the effort to report measures and meet data completeness requirements.

Medicare Diabetes Prevention Program (MDPP) PHE Permanent Exceptions

CMS Proposal: The MDPP was developed to prevent Medicare enrollees with pre-diabetes from converting into full diabetes. Participating entities give structured, coach-led sessions using a Centers for Disease Control and Prevention (CDC) curriculum to provide training related to diet, exercise, and weight management. During the PHE, CMS waived the fee to participate, resulting in an increase in participation. Following expiration of the PHE, CMS is proposing to continue the waiver of the enrollment application fee beginning on January 1, 2022. CMS is additionally proposing to increase the performance payments when patients achieve a five percent weight loss goal, as well as proposing changes to beneficiary eligibility after January 1, 2022. These changes are intended to minimize barriers to participation and enhance the program.

ACP Comments: ACP applauds extending the waiver of “provider’ enrollment application fees after the PHE as a way to increase participation.

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

Advanced Alternative Payment Models (APMs)

ACP Comment: ACP is concerned and urge CMS that 2020 and 2021 performance data should not adversely impact shared savings or other model payments, as practices are still very much

entrenched in battling the PHE and face a long recovery. CMS will also need to consider the lasting effect of the PHE on future performance measure benchmarks, financial benchmarks, patient attribution, risk adjustment, and other programmatic methodologies. **ACP encourages CMS to work with the physician community to improve payment model design and implementation so that physicians are more willing to participate voluntarily in APMs. To further encourage APM participation, ACP also recommends that incentive payments for APM participation be extended beyond the MACRA 2024 deadline.**

COVID-19 has exacerbated the underlying issues with the fee-for-service (FFS) payment system. Many physician practices are hungrier for FFS alternatives than ever, particularly models with predictable, prospective payments. Practices in APMs were better equipped to operationalize a more rapid pandemic response and in many cases, better able to weather it financially. CMS should be working to introduce new Advanced APMs to meet the anticipated increased demand for FFS alternatives due to COVID-19. As new models are being developed, there should be more transparency from CMMI so that the designs are more attractive to participation.

ACP appreciates CMS' recent finalization of several new models, including the Primary Care First Model. However, we ask that CMS recognize our commitment to advancing Medicare's transition to value based care by creating a bridge for practices transitioning from CPC+ to their next model of choice, which for many would be participating in another CMMI model such as Primary Care First (PCF). A bridge will provide the flexibility and financial security needed to ensure the gains made over the last five to 10 years are not lost by practices reverting into fee-for-service and will allow practices to continue to provide enhanced primary care services to patients and communities without disruption. We do not believe that the PCF model provides an adequate bridge. We encourage CMS to maintain pace, with an emphasis on models that would address outstanding needs, including specialty-focused and multi-payer models. ACP implores HHS to prioritize ACP's Medical Neighborhood Model, which was recently recommended by the PTAC (Physician-Focused Payment Model Technical Advisory Committee) for pilot testing. We welcome an opportunity to further discuss our model and help ready it for testing or implementation.

ACP continues to strongly oppose CMS' new approach for distributing Advanced APM incentive payments that prioritizes payment year TINs. Doing so minimizes the clinical care team model and moves further from actions completed during the performance year. ACP urges instead for CMS to make incentive payments earlier in the payment year, which lessens the window for NPI-TIN changes to occur. In addition, there needs to be an improved process for clinicians to notify CMS of any affiliation changes (i.e., a change of TIN between performance year and payment year) so that incentive payments are paid correctly. The College also strongly objects to CMS' proposed 60-day cutoff for claiming incentive payments. As an alternative, we recommend the date Advanced APM payments for the subsequent year are announced. ACP greatly appreciates CMS finalizing a new targeted review process for QP determinations, which

ACP has long advocated for. However, the College remains concerned that the scope is too limited.

