



December 21, 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; and 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 final rulemaking regarding changes to the Medicare Physician Fee Schedule (MPFS), 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 the letter. We are confident that these recommended changes would improve the strength of these policies and help to promote access to affordable care for Medicare patients, while dually supporting physicians in their ability to deliver innovative care and protect the integrity of the Medicare trust funds. We appreciate this opportunity to offer our feedback and look forward to continuing to work with CMS to implement policies that support and improve the practice of internal medicine.

## Table of Contents

Summary of Top Priority Recommendations.....	3
Regulatory Impact Analysis.....	9
Payment and Documentation Proposals for Evaluation and Management (E/M) Services.....	11
Telehealth.....	14
Vaccine Administration Services.....	18
Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) furnished by Opioid Treatment Programs (OTPs) Services.....	19
Updates to Physician Self-Referral Regulations under Stark Law.....	20
Requiring Certain Manufacturers to Report Drug Pricing Information for Part B, and Other Items.....	21
Electronic Prescribing of Controlled Substances (EPCS).....	21
Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging.....	22
Innovative Technology and Artificial Intelligence (AI) Request for Information.....	23
Advancing to Digital Quality Measurement and the Use of FHIR® in Physician Quality Programs – Request for Information.....	23
Health Equity Initiative.....	24
Quality Payment Program (QPP).....	25
MIPS Value Pathway (MVP).....	25
PY 2022 MIPS Changes.....	29
PY 2022 Scoring and PY 2021 Performance Feedback.....	29
APM Performance Pathway (APP).....	33
Medicare Shared Savings Program (MSSP).....	34
Medicare Diabetes Prevention Program (MDPP) PHE Permanent Exceptions.....	35
Advanced Alternative Payment Models (APMs).....	35
Conclusion.....	36

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

A) **Regulatory Impact Analysis**

- i. ACP believes the decrease in the conversion factor is a disappointing devaluation of E/M services, which collectively represent a significant portion of the work of internal medicine physicians. The College remains concerned that the realized impact to physicians will be even greater when coupled with the huge losses of revenue from the COVID-19 pandemic and huge losses in practice volumes experienced by internal medicine specialists and other frontline physicians.
- ii. At the outset of CMS' rulemaking process, physicians were set to experience massive cuts to Medicare payments. It is the College's strong belief that cutting Medicare reimbursement to the nation's physicians during a pandemic is simply unacceptable. Therefore, ACP deeply appreciates that the Senate recently passed legislation, S. 610, the Protecting Medicare and American Farmers from Sequester Cuts Act, which had previously been passed by the House, that includes a provision providing for a temporary three percent increase to *all* services under the MPFS. Moving forward, the College continues to urge CMS and Congress to remain cognizant of the effect that these payment cuts, albeit largely suspended for now, and revenue reductions due to the COVID-19 pandemic have on the ability of health care to invest in care transformations, such as the move to value-based care. ACP encourages CMS to quickly publish revised tables displaying the impact of congressional action on RVUs and payments.

B) **Payment and Documentation Proposals for Evaluation and Management (E/M) Services**

- i. **Refinements to "Split" or "Shared" E/M Visits:** The College encourages the Agency to identify one appropriate path forward to better inform physicians and their care teams of the required actions for implementation. Regarding the required use of a modifier on the claim to identify these services, ACP continues to urge CMS not to require a modifier to be reported for split (or shared) visits, as this policy is contrary to the purpose of the new E/M code structure: alleviating burden. 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 policy and to lend clarity to reporting in CPT Guidelines.
- ii. **Teaching Physician Services and Primary Care Exception Flexibilities:** ACP continues to believe that both time and MDM should be allowed as options for selecting the appropriate level of visit and should extend to all times when the teaching physician was present via audio, video, or in-person. Therefore, the College re-emphasizes its recommendations that *both* time and MDM be allowed as options for selecting the appropriate level of visit. ACP also continues to encourage CMS to maintain modifications that grant attending physicians and residents/fellows additional flexibilities that prioritize patient safety and meeting patients where they are.

C) **Telehealth**

- i. **Temporary Additions to the Medicare Telehealth Services List, and Codes Not Granted Category 3 Status:** ACP appreciates CMS finalizing its 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 supports this extension, [we continue to 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. The College strongly encourages CMS add codes 99441-99443 back to the Category 3 list and retain these services until at least the end of CY23.

- ii. **New Originating Site:** The College continues to recommend that CMS permanently extend the policy to waive geographical and originating site restrictions after the conclusion of the PHE for *all* telehealth services. The College is also disappointed that CMS finalized the requirement that an in-person, non-telehealth visit must be furnished at least every 12 months for these mental health services. The College believes that there are many positive aspects of both phone and video visits that benefit patients (i.e., access to other family members, transportation issues, the ability to check medications, etc.) and urges the Agency to avoid any physician requirements that have no solid rationale or clinical application, including requiring a physician to see a patient in person for a mental health exam.
- iii. **Payment for Services Using Audio-Only Communication Technology:** The College remains supportive of broadened flexibilities to allow other evaluation and management (E/M) services to be provided using audio-only communication. ACP vigorously opposes CMS' policy to end coverage for audio-only E/M services (CPT codes 99441-99443) at the end of the PHE and continues to believe that coverage should extend at least to the end of 2023, along with other temporarily covered telehealth services. The College continues to believe that CMS should 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.
- iv. **Direct Supervision:** Based on the experience and learnings of patients and clinicians who are utilizing these supervision flexibilities, [ACP continues to believe](#) 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.
- v. **Virtual Check-In Code:** ACP reiterates our strong disagreement with any conflation by CMS between virtual check-ins, regardless of length, with an audio-only E/M service. Telephone E/M services are not just a longer virtual check-in service; they are an E/M service. Additionally, while ACP does not support the use of G2252 as a replacement for telephone E/M visits, it should be noted that the crosswalk to the current value of 99442 continues to be flawed. Rather than adopting a substitute and establishing a workaround for parity, ACP 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.

#### **D) Vaccine Administration Services**

- i. The College continues to strongly urge 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. ACP further urges CMS to make payment for CPT code 99401 retroactive for physicians that have provided this service on or after January 1, 2021.

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

- i. ACP [recommends](#) reducing barriers to accessing medications to treat opioid use disorder, including eliminating onerous prior authorization requirements for buprenorphine, and exploring limiting restrictions on office-based methadone treatment provided by trained physicians.

#### **F) Updates to Physician Self-Referral Regulations under Stark Law**

- i. The College believes the finalized policy around “indirect compensation arrangements” is counterproductive and reintroduces the burdensome elements of Stark, since rather than being excluded from the definition altogether because they are not deemed to create a financial relationship, these arrangements will need to satisfy an exception. Considering the legal and regulatory complexities of the Stark Law, ACP is supportive of the intent behind CMS’ proposals and subsequent clarifications. However, echoing our previous concerns regarding the ‘turnaround-time’ for compliance, significant burden will arise from the finalized compliance timeline. Therefore, ACP strongly recommends CMS re-examine the ever-growing complexity of the statute, the likelihood its policy will succeed in lending greater clarity to the regulations, and continue to collaborate with health care entities and physicians to better understand the downstream effects and burden of Stark regulations.

#### **G) Requiring Certain Manufacturers to Report Drug Pricing Information for Part B, and Other Items**

- i. [ACP renews its call](#) for the federal government to go further in requiring the reporting of additional price and cost information, including the disclosure of actual material, production, and research and development costs to regulators. [The College further implores CMS](#) to explore, study, and implement additional approaches that are effective

in aligning Medicare Part B 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.

#### **H) Electronic Prescribing of Controlled Substances (EPCS)**

- i. Where the practice is less burdensome for both patients and clinicians, [ACP supports the use of electronic prescribing for controlled substances](#), though we caution it is not always true that e-prescribing of controlled substances is *actually* less burdensome. [ACP continues to recommend](#) CMS study the true costs and implications of this mandate on clinicians. Additionally, ACP strongly recommends that a backup system, such as paper or telephone, be established in order to accommodate systems going down or other technological barriers. In looking forward to January 1, 2023, CMS should pay close attention to the real, true conditions in practices and the downstream implications of its policies – especially to small, independent practices and those in rural areas – and be willing to extend the date of compliance actions in further rulemaking if it is determined that a significant percentage of small, rural, or independent practices are still facing implementation barriers.

#### **I) Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging**

- i. The College continues to believe that CMS should continue voluntary participation in the AUC Program. Physicians and other health care professionals are unprepared for yet another burdensome regulatory requirement.

#### **J) Innovative Technology and Artificial Intelligence (AI) – Request for Information**

- i. The College re-emphasizes its belief that, because of its importance and implications, this RFI should be removed from the MPFS rulemaking process and should be re-opened to allow more time to gather stakeholder feedback. The College continues to caution against establishing precedent-setting payment policy based on limited experience and data.