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 Calendar Year 2022 and beyond. We are confident these recommended changes would improve the strength of these proposals and help promote access to affordable care for Medicare patients, while supporting physicians in their ability to deliver innovative care and protecting the integrity of the Medicare trust funds. We appreciate the opportunity to offer our feedback and look forward to continuing to work with the Agency to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Director, Regulatory Affairs for the American College of Physicians, at boutland@acponline.org or 202-261-4544 with comments or questions about the content of this letter.

Appendix A

Quality Measure Number	Quality Measure Name	Quality Measure - Description	Proposed to be Included in CY2022 MPFS'	ACP Review - Date and Decision	ACP Rationale
Q047	Advanced Care Plan	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	Optimizing Chronic Disease Management MVP, Advancing Care for Heart Disease MVP, Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP	19-Nov-17 Does NOT Support	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.

Q111	Pneumococcal Vaccination Status for Older Adults	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	Advancing Rheumatology Patient Care MVP	19-Nov-17 Does NOT Support	ACP does not support QPP measure 111: "Pneumococcal Vaccination Status for Older Adults." While this measure represents an important clinical concept, implementation could promote treatment overuse if patients seek medical care from multiple providers and/or have poor medical record continuity. In addition, the developer should update the numerator specifications to align with current clinical recommendations on pneumococcal vaccination.
Q128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2	Advancing Care for Heart Disease MVP	19-Nov-17 Does NOT Support	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.
Q130	Documentation of Current Medications in the Medical Record	Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over the counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration	Advancing Rheumatology Patient Care MVP	19-Nov-17 Does NOT Support	ACP does not support QPP measure 130: "Documentation of Current Medications in the Medical Record." While this measure represents an important clinical concept, there is a lack of high-quality evidence to support its inclusion in accountability programs, it is burdensome for clinicians to document complete medication lists at every patient visit, and encouraging documentation at every visit could result in underuse of more valuable clinical services. Additionally, interventions intended to improve the medication reconciliation process have not necessarily resulted in improved quality outcomes. Furthermore, this is a "check the box" measure. Attestation for these visits may become routine but does not add value. A more appropriate measure may encourage documentation of medication lists according to clinical necessity and incentivize a standardized, methodological approach to reconciliation,

				<p>according to clinician practice level (e.g., physician, nurse, medical assistant) that leads to improvements in the medication management process. Furthermore, independent patient, system, and practice variables (incomplete patient information, unavailable drug information, miscommunication of drug orders, and insufficient information flow) can impede the physician's ability to complete an accurate medication list. Consequently, clinical judgements may be based on incomplete clinical information.</p> <p>The PMC sub-committee recently reviewed this measure, in July 2021, to respond to the feedback requested by the CMS and Mathematica and this was their response: The ACP continues NOT to support the measure. The committee acknowledges that medication-related mistakes are clearly a source of poor outcomes and an accurate list of medications is a prerequisite to avoid them. In practice, true reconciliation is a time consuming and thus usually an imperfect task in an ambulatory context. It is unreasonable to require a 100% medication reconciliation at every visit, every time, for all the things that the patient is taking. That includes supplements, vitamins, and the like, which proves to be a significant barrier. Details about these are often missing and their role in medication safety is not clear. Since that is not how medication lists are typically handled, this</p>
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					<p>becomes a "check the box attestation". This measure would be improved if the denominator was revised to focus on an annual reconciliation as well as when a new medication is prescribed and after a hospitalization. If the denominator is revised and not every visit is included, it will also eliminate the EHR related issues that come with cancelled visits or other such scenarios. There isn't any evidence cited that links attesting to medication reconciliation to quality outcomes and in particular medication safety. The PMC also notes that there haven't been any updates to the evidence in the draft 2022 specifications.</p>
Q180	Rheumatoid Arthritis (RA): Glucocorticoid Management	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone \geq 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months	Advancing Rheumatology Patient Care MVP	19-Nov-17 Does NOT Support	<p>ACP does not support QPP measure 180: "Rheumatoid Arthritis: Glucocorticoid Management." The developers did not provide adequate information for us to meaningfully evaluate the validity of this measure. Although we recognize the importance of managing the lowest effective dose of glucocorticoids and using alternative therapies when possible, both the numerator and the denominator are poorly specified. The measure specifications do not include</p>