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

- i. The College continues to believe that CMS' finalization of its plan to move fully to digital quality measures (dQMs) by 2025 is far too aggressive and unreasonable. Therefore, the College continues to ask CMS to focus on one significant modification at a time and support the transition to MVPs being the priority, given that their development is further along than dQMs and because they are more comprehensive of a change. While the College remains supportive of FHIR, we must reiterate that small and independent practices that are dependent upon third-party vendors to enable this functionality are worried by these proposals. As before, 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.

## L) Health Equity Initiative

- i. **While the College agrees that the collection of this data is a valuable effort, we recommend postponing any additional requirements until staffing shortages have eased.** The College proposes that when CMS considers adding something new to the physician workload, there also be consideration of whether anything else in the workload could stop being done (e.g., consider eliminating other current collection requirements that may be of lower overall value to patient care or CMS' goals). ACP also proposes that CMS consider technology or informatics-based solutions for collecting this data that would not require actual staff time. ACP strongly believes CMS should develop the kind of information exchange system that would allow health systems to connect with state identification databases to reduce clinician burden and increase accuracy of information.

## M) MIPS Value Pathway (MVP)

- i. **Promoting Interoperability:** ACP remains committed to the idea of MVPs moving toward a wholesale departure from traditional MIPS in order to offer a true on-ramp for practices to APMs and is concerned these finalized regulations do not fully address issues raised by the College in [earlier comments](#).
- ii. **MVP Review: Quality Measure, Patient Reported Outcome Measure, Population Health Measure and Cost Measure:** ACP does not support CMS' inclusion of the new measure "Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure" (PCPCM PROM) to the Optimizing Chronic Disease Management MVP. ACP also does not support the TPCC (Total Per Capita Cost) cost measure, which the Agency finalized to be included in three MVPs. 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; however, we do not support the current use of one-size-fits-all cost metrics. The College additionally does not support the MIPS 479 - Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the MIPS Eligible Clinician Groups measure because of uncertain validity.

## N) PY 2022 Scoring and PY 2021 Performance Feedback

- i. ACP supports the approach of aligning MVP Scoring with Traditional MIPS Scoring, and the College appreciates CMS introducing a new scoring policy for new measures from 2022. However, we do not support CMS removing the high-priority measures and end-to-end electronic bonuses in PY 2022. Additionally, the College opposes CMS' proposal to make MVP participation mandatory starting in PY 2028.
- ii. **Quality Category: Quality Measure Scoring Changes:** ACP does not support CMS' decision to remove the high priority/outcome measure bonuses from Traditional MIPS Quality scoring during this PHE in 2022. We continue to urge CMS to reconsider the removal of the three-point floor for scoring measures from 2023 performance period.
- iii. **Promoting Interoperability Changes:** While the College strongly agrees that the accurate, timely collection of this information is crucial, we encourage CMS to, at minimum, delay the timeline for making the Immunization Registry Reporting a required

measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category. With widespread reports of physician burnout and the knowledge 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.

- iv. **Improvement Activities (IA) Category:** ACP continues to be concerned that the criteria to “drive improvements that go beyond purely common clinical practices” is unrealistic. ACP believes the current weighting system is sufficient to help physicians prioritize high-weighted activities that go beyond standard clinical activities.
- v. **Cost Performance Category:** ACP continues to have specific concerns about these finalized regulations, 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. We continue to urge CMS whenever possible to make technical improvements to measures, as opposed to removing them.

#### **O) APM Performance Pathway (APP)**

- i. ACP supports efforts to promote consistency across the QPP and to offer clinicians flexible reporting options, which reduces burden. The College supports 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.
- ii. **Complex Patient Bonus:** The College encourages CMS to continue to support the reporting bonuses in future reporting years. However, ACP is critical of CMS making the complex patient bonus more tedious by adding the social complexity component and by removing the high-priority measure and e-prescribing bonuses.

#### **P) Medicare Shared Savings Program (MSSP)**

- i. ACP maintains strong reservations about the alignment of ACO and MIPS quality standards. ACP continues to encourage CMS to work collaboratively with the ACO, vendor, and medical community to resolve these barriers.

#### **Q) Advanced Alternative Payment Models (APMs)**

- i. ACP continues to strongly oppose CMS' new approach for distributing Advanced APM incentive payments that prioritizes payment year TINs, which minimizes the clinical care team model and moves further from actions completed during the performance year. ACP is not supportive of CMS' decision to make no changes to timing of incentive payments to earlier in the payment year, which would have lessened the window for NPI-TIN changes to occur.



## II) PFS Detailed Recommendations:

### Regulatory Impact Analysis

**CMS Finalized Policy:** For CY22, CMS finalized the proposed \$33.59 conversion factor. This represents a nearly four percent decrease from the \$34.89 conversion factor for 2021, and a nearly seven percent decrease from the 2020 conversion factor. The reduction reflects the expiration of the 3.75 percent increase for services furnished in 2021, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Social Security Act, and a budget neutrality adjustment of -0.10 percent. [Table 136](#) shows the overall estimated impact on total allowed charges for internal medicine. The specialty impacts displayed in [Table 136](#) reflect changes that take place within the pool of total RVUs. Therefore, this table includes any changes in spending which result from finalized policies within budget neutrality, such as the revaluation of Evaluation and Management (E/M) codes in CY21 or the clinical labor pricing update in CY22 but does not include any changes in spending which result from finalized policies outside of budget neutrality. The expiration of the 3.75 percent Consolidated Appropriations Act (CAA) of 2021 provision for CY22 is a statutory change that takes place outside of budget neutrality, and therefore is not captured in the specialty impacts displayed in [Table 136](#).

In the CY22 final rule, the Agency additionally reminded commenters that CMS does not have the legal authority to alter the 3.75 percent increase in PFS payment amounts that was specified under section 101 of the CAA (2021) for services furnished during CY21. This means that the expiration of this 3.75 percent increase in payment amounts will result in the CY22 conversion factor being calculated as though the 3.75 percent increase for the CY21 conversion factor had never been applied.

**ACP Comments:** As stated in [our comments on the CY22 proposed rule](#), **ACP believes the decrease in the conversion factor is a disappointing devaluation of E/M services, which collectively represent a significant portion of the work done by internal medicine physicians.** The College remains concerned that the realized impact to physicians will be even greater when coupled with the huge losses of revenue from the COVID-19 pandemic and huge losses in practice volumes experienced by internal medicine specialists and other frontline physicians. Unfortunately, though temporary measures were implemented during the PHE and more recently by congressional leaders, these cannot adequately address the ongoing structural problems with the MPFS. The physician community will eventually be expected to withstand steep cuts, which could result in many beneficiaries losing timely access to essential health care services.

At the outset of CMS' rulemaking process, physicians were set to experience massive cuts to Medicare payments. Together, the Medicare sequestration and PAYGO sequester cuts would have reduced Medicare payments to physicians by about six percent. These cuts are in addition to the 3.75 percent reduction in Medicare reimbursements that CMS finalized in the MPFS. **It is the College's strong belief that cutting Medicare reimbursement to the nation's physicians during a pandemic is simply unacceptable.**

**Therefore, ACP deeply appreciates that the Senate recently passed legislation, S. 610, the Protecting Medicare and American Farmers from Sequester Cuts Act, which had previously been passed by the House, that includes a provision providing for a temporary three percent increase to all services under the MPFS.** This is a slight decrease from the 3.75 percent provided by Congress last year for FY21 under the CAA (2021). The College is also pleased that the House and Senate acted to provide a three-month

delay of the Medicare sequester payment reductions (January 1, 2022 – March 31, 2022), a three-month, one percent reduction in Medicare sequester payment reductions (April 1, 2022 – June 30, 2022), and included a provision that would delay the application of the PAYGO cuts from 2022 to 2023. Taken together, these measures will mitigate a substantial portion of the cuts that were set to take effect on January 1, 2022. We continue to note, however, that our greatest public health and financial challenges lie ahead, and these actions are unsustainable to the point of requiring structural change.

**Moving forward, the College continues to urge CMS and Congress to remain cognizant of the effect that these payment cuts, albeit largely suspended for now, and revenue reductions due to the COVID-19 pandemic have on the ability of health care to invest in care transformations, such as the move to value-based care.** It is very expensive to transform the way that physicians deliver care to a model that breeds accountability, value, and outcomes. For the betterment of both physicians and patients, it is necessary that the health care community is equipped with the environment and resources to do so. [ACP continues to advocate for these transformations](#), but the constant state of flux regarding payment and revenue makes it increasingly difficult as practices – especially small and independent – need to invest in personnel, technology, and infrastructure. These are impossible tasks considering the circumstances.

**For these reasons, ACP would welcome the opportunity to work with both CMS and Congress to address long-term challenges associated with Medicare payment policy, especially the budget neutrality provision in the MPFS.** The College re-emphasizes our deep appreciation for the recent acts of congressional leaders and remains encouraged by ongoing discussions with leadership and staff who acknowledge the need to maintain and address payment stability for physicians. The fact remains, though, that both physicians and beneficiaries deserve more, and subsequent action must be taken to avert situations like these in the future and move us towards structural change. **As CMS grapples with the effect of recent legislation on payments under the MPFS, ACP encourages CMS to quickly publish revised tables displaying the impact of congressional action on RVUs and payments.**

#### Clinical Labor Pricing

**CMS Finalized Policy:** In the CY22 MPFS final rule, CMS finalized its proposed changes to the practice expense (PE) methodology, in particular, the clinical labor pricing component. The Agency stated that it believes the update to the clinical labor pricing is necessary to maintain relativity with the recent supply and equipment pricing update, as well as to address the disparity between CMS' clinical wage data and the market average for clinical labor. CMS last updated the clinical labor component almost twenty years ago when the Agency used 2002 Bureau of Labor Statistics (BLS), with some supplementation from other sources. CMS will follow the same approach in the CY22 final rule, using 2019 BLS data, with some supplementation. To address the effect that the budget neutrality adjustment will have, CMS will implement the new values with a four-year transition period. Specific to internal medicine, payments to services comprising internal medicine would be expected to increase as a result of this clinical labor pricing update, since there is a higher share of direct costs associated with clinical labor.

**ACP Comments:** ACP is pleased that CMS finalized the phased-in implementation of the clinical labor update over four years to transition from the current prices to the final updated prices in 2025. The College is encouraged that the Agency has recognized these provisions to update the clinical labor rates in conjunction with the final year of the supply and equipment pricing update are necessary. Additionally, we agree that this multi-year implementation will help to address concerns that current

wage rates are inadequate, do not reflect current labor rate information, and that updating the supply and equipment pricing without updating the clinical labor pricing creates distortions in the allocation of the direct PE. While ACP understands that these payment impacts do not show the impact of the expiration of the 3.75 percent increase to MPFS payments for 2021 from the CAA (2021), we are hopeful that internal medicine physicians who rely primarily on clinical labor rather than supplies or equipment will receive relative increases that are appropriately commensurate with their costs.

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

### Refinements to “Split” or “Shared” E/M Visits

**CMS Finalized Policy:** CMS has finalized several policies related to split (or shared) visits, including:

- *Medical Record Documentation:* For purposes of documentation requirements for these services, CMS finalized that, by 2023, the “substantive portion” of the visit will be defined as more than half of the total time spent. For 2022, the “substantive portion” can be history, physical exam, medical decision-making, or more than half of the total time (except for critical care, which can only be more than half of the total time). Additionally, documentation in the medical record must identify the two individuals who performed the visit. The individual providing the substantive portion must sign and date the medical record.
- *Same Group:* CMS has finalized its policy to define split (or shared) E/M visits as E/M visits provided in the facility setting by a physician and a non-physician practitioner (NPP) in the same group. The visit would be billed by the physician or NPP who provides the substantive portion of the visit.
- *Claim Identification:* CMS has also finalized that a modifier is required on the claim to identify these services to help inform policy and ensure program integrity.

**ACP Comments:** In our comments on the CY22 proposed rule, we emphasized to CMS the importance of physicians having one consistent set of guidelines in reporting their services. In the CY22 final rule, the Agency has finalized that, by 2023, the substantive portion of the visit will be defined as more than half of the total time spent. For 2022, the substantive portion can be history, physical exam, or more than half of the total time (except for critical care, which can only be more than half of the total time). **Given the difference from year-to-year in what qualifies as a “substantive portion,” ACP is concerned that the finalized policy will significantly add administrative burden to an already burdensome task and will only further complicate medical record documentation for these visits.** For those physicians that have deeply integrated NPP’s into their care teams and practice, this change will be especially burdensome and problematic. **Therefore, the College encourages the Agency to identify one appropriate path forward to better inform physicians and their care teams of the required actions for implementation.**

Regarding the required use of a modifier on the claim to identify these services, **ACP continues to urge CMS not to require a modifier to be reported for split (or shared) visits, as this policy is contrary to the purpose of the new E/M code structure: alleviating burden.** Much like the finalized policy for medical record documentation, the required use of a modifier will only increase the administrative burden that physicians face and will ultimately prove to be more problematic than beneficial.

Overall, the College is concerned about the finalized policy from CMS for “split” or “shared” E/M visits. This shift in payment for physician time will be detrimental to many practices in internal medicine and sets a bad precedent for inpatient visits in future years. When taken in conjunction with the aforementioned cuts to physician payments in the MPFS, this will only depreciate the value physicians bring to the table. To address some of these concerns, **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 policy and to lend clarity to reporting in CPT Guidelines.**

#### Critical Care Services

**CMS Finalized Policy:** In a reversal to its initial proposal, CMS finalized that critical care services may be paid on the same day as other E/M visits by the same practitioner or another practitioner in the same group of the same specialty. The practitioner is required to document that the E/M visit was provided prior to the critical care service at a time when the patient did not require critical care, the visit was medically necessary, and the services were separate and distinct. The Agency also stated there cannot be any duplicative elements from the critical care service provided later in the day. CMS is additionally finalizing its proposal that the modifier -25 must be reported on the claim.

**ACP Comments:** **ACP is greatly appreciative of CMS’ finalized policy regarding payment and reporting requirements for E/M services performed on the same date as a critical care visit.** The College believes the Agency’s shift away from its initial proposal is positive, though we are concerned that the billing and reporting requirements are burdensome. In our comments on the CY22 proposed rule, we emphasized our concern 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 stated this was contrary to CPT’s specific instruction and although not typical, there are instances where a patient may be seen on an inpatient floor, ED, or clinician office, and then later require critical care services on the same day. ACP is encouraged to see that CMS has taken heed of these concerns and will allow each visit to be reported and paid as a separate service.

#### Office Visits Included in Codes with a Surgical Global Period

**CMS Finalized Policy:** In another reversal to its proposed policy, CMS finalized that critical care services may be paid separately in addition to a procedure with a global surgical period if the critical care is unrelated to the surgical procedure. Additionally, preoperative and postoperative critical care may be paid if the patient is critically ill (per the critical care definition), requires full attention of the physician, and the critical care is above and beyond and unrelated to the specific surgical procedure performed. The Agency is also creating a new modifier for use on these claims to identify that the critical care is unrelated to the procedure.

The Agency additionally stated it found the comments about how the proposed policy would negatively impact the quality and safety of patient care, health system resiliency, health equity, and the surgical workforce especially compelling. Thus, after considering these comments, CMS decided not to finalize the proposal to always bundle critical care visits with procedure codes that have a global surgical period.

**ACP Comments:** As discussed in our comments to the CY22 proposed rule, the College believes this is an inaccurate position and advocated heavily for the reversal of such proposal. In light of this, **ACP is very pleased that CMS reversed course from its initial proposal and will allow critical care services to be**

**paid separately in addition to a procedure with a global surgical period if the critical care is unrelated to the surgical procedure.**

Teaching Physician Services and Primary Care Exception Flexibilities

**CMS Finalized Policy:** At this time, qualifying activities for selecting the office/outpatient E/M visit level using the reporting practitioner’s time are specified by the CPT guidebook. In the 2021 CPT E/M guidelines, the CPT Editorial Panel published a correction addressing teaching physician time by excluding time spent in “teaching that is general and not limited to discussion that is required for the management of a specific patient.” CMS is clarifying that only time spent by the teaching physician performing qualifying activities listed by CPT (with or without direct patient contact on the date of encounter), including the time the teaching physician is present when the resident is performing such activities, may be counted for purposes of visit level selection. Regarding extension beyond the COVID-19 pandemic, CMS stated that the issue of making the virtual presence flexibility permanent and extending the flexibility to include residency training centers located inside a metropolitan statistical area was not part of their proposal for general primary care office/outpatient E/M visit level selection.

CMS also acknowledged opposition to their proposal to allow medical decision-making (MDM) as the only option for E/M visit level selection under the primary care exception; however, they believe that using MDM to inform office/outpatient E/M visit level selection, rather than time, is appropriate given concerns about accuracy of counting time spent by residents in training. CMS believes that MDM is far more practical and less burdensome because it allows residents in training to take more time to perform services. Therefore, CMS is finalizing their proposal that MDM is used to determine the visit level for office/outpatient E/M visits furnished under the primary care exception.