					appropriate exclusions for patients prescribed prednisone therapy for a symptomatic flare. A cleaner measure may specify “patients with rheumatoid arthritis (RA) who are on glucocorticoids” in the denominator statement. Additionally, the current American College of Rheumatology (ACR) clinical guidelines demonstrate the importance of assessing glucocorticoid use, but only in patients who have specifically been prescribed glucocorticoid therapy.
Q187	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	This measure captures the proportion of acute ischemic stroke patients who arrive at this hospital within 2 hours of time last known well for whom IV t-PA was initiated at this hospital within 3 hours of time last known well	Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP	7-Apr-14 Does NOT Support	NQF 0437: “STK 04: Thrombolytic Therapy” ACP believes that the measure specification requires further clarification. It is not clinically specific regarding the indications for treatment. There is evidence that the harms of thrombolytic therapy may outweigh the benefit in some cases, especially if the full exclusion criteria published by the National Institute of Neurological Disorders and Stroke and others are not followed. This should be made explicit in the measure exclusion criteria. There also are specific qualifications hospitals must meet in order to provide tPa. The absence of such conditions should also be noted as an exclusion criterion. There may also be regional variations in the availability of qualifying institutions, potentially making this measure inapplicable to all physicians in some areas.

<p>Q236</p>	<p>Controlling High Blood Pressure</p>	<p>Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period</p>	<p>Optimizing Chronic Disease Management MVP, Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP</p>	<p>6-May-21 Does NOT Support</p>	<p>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.</p> <p>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</p>
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					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.
Q238	Use of High-Risk Medications in Older Adults	Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported: a. Percentage of patients who were ordered at least one high-risk medication b. Percentage of patients who were ordered at least two different high-risk medications	Advancing Care for Heart Disease MVP	19-Nov-17 Does NOT Support	ACP does not support QPP measure 238: "Use of High-Risk Medications in the Elderly." While it is clinically important to monitor high-risk medications in elderly adults, implementation may result in underuse of clinically appropriate pharmacotherapy in adults aged > 65 years. Furthermore, developers cite the controversial American Geriatrics Society Beers Criteria to form the basis of the measure, which is based on expert opinion as opposed to high-quality evidence. Moreover, we note several issues with the measure specifications. First, the denominator may inaccurately define “elderly adults” as > 65 years of age. Developers should consider revising the specifications to include a more appropriate definition that would classify “elderly adults”

					<p>according to mental and functional status or increase the denominator threshold to > 80 years of age. Second, the denominator specifications do not stratify patients into well-defined risk groups. It's conceivable for some patients 66 years and older to tolerate high risk medications as appropriate treatment. Third, the measure specifies medications that are not presumed to be high risk in all elderly adults (e.g., acetaminophen), and fourth, the specifications do not include exclusion criteria for patient preference. Finally, while this measure is appropriate for health plan-level assessment, individual clinicians may encounter interoperability barriers to patient information access.</p>
Q398	Optimal Asthma Control	Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation	Optimizing Chronic Disease Management MVP	19-Nov-17 Does NOT Support	<p>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</p>

					<p>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.</p>
Q441	<p>Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)</p>	<p>The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: Most recent blood pressure (BP) measurement is less than 140/90 mm Hg -- And Most recent tobacco status is Tobacco Free --</p>	<p>Advancing Care for Heart Disease MVP, Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP</p>	<p>19-Nov-17 Does NOT Support</p>	<p>ACP does not support QPP measure 441: "IVD: All or None Outcome Measure." The developers did not provide adequate information for us to appropriately review the measure. We rated the measure based on the specifications provided on the MIPS website. We do not support this measure because it disregards patient preferences, specifications do not consider factors beyond the clinicians control (e.g., patient adherence, patient access), and it does not align with the Eighth Joint National Committee (JNC-8) recommendations for hypertension management.</p>

		And Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And Statin Use			
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