**ACP Comments:** As discussed in our comments to the CY22 proposed rule, **ACP continues to believe that both time and MDM should be allowed as options for selecting the appropriate level of visit. This should extend to all times when the teaching physician was present via audio, video, or in-person.** In either the non-teaching or teaching setting, physicians will spend time reviewing the chart and discussing, among other tasks, and all of this time should count in determining the E/M visit level. The College is disappointed that the finalized policy from CMS does little to consider the time spent by the teaching physician completing these tasks. Therefore, ACP re-emphasizes its recommendation that both time and MDM be allowed as options for selecting the appropriate level of visit.

Additionally, while the College understands the intent of the finalized policy is to guard against the possibility of inappropriate coding that reflects residents’ inefficiencies rather than a measure of the total medically necessary time required to furnish the E/M services, we are concerned this is misguided. As stated in our comments on the CY22 proposed rule, 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. Likewise, it remains in question whether there is any evidence to support CMS’ assertion regarding the inefficiencies of residents in the context of the primary care exception.

For these reasons, **ACP continues to encourage CMS to maintain modifications that grant attending physicians and residents/fellows additional flexibilities that prioritize patient safety and meeting them where they are.** These important steps promote efficient patient care and allow physicians and supervisees to work together unencumbered by social distancing restrictions. As physicians continue to fight to control the spread of infection, we urge CMS to continue these modifications for a period after

the PHE ends. To be most flexible, this extension should last at least through the end of 2023 with an option to extend it further, based on the experience and learnings of patients and physicians who are utilizing these supervision flexibilities.

## Telehealth

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

**CMS Finalized Policy:** CMS is finalizing its proposed revised timeframe for inclusion of the services added to the Medicare telehealth services list on a temporary, Category 3 basis. The Agency will retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023.

**ACP Comments:** ACP appreciates CMS finalizing its 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 supports this extension, [we continue to 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.** ACP also appreciates the Agency adding CPT codes 93797 and 93798 and HCPCS codes G0422 and G0423 to the Category 3 Medicare telehealth services list. **The College strongly encourages CMS add codes 99441-99443 back to the Category 3 list and retain these services until at least the end of CY23.**

### New Originating Site

**CMS Finalized Policy:** CMS is finalizing its proposals with some modifications. Specifically, the Agency is: adding the home of a beneficiary as an originating site for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders and specifying that the geographic restrictions do not apply to these services; adding the conditions of payment requiring an in-person, non-telehealth visit within six months of the mental health telehealth service in the patient's home, and; adding the exception for subsequent mental health telehealth services when the risks and burdens outweigh the benefits of this requirement. CMS is also modifying the proposed amendments to clarify that payment will not be made for a telehealth service furnished under the rule unless the following conditions are met:

- (1) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within six months prior to the initial telehealth service;
- (2) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, at least once within six months of each subsequent telehealth service described in this paragraph, with exceptions as noted above, and;
- (3) The requirements of paragraph (2) may be met by another physician or practitioner of the same specialty and subspecialty in the same group as the physician or practitioner who furnishes the telehealth service, if the physician or practitioner who furnishes the telehealth service described under this paragraph is not available.

The Agency is also finalizing that an in-person, non-telehealth visit must be furnished at least every 12 months for these services; exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and; more frequent visits are allowed under CMS policy, as driven by clinical needs on a case-by-case basis.

The Agency has additionally finalized its proposal to add a rural emergency hospital as a permissible originating site and clarified that, as proposed, its definition of home can include temporary lodging such as hotels and homeless shelters, as well as locations a short distance from the beneficiary's home.

**ACP Comments:** The College thanks CMS for adding the home of a beneficiary as an originating site for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders and for specifying that the geographic restrictions do not apply to these services. **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.**

However, the College is disappointed that CMS did not broaden the scope of services for which geographic restrictions do not apply to include telehealth services furnished *not only* for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, but also all other telehealth services as approved at the time, effective for services furnished on or after the end of the PHE. **The College continues to recommend that CMS permanently extend the policy to waive geographical and originating site restrictions after the conclusion of the PHE for *all* telehealth services.**

**The College is also disappointed that CMS finalized the requirement that an in-person, non-telehealth visit must be furnished at least every 12 months for these mental health services.** The College believes that there are many positive aspects of both phone and video visits that benefit patients (i.e., access to other family members, transportation issues, the ability to check medications, etc.) and sees no solid rationale or clinical application for requiring a physician to see a patient in person for a mental health exam. This requirement is not based on medical necessity, and the College is opposed to imposing regulations that do not improve patient safety or outcomes. This policy would additionally hamper many psychiatrists who care for patients outside of their locality from continuing to care for many of their patients, unless the in-person visit could be local for the patient and conducted in partnership with a primary care physician. If CMS' imposition of this requirement is based on fraud and abuse concerns for audio-only visits, the Agency should consider the many informatics solutions could be implemented to eliminate such concerns (e.g., two-factor authentication).

#### Payment for Services Using Audio-Only Communication Technology

**CMS Finalized Policy:** CMS is finalizing its proposal to create a service-level modifier for use to identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. The Agency is amending the current definition of "interactive telecommunications system" for telehealth services – which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner – to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients if:

- (1) The patient is located in their home at the time of service;
- (2) The distant site physician or practitioner has the technical capability at the time of the service to use an interactive telecommunications system that includes video, and;
- (3) The patient is not capable of, or does not consent to, the use of video technology for the service.

CMS is also clarifying that substance use disorder (SUD) services are considered mental health services for purposes of the amended definition of "interactive telecommunications system" to include audio-

only services. The Agency anticipates that this will have a positive impact on access to care for mental health conditions and contribute to overall health equity.

Outside of the context of mental health services, CMS did not approve any policies related to pay parity for E/M services and did not provide any additional information on such. Currently, pay parity provisions for E/M services are set to expire at the end of the PHE.

**ACP Comments:** ACP is extremely supportive of CMS expanding audio-only communications technology for mental health telehealth services. **ACP continues to believe that because audio-only telehealth services are an important tool for physicians to improve health equity and patient access, it should not be limited to only patients seeking behavioral and mental health services. The College remains supportive of broadened flexibilities 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 four or five E/M visit codes, CMS is adding burden to both the clinician and the patient.

**ACP vigorously opposes CMS' policy to end coverage for audio-only E/M services (CPT codes 99441-99443) at the end of the PHE and continues to believe that coverage should extend at least to the end of 2023, along with other temporarily covered telehealth services.**

The College is disappointed that outside of the context of mental health services, CMS did not approve any policies related to pay parity for E/M services and did not provide any additional information on such. Currently, pay parity provisions for E/M services are set to expire at the end of the PHE. **The College continues to believe that CMS should 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’ 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 also be inappropriate to treat documentation requirements for audio-only services and in-person visits differently as they are, indeed, not different.

#### Direct Supervision

**CMS Finalized Policy:** Prior to the PHE, direct supervision required the “immediate availability” of the supervising physician or other practitioner. CMS interpreted this to mean in-person, physical availability,



and virtual availability was not permitted. During the PHE, CMS amended the definition of “direct supervision” to allow the supervising physician (or other practitioner) to be immediately available through a virtual presence, using real-time audio/video technology. CMS has finalized its continuation of this policy through the end of the year in which the PHE ends or December 31, 2021, whichever is later.

**ACP Comments:** ACP was pleased to see CMS respond to the needs of clinicians by finalizing an extension of this flexibility to continue to provide direct supervision via interactive audio/video technology through the end of the year in which the PHE ends or December 31, 2021, whichever is later. **Based on the experience and learnings of patients and clinicians who are utilizing these supervision flexibilities, [ACP continues to believe](#) 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 Finalized Policy:** For CY22, CMS is finalizing its proposal to permanently establish separate coding and payment for the longer virtual check-in service described by HCPCS code G2252 using a crosswalk to the value of CPT code 99442, as proposed. As stated in the CY21 MPFS final rule, the Agency believes that the value of CPT code 99442 most accurately reflects the resources associated with a longer service delivered via synchronous communications technology, which can include audio-only communications. In support of the crosswalk to the CPT code 99442, CMS notes this is consistent with its approach to valuing the virtual check-in service (HCPCS code G2012), which used CPT code 99441 as the basis for the valuation. HCPCS code G2252 and CPT code 99442 both describe 11-20 minutes of medical discussion when the practitioner may not necessarily be able to visualize the patient and is used when the acuity of the patient’s problem is not necessarily likely to warrant a visit, but when the needs of the particular patient require more assessment time from the practitioner. In the case of HCPCS code G2252, the additional time would be used to determine the necessity of an in-person visit and result in a work time/intensity that is similar to the crosswalk code.

**ACP Comments:** ACP reiterates our strong disagreement with any conflation by CMS between virtual check-ins, regardless of length, with an audio-only E/M service. Telephone E/M services are not just a longer virtual check-in service; they are an E/M service.

Additionally, **while ACP does not support the use of G2252 as a replacement for telephone E/M visits, it should be noted that the crosswalk to the current value of 99442 continues to be flawed.** For G2252 (work RVU = 0.50), the associated physician work RVUs are considerably lower than those for 99442 (work RVU = 1.30) and 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 a crosswalk to the value of 99213 (work RVU = 1.30). The use of G2252 would provide considerably less resources to physicians to enable them to provide effective care for their patients. The devaluation of G2252, then, may lead to many physicians deciding against using G2252, despite the Agency’s best intentions.

**Rather than adopting a substitute and establishing a workaround for parity, ACP 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 further or consider making permanent, based on the experience and learnings of patients and physicians who are utilizing these services. The College additionally encourages CMS to work with physician stakeholder groups and the CPT Editorial Panel to ensure that coding and payment options for these services are made widely available.

### **Vaccine Administration Services**

**CMS Finalized Policy:** In the CY22 MPFS proposed rule, CMS announced a new add-on payment with a national rate of \$35.50 when a COVID-19 vaccine is administered in the home. The Agency has finalized this policy and will continue making the additional payment when a COVID-19 vaccine is administered in a beneficiary’s home under certain circumstances until the end of the year in which the PHE expires. CMS noted that it believes this extension will maximize access to COVID-19 vaccines for vulnerable homebound beneficiaries during the gradual return to normal conditions following the formal termination of the PHE. For purposes of the add-on payment, CMS will maintain the policy that a home can be a private residence, temporary lodging (e.g., a homeless shelter or hostel), an apartment in an apartment complex or a unit in an assisted living facility or group home, or a patient’s home that is made “provider-based” to a hospital during the PHE for COVID-19. In response to stakeholder feedback that encouraged CMS to consider maintaining the additional payment for in-home COVID-19 vaccination beyond the PHE and extending it to other preventive vaccines, the Agency stated it will continue to engage with the health care community to evaluate this topic.

**ACP Comments:** The College appreciates that CMS finalized its proposal to pay \$30 per dose for the administration of the influenza, pneumococcal and hepatitis B virus vaccines and to maintain the current payment rate of \$40 per dose for the administration of the COVID-19 vaccines through the end of the calendar year in which the ongoing PHE ends. ACP believes these policies will provide the financial support physicians need to continue administering crucial vaccines to their patients. This is particularly important as routine vaccination rates among adults have declined during the COVID-19 pandemic.

**ACP was also glad to see the Agency finalize its proposal to include a \$35 add-on payment 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. This will help increase access and reduce the barriers to vaccination for high-risk and vulnerable populations.

**The College continues to strongly urge 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. With the additional recommendations for COVID-19 booster doses, there is an increased need for vaccine counseling. ACP further urges CMS to make payment for CPT code 99401 retroactive for physicians that have provided this service until January 1, 2021.

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

**CMS Finalized Policy:** CMS has included the following in the CY22 final rule:

#### *Medicare Payments to OTPs*

CMS is finalizing the proposal to codify the application of the annual updates and locality adjustments to the non-drug component of the codes describing add-on payments for opioid antagonist medications (i.e., naloxone) that were new for CY21. In addition, CMS has finalized the proposal to clarify that the prohibition on duplicative payments applies to drugs provided as part of an add-on payment, as well as the bundled payment.

#### *OTP Coding and Payment for New Nasal Naloxone Product*

CMS is finalizing the proposal to establish a new code for a higher dose of naloxone hydrochloride nasal spray; the new code is G1028. The agency is also updating the code descriptor for HCPCS code G2215 to be “Take-home supply of nasal naloxone; 2-pack of 4mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program”.

#### *Counseling and Therapy furnished via Audio-Only Telephone*

CMS is finalizing its proposal to allow OTPs to furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the PHE for COVID-19 when audio/video communication is not available to the beneficiary, provided all other applicable requirements are met. “Not available to the beneficiary” includes situations where the beneficiary is not capable or has not consented to use of two-way communication technology because audio/video communication technology is not able to be used in furnishing services to the beneficiary. The Agency will defer to the judgment of treating clinicians to determine when audio-only or audio/video counseling or therapy are appropriate and whether there are certain circumstances, such as when patients are considered to be high risk, when in-person services are needed.

CMS is also finalizing the proposal that service-level modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) be appended to claims submitted for the counseling and therapy add-on code (HCPCS code G2080) when services are furnished via an audio-only interaction. Following the COVID-19 PHE, if two-way interactive audio/video communication technology is used and billed under G2080, OTPs will be required to use modifier 95 in claims. For purposes of the bundled payment for additional counseling or therapy services furnished using audio-only technology, the Agency is amending its proposal to require that after the COVID-19 PHE, the practitioner must certify that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because audio/video communication technology was not available to the beneficiary.

**ACP Comments:** The opioid epidemic has had a devastating impact on the United States and the coronavirus pandemic has exacerbated the crisis. Provisional data from the [Centers for Disease Control](#)

[and Prevention](#) show an accelerated increase in drug overdose fatalities during the pandemic. To enable social distancing, stay-at-home orders, and other pandemic response policies, the federal government took vital action to prevent disruptions in care for patients undergoing treatment for opioid use disorder, including permitting alternatives to in-person treatment for patients who receive care through opioid treatment programs (OTPs). CMS permitted OTPs to conduct counseling and therapy via audio-only communication when audio-video technology is unavailable to the beneficiary. **ACP commends CMS for finalizing the proposal to extend this policy after the conclusion of the PHE, which will help maintain continuity of care.** Additionally, ACP [recommends](#) reducing barriers to accessing medications to treat opioid use disorder, including eliminating onerous prior authorization requirements for buprenorphine, and exploring limiting restrictions on office-based methadone treatment provided by trained physicians.

### **Updates to Physician Self-Referral Regulations under Stark Law**

**CMS Finalized Policy:** CMS is finalizing its proposal to amend the provisions of 42 CFR § 411.354(c)(2) identifying unbroken chains of financial relationships that constitute “indirect compensation arrangements” to ensure that a longstanding prohibition on certain per unit of service-based compensation formulas for determining charges for the rental of office space and equipment remains within the scope of the law. Additionally, CMS is adding provisions to assist stakeholders in identifying the individual unit to be analyzed under the provisions of § 411.354(c)(2)(ii)(A)(2)(i) through (iv), stating it believes this clarity will help facilitate compliance without adding burden.

**ACP Comments:** Over the years, significant confusion has arisen regarding when an “indirect compensation arrangement” triggers the Stark Law, which has led to frustration, especially for attenuated, innocuous physician relationships. ACP is appreciative of CMS’ acknowledgment of these concerns in the December 2, 2020, final rule that implemented significant Stark Law regulatory changes; specifically, the recognition of the unnecessarily burdensome process where the prior regulatory scheme casted a wide net to include the vast majority of unbroken chains of financial relationships between an entity and a physician, which then had to be weeded out through applicability of a Stark Law exception. Accordingly, in that final rule, CMS changed when an indirect compensation arrangement is deemed to exist by significantly narrowing the scope of its application. The College welcomed these changes as they reduce the number of financial relationships subject to the Stark Law and reduces some of the confusion around applicability.

Unfortunately, however, CMS has yet again revised the applicable regulation (42 CFR 411.354(c)(2)) in the CY22 MPFS final rule to broaden the scope of indirect compensation arrangements. Under the new rule, many indirect arrangements will now be “indirect compensation arrangements”. **The College believes the finalized policy around “indirect compensation arrangements” is counterproductive and reintroduces the burdensome elements of Stark** since rather than being excluded from the definition altogether because they are not deemed to create a financial relationship, these arrangements will need to satisfy an exception. Given the back-and-forth revisions to the Stark regulations over the past two years, it is possible that, without changing any details, a particular financial relationship may (1) have had an indirect compensation arrangement before January 19, 2021 (the effective date of the prior final rule), then, (2) not had an indirect compensation arrangement for the remainder of 2021, and (3) will now have an indirect compensation arrangement again starting in 2022. With physicians already stretched thin and lacking the resources to dedicate a compliance team to these matters, this

inconsistency is incredibly burdensome and will only lessen the likelihood of conformity with the revised regulation.

**Considering the legal and regulatory complexities of the Stark Law, ACP is supportive of the intent behind CMS' proposals and subsequent clarifications.** However, echoing our previous concerns regarding the 'turnaround-time' for compliance, significant burden will arise from the finalized compliance timeline. For small and independent physicians who do not retain large legal and compliance teams, this is a tall task. Therefore, **in future rulemaking, ACP strongly recommends CMS re-examine the ever-growing complexity of the statute, the likelihood its policy will, in fact, lend greater clarity to the regulations, and continue to collaborate with health care entities and physicians 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 Finalized Policy:** CMS is finalizing their proposal 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 commends CMS for finalizing requirements for manufacturers of drugs and biological products covered under Medicare Part B to provide CMS with regular and accurate average sales price information in order to ensure accurate payment.** Improved price transparency is an important first step to addressing the escalating price of prescription drugs; however, ACP is concerned that the true price of the drug remains distorted as the reported ASP includes discounts, rebates, and other payments and differs from the list price. [ACP renews its call](#) for the federal government to go further in requiring the reporting of additional price and cost information, including the disclosure of actual material, production, and research and development costs to regulators. [The College further implores CMS](#) to explore, study, and implement additional approaches that are effective in aligning Medicare Part B 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 Finalized Policy:** The Agency is finalizing its proposal to extend the date of compliance actions to no earlier than January 1, 2023. CMS is also finalizing its proposal that the earliest date of compliance actions against prescribers writing Part D controlled substance prescriptions for beneficiaries in long-term care (LTC) facilities to be no earlier than January 1, 2025, to allow adequate time for EPCS to be adopted across the industry. In order to implement this provision, CMS will be excluding LTC prescriptions from its counting of compliance actions to help ensure that prescribers writing prescriptions for beneficiaries in these facilities do not have these prescriptions counted against them for purposes of the compliance threshold and the number of prescriptions written per prescriber for purposes of determining who is classified as a small prescriber under the rule.

The Agency is finalizing this provision as proposed, which would require prescribers to prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically, except in cases where an exception or waiver applies. CMS notes that prescriptions for beneficiaries in LTC facilities would be excluded from the calculation of the compliance threshold until the January 1,

2025, compliance threshold calculation is made, which would be using data beginning on January 1, 2024. CMS will determine compliance with the EPCS requirement by examining prescription drug events (PDE) data at the end of the calendar year (86 FR 39330), which is why the Agency will begin considering data for Part D prescriptions written for beneficiaries in LTC facilities on January 1, 2024, and continuing through December 31, 2024, for compliance actions that CMS takes on or after January 1, 2025.

**ACP Comments:** Where the practice is less burdensome for both patients and clinicians, [ACP supports the use of electronic prescribing for controlled substances](#), though we caution it is not always true that e-prescribing of controlled substances is *actually* less burdensome. **ACP commends CMS for extending the date of compliance actions to no earlier than January 1, 2023, 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. Also, since e-prescribing adds an unfunded mandate whereby participating clinicians must pay an annual fee to use—and there are broadband issues for some clinicians—e-prescribing is often an additional burden. **For these reasons, [ACP continues to recommend](#) CMS study the true costs and implications of this mandate on clinicians.**

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 systems going down or other technological barriers.** In looking forward to January 1, 2023, CMS should pay close attention to the real, true conditions in practice and the downstream implications of its policies – especially to small, independent practices and those in rural areas – and be willing to extend the date of compliance actions in further rulemaking if it is determined that a significant percentage of small, rural, or independent practices are still facing implementation barriers.

#### **Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging**

**CMS Finalized Policy:** CMS finalized its proposal to delay the penalty effective date of the AUC program until January 1, 2023, or the January 1 that follows the end of the declared COVID-19 PHE, whichever is later. The payment penalty phase had been previously set to begin January 1, 2022. When the penalty phase begins, CMS will return claims for correction and resubmission. Furnishing professionals will be allowed to modify an order with a replacement and/or additional imaging service, if they are unable to reach the ordering professional for a new order, and may append the claim for the original order.

**ACP Comments:** **ACP is grateful for the delay until 2023 and thanks CMS for the decision to return claims that fail AUC processing edits rather than deny them.** While the College recognizes that consultation of AUC for advanced diagnostic imaging tests is important, **we continue to believe that CMS should continue voluntary participation in the AUC Program.** Physicians and other health care professionals are unprepared for yet another burdensome 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 during the ongoing COVID-19 pandemic.

## **Innovative Technology and Artificial Intelligence (AI) - Request for Information**

**CMS Finalized Policy:** In the [CY22 MPFS proposed rule](#), CMS solicited 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 this proposed rule, CMS also posed several questions regarding coverage of AI and other innovative technologies.

In the CY22 MPFS final rule, CMS thanked commenters and said the information submitted would be taken under advisement in potential future rulemaking.

**ACP Comments:** The College remains pleased with CMS for initiating a discussion on the use of AI and other innovative technologies and was glad the Agency accepted feedback on this topic without finalizing any policy. **The College re-emphasizes its belief that, because of its importance and implications, this RFI should be removed from the MPFS rulemaking process and should be re-opened to allow more time to gather stakeholder feedback.**

The College believes 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 continues to caution 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.**

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

**CMS Finalized Policy:** CMS has finalized their plan to move fully to digital quality measures (dQMs) by 2025, with the acknowledgement that the timeline may vary across CMS' quality programs. CMS believes that their efforts to move to dQMs align with efforts described in the Office of the National Coordinator for Health Information Technology's (ONC) 21<sup>st</sup> Century Cures Act final rule and will coordinate with HL7's ongoing work to advance FHIR®. CMS plans to use policy levers and work with stakeholders, (e.g., programs, agencies, and private payers) to solve the issue of interoperable data exchange and to transition to full digital quality measurement.

While CMS will not be responding to specific comments submitted in response to this Request for Information in the CY22 MPFS final rule, the Agency will actively consider all input as it develops future regulatory proposals or future sub-regulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions may be addressed through separate and future notice and comment rulemaking, as necessary.

**ACP Comments:** The College continues to believe that CMS' finalization of its plan to move fully to digital quality measures (dQMs) by 2025 is far too aggressive and unreasonable. Progress on many other fronts is necessary before quality measures can function in a truly digital way. In addition to building data collection systems and adapting to new data structure and storage mechanisms, dQMs will also require changes to workflow 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 MIPS Value Pathways (MVPs) as a starting point to transition to APMs seems untenable. We also note that it would be particularly challenging for independent practice physicians and solo

practitioners to keep up with these changes given their slower adoption of electronic health records as compared to practices that exist within large health care systems. Therefore, **the College continues to ask CMS to focus on one significant modification at a time and supports the transition to MVPs being the priority given that their development is further along than dQMs and because they are more comprehensive of a change.**

**The College remains pleased that CMS is working in collaboration with ONC on improving interoperability and promoting the adoption of Fast Healthcare Interoperability Resource® standards and standards-based application programming interfaces (APIs).** While the College remains supportive of FHIR, we must reiterate 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 remains 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. As before, 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 Finalized Policy:** CMS made several proposals to advance health equity, consistent with President Biden’s recent [Executive Order 13985](#). The CY22 MPFS proposed rule included a Request for Information asking for feedback on the Agency’s efforts to collect additional data to identify and respond to health disparities in its programs and policies. The Agency noted several strategies it considered, including clinician and/or public-facing reports on MIPS quality measures stratified by dual-eligible status, race, and other factors. CMS also sought 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.

In the CY22 MPFS final rule, CMS did not finalize any rules regarding this initiative. CMS thanked commenters and said the information submitted would be taken under advisement in potential future rulemaking.

**ACP Comments: While the College agrees that the collection of this data is a valuable effort, we recommend postponing any additional requirements until staffing shortages have eased.** The College proposes that when CMS considers adding something new to the physician workload, there also be consideration of whether anything else in the workload could stop being done (e.g., consider eliminating other current collection requirements that may be of lower overall value to patient care or CMS’ goals). ACP also proposes that CMS consider technology or informatics-based solutions for collecting this data that would not require actual staff time. ACP strongly believes CMS should develop the kind of information exchange system that would allow health systems to connect with state identification databases to reduce clinician burden and increase accuracy of information.

Furthermore, ACP believes that requiring data collection is only one portion of data sharing being effective or useful. For example, some clinicians have concerns about pulling out even rudimentary data from EHRs because the information is not standardized in how it is stored, reported, or formatted. ACP



also believes that many patients will not be willing to share significant personal information with physicians, let alone the federal government, and the College worries that additional collection requirements could end up vilifying physicians in patients' eyes.

**The College remains concerned about the undue burden this data collection requirement will have on frontline clinicians and their staff, especially during this time of extreme staffing shortages in health care.** In many cases, the frontline doctor is not the staff member collecting this data. In some practices, additional requirements around social drivers of health (SDOH) data collection would mean the patient taking longer to get from the waiting room to the exam room. Therefore, ACP believes the appropriate target for direct questions about or field-testing of proposed new data collection requirements should actually be the nurses, medical assistants, scribes, etc. However, even this can be problematic because of widespread staffing shortages that result in clinicians doing much of the work that should be done by staff. Moreover, in many practices, SDOH data is not actually being collected, and is instead being made up by staff who are making assumptions about people based on appearance. **ACP strongly believes that there is a need to train other members of the clinical staff team to ask the right questions and properly collect the data and that for data to be collected properly.** There also must be system-wide, administrative buy-in and infrastructure in place.

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

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

##### Quality Measures

**CMS Finalized Policy:** The CY22 MPFS final rule maintains the data completeness criteria threshold of 70 percent for the 2022 and 2023 performance periods. For performance period 2022, the quality performance category weight is set at 30 percent.

CMS also finalized the Optimizing Chronic Disease Management MVP which includes nine quality measures and 12 improvement activities, the Advancing Rheumatology Patient Care MVP which includes nine quality measures and 11 improvement activities, and the Advancing Care for Heart Disease MVP which includes eight quality measures and 11 improvement activities.

In the final rule, CMS additionally suggests that "to the extent feasible" MVPs should include a maximum of 10 quality measures and 10 improvement activities.

**ACP Comments: ACP is pleased that CMS decided to maintain the data completeness criteria threshold of 70 percent.** Data completeness requirements have a direct and significant impact on physician burden and pull from practice resources that could be used toward direct patient care. The decision to not increase the threshold to 80 percent for PY 2023 will alleviate physician burden and improve patient care.

##### Improvement Activities

**CMS Finalized Policy:** As with the MIPS, groups and sub-groups will select two medium-weighted or one high-weighted activity, or participation in a patient-centered medical home (PCMH), if available in the MVP.

For the CY22 performance period/2024 MIPS payment year and future years, CMS finalized adding seven new improvement activities, modifying 15 previously adopted improvement activities, and removing six previously adopted improvement activities. For performance period 2022, the improvement activities category weight is set at 15 percent.

**ACP Comments: ACP appreciates the effort to streamline improvement activities and to eliminate duplicates.**

#### Promoting Interoperability

**CMS Finalized Policy:** In order to give MIPS-eligible clinicians time to familiarize themselves with MVPs and subgroup reporting, CMS finalized its proposal to delay public reporting of new improvement activities and Promoting Interoperability measures and attestations reported via MVPs by one year and begin publicly reporting subgroup-level performance information in performance year (PY) 2024, on the compare tool hosted by HHS. The Agency finalized calculation of the Promoting Interoperability performance category score for an MVP Participant using specific methodology detailed in the rule, with some exceptions.

**ACP Comments: The College appreciates CMS finalizing its proposal to delay public reporting of new improvement activities and Promoting Interoperability measures and attestations reported via MVPs by one year. However, ACP remains committed to the idea of MVPs moving toward a wholesale departure from traditional MIPS in order to offer a true on-ramp for practices to APMs and is concerned these regulations do not fully address issues raised in [earlier comments](#). For the MVP pathway to be a step in the right direction, it is critically important to include measures that are methodologically sound, evidence-based, and addressing areas of clinical significance.**

#### MVP Review: Quality Measure, Patient Reported Outcome Measure, Population Health Measure and Cost Measure

**CMS Finalized Policy:** CMS finalized that they would be starting to transition to MVPs from the 2023 performance year. In response to the comments received, the Agency delayed the requirement of multispecialty groups needing to form subgroups in order to report MVPs to 2026. Subgroup reporting will be voluntary in 2023, 2024, and 2025. CMS highlighted that they would be requiring QCDRs, Qualified Registries, and Health IT vendors to support MVPs, starting from 2023.

CMS finalized the below seven MVPs that will be available to report in 2023:

1. [Advancing Rheumatology Patient Care](#)
2. [Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes](#)
3. [Advancing Care for Heart Disease](#)
4. [Optimizing Chronic Disease Management](#)
5. [Adopting Best Practices and Promoting Patient Safety within Emergency Medicine](#)
6. [Improving Care for Lower Extremity Joint Repair](#)
7. [Support of Positive Experiences with Anesthesia](#)

The MVP participants will be required to report on four Quality measures, out of the quality measures included in that MVP, where one must be an outcome measure. Participants can report on a high-priority measure to meet this requirement if an outcome measure is not included in the MVP. Other

than Quality, MVPs will also have to report on Improvement Activities Performance Category, Cost Performance Category, and an MVP agnostic Foundational Layer.

CMS has included two new quality measures in the MVPs. One is a population health measure, Clinician and Clinician Group Risk standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Q484), which is included in all seven MVPs' Foundational Layer. The other new measure is the Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM), which is included in the Optimizing Chronic Disease Management MVP.

The MVP agnostic Foundational Layer has two parts:

- (1) Population Health Measure: MVPs will have to report on one of these two available measures, and:
  - Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups
  - Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions
- (2) Promoting Interoperability Measures.

The scoring of the Quality category for MVPs differs slightly from that of the traditional MIPS. There is no three-point floor available for MVPs. Existing measures with no benchmark will score zero but new measures without a benchmark will score a seven-point floor in the first year and five-point floor in the second year. Like traditional MIPS, CMS has finalized the removal of end-to-end electronic reporting and high priority/outcome measure bonus points from the 2022 performance period. The score of the Population Health Measure will be added to the Quality Score for MVPs.

Though CMS acknowledged that their existing portfolio of patient reported outcome measures are limited and may not be applicable to all specialties and subspecialties, CMS is not taking any further action at this time. The Agency thanked commenters and stated the information submitted would be taken under advisement in potential future rulemaking.

CMS also finalized the inclusion of the TPCC (Total Per Capita Cost) cost measure for three MVPs (Advancing Rheumatology Patient Care, Advancing Care for Heart Disease, and Optimizing Chronic Disease Management) as proposed (displayed in [Table 54](#) and Tables [A](#), [C](#), and [D](#)).

**ACP Comments: ACP continues to believe that the MVP pathway could be a step in the right direction if included measures are cohesive, methodologically sound, evidence-based, and addressing specific clinical areas of importance.** ACP worked closely with CMS in developing the Optimizing Chronic Disease Management MVP that has been finalized to be included in the MVP pathway, starting in 2023. 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. The College additionally believes that the start of MVPs in 2023 gives practices, large organizations, registries, and Health IT companies adequate time to get equipped for the MVP pathway requirements.

**In response to our comments, ACP appreciates that CMS delayed the requirement of multispecialty groups needing to form subgroups in order to report MVPs to 2026.** We believe that allowing multispecialty groups to create subgroups is beneficial; however, we were opposed to the idea of making that a requirement by 2025. We believe that all practices, including multispecialty practices,

would need an adjustment period to get used to MVP reporting. Making any such requirements that early would only create more challenges in their path to success.

The College also appreciates that CMS is starting with seven broad MVPs in 2023. That gives most practices some option to participate and try reporting through this new pathway. We look forward to CMS adding an MVP addressing preventive care and more MVPs for additional specialties in the near future.

After the 2022 proposed rule was published, 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 to Internal Medicine, and provided our comments.

We noticed that CMS has finalized the inclusion of the new measure, Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PROM) to the Optimizing Chronic Disease Management MVP. This measure has also been finalized to be added to the internal medicine specialty measure set. As commented before, **ACP reviewed this measure in January 2021 and does not support it. We appreciate CMS providing commenters with the measure's testing results in the CY22 final rule; however, our concerns regarding the measure's appropriateness in every clinical situation, especially to internal medicine, remain the same.**

**ACP also does not support the TPCC (Total Per Capita Cost) cost measure.** The College noted that CMS has finalized the inclusion of that measure in three MVPs. **As we commented previously, 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.** However, we do not support the current use of one-size-fits-all cost metrics. While every clinician plays an important role in controlling costs, their ability to influence costs at different points in the process can vary widely.

**The College additionally reviewed the Population Health Measures that have been finalized to be included in MVPs in 2023, and ACP does not support the MIPS 479 - Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the MIPS Eligible Clinician Groups measure because of uncertain validity.** The Performance Measurement Committee at ACP reviewed this measure and found that the importance and impact of the measure was in question, and there was no evidence to demonstrate its impact on health outcomes at the group practice level. There were also significant concerns regarding gaming that have been documented with the hospital level measure (i.e., putting patients in observation status for a few days so they will not count as a readmission). One way to mitigate this concern is to incorporate an exclusion related to excess days of acute care, which is an approach that has been well validated in cardiac care. Another issue relates to the measure's reliability, particularly with volumes below 200. This needs to be accounted for in some way with an exclusion or a low volume threshold when implemented. The risk adjustment was marginal and did not include social determinants or measures of income. Finally, there are concerns about the attribution approach and the multiple attribution model. This approach can lead to bias against attribution groups that are not aligned financially.

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

## **PY 2022 MIPS Changes**

### *PY22 Reporting Exemptions Due to COVID-19*

**CMS Finalized Policy:** CMS finalized continuing its MIPS extreme and uncontrollable circumstances exceptions for the 2022 performance year on a case-by-case basis.

**ACP Comments:** **ACP applauds CMS for continuing its MIPS extreme and uncontrollable circumstances exceptions for the 2022 performance year on a case-by-case basis.** MIPS-eligible clinicians, groups, and virtual groups may submit an application to reweight any or all MIPS performance categories if they have been affected by extreme and uncontrollable circumstances that impact these categories. Individual MIPS-eligible clinicians will have all four performance categories reweighted to zero percent and receive a neutral payment adjustment in 2023 unless they submit data. 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. The College commends CMS for making this important and necessary extension.

### **PY 2022 Scoring and PY 2021 Performance Feedback**

**CMS Finalized Policy:** CMS delayed MVPs until 2023. It will begin as optional, but eventually CMS intends to sunset traditional MIPS and require reporting via MVPs. MIPS-eligible clinicians will generally be able to participate in MVPs, with limited exceptions. CMS will start with seven MVPs and plans to add more in the future. CMS still aims to sunset traditional MIPS and replace it with MVPs starting with PY 2028. CMS also finalized their proposal to remove measure bonus points for reporting high priority measures and for submitting with end-to-end electronic reporting beginning in the 2022 MIPS performance period.

CMS finalized the removal of the three-point scoring floor for measures that can be reliably scored against a benchmark to be implemented in CY23 (except in the case of small practices, for which CMS will maintain the three-point floor).

**ACP Comments:** **ACP supports the approach of aligning MVP Scoring with Traditional MIPS Scoring and the College appreciates CMS introducing a new scoring policy for new measures from 2022. However, the removal of the three-point floor for measures without a benchmark from 2023 can weigh heavily on the practices that are already struggling with this pandemic, unless the situation improves drastically in 2022.** We also do not support CMS removing the high-priority measures and end-to-end electronic bonuses in PY 2022.

As stated in our comments on the MPFS proposed rule, **ACP opposes CMS' proposal to make MVP participation mandatory starting in PY 2028.** 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.

### *Quality Category: Data Completeness*

**CMS Finalized Policy:** CMS has not made significant changes to the Quality Category for PY22. Quality will be 30 percent of the total score, compared to 40 percent in 2021. CMS had initially proposed to

increase the data completeness threshold to 80 percent, from 70 percent in 2021. In the CY22 final rule, CMS stated that it was maintaining it at 70 percent for the 2022 and 2023 performance periods in response to the comments received. CMS finalized that it would use the CMS Web Interface as a quality reporting option for the 2022 performance period.

**ACP Comments: The College appreciates CMS not increasing the data completeness threshold to 80 percent and instead choosing to maintain the same at 70 percent for 2022 and 2023.** With the current PHE, the increased data completeness requirement would have only created more challenges for practices. ACP is happy to see that CMS is offering CMS Web-Interface reporting as a quality reporting option in 2022.

Quality Category: Quality Measure Scoring Changes

**CMS Finalized Policy:** The overall scoring and the scoring for the Quality Section has some changes. CMS finalized that it would be increasing the performance threshold for the total score to 75, from 60. There is an additional threshold of 89 points for exceptional performance. The Agency also mentioned it would be using 2020's performance data as the historical benchmark for 2022 reporting because their research showed that it would be able to create reliable benchmarks with 2020 data. For the Quality section scoring, CMS has finalized the removal of end-to-end electronic reporting and high priority/outcome measure bonus points from the 2022 performance period. However, in response to comments concerning the removal of three-point floor during this PHE, CMS finalized that it would be delaying the removal of three-point floor for measures until the CY 2023 performance period. The Agency additionally finalized the removal of the following four measures from the internal medicine set:

1. Falls: Risk Assessment
2. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier
3. Pain Brought Under Control Within 48 Hours
4. Medication Management for People with Asthma

MIPS scoring, as statutorily required, will be as follows for PY22:

- Traditional MIPS (individuals, groups, virtual groups): Quality 30 percent, Cost 30 percent, Promoting Interoperability 25 percent (no change), and Improvement activities 15 percent (no change);
- Traditional MIPS (APM entities) did not change: Quality 55 percent, Cost zero percent, Promoting Interoperability 30 percent, Improvement Activities 15 percent, and;
- APM Performance Pathway did not change: Quality 50 percent, Cost zero percent, Promoting Interoperability 30 percent, Improvement Activities 20 percent.

CMS will continue to double the complex patient bonus (five points x two) for the 2021 MIPS performance year. For PY22, the Agency will limit the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC score and dual eligible patients). The maximum bonus will increase to 10 points.

CMS also finalized their proposal to establish the performance threshold using the mean and the CY 2017 performance period/2019 MIPS payment year data, which sets the performance threshold at 75 points.

**ACP Comments: ACP does not support CMS' decision to remove the high priority/outcome measure bonuses from Traditional MIPS Quality scoring during this PHE in 2022.** We continue to urge CMS to reconsider the removal of the three-point floor for scoring measures from 2023 performance period. Unless the situation improves dramatically in 2022, this removal can weigh heavily on the practices that are already struggling with this pandemic.

The College understands that it is a statutory requirement to raise the performance threshold during the first five years of the MIPS program. However, setting 2022 performance year's threshold to 2017's means a final score of 75 points, and this does not seem appropriate. 2017 was MIPS' transition year, and the scoring was lenient. Using that benchmark, which is significantly higher than last year's 60-point threshold when the scoring rules have become strict, seems penalizing.

ACP is supportive of the removal of three of the four measures removed from the internal medicine set (Falls: Risk Assessment, Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier, and Pain Brought Under Control Within 48 Hours). However, ACP is disappointed in CMS' decision to remove the Medication Management for People with Asthma measure, as implementation may have promoted patient adherence to prescribed controller medication therapy.

#### Promoting Interoperability Changes

**CMS Finalized Policy:** CMS finalized their proposal to make the Immunization Registry Reporting a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the CY22 performance period/CY24 MIPS payment year. The Agency believes that making the Immunization Registry Reporting measure required will increase the reporting of immunization data by health care clinicians and other providers to public health agencies and that it is critical for the COVID-19 vaccination response because it will provide a better view of the vaccines administered and distributed at national, state, and local levels. The Agency believes requiring the measure will reduce the regulatory and administrative burden health care practitioners experience when exchanging information with immunization registries.

CMS additionally finalized these proposals:

- Beginning with the CY22 performance period/CY24 MIPS payment year, a MIPS-eligible clinician will receive 10 points for the Public Health and Clinical Data Exchange objective if they report a "yes" response for each of the following required measures: Immunization Registry Reporting, and Electronic Case Reporting. If a MIPS-eligible clinician can claim an exclusion for one or more of these required measures, they will receive 10 points for the objective if they report a "yes" response for one measure and claim an applicable exclusion for which they qualify for the remaining measure. If the MIPS-eligible clinician fails to report on any one of the two measures required for this objective or reports a "no" response for one or more of these measures, the MIPS-eligible clinician will receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Promoting Interoperability performance category. If a MIPS-eligible clinician claims applicable exclusions for which they qualify for both required measures, the Agency will redistribute the points associated with the objective to the Provider to Patient Exchange objective.
- The Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures will be optional and available for bonus points beginning with

the CY22 performance period/CY24 MIPS payment year. A MIPS-eligible clinician may earn five bonus points if they report a “yes” response for either the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure.

- CMS is removing the three exclusions established in the CY19 MPFS final rule (83 FR 59815-59817) for the Public Health Registry Reporting measure, Clinical Data Registry Reporting measure, and the Syndromic Surveillance Reporting measure.

**ACP Comments: ACP is disappointed CMS has decided to finalize its proposal to make the Immunization Registry Reporting a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the CY22 performance period/CY24 MIPS payment year.** While the College strongly agrees that the accurate, timely collection of this information is crucial and admires CMS’ desire to ensure that data are collected in a uniform way, we believe this should be a function of local and state public health agencies. ACP objects to it being a required measure under the “Public Health and Clinical Data Exchange” objective of the Promoting Interoperability category within MIPS, as it will place the onus on the MIPS-eligible clinician for something that is far out of their control.

**The College encourages CMS to, at minimum, delay the timeline for making the Immunization Registry Reporting a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category.** With widespread reports of physician burnout and the knowledge 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.

**The College is supportive of the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures being optional and available for bonus points beginning with the CY22 performance period/CY24 MIPS payment year.** While the points are less, the minimum needed to earn the points is less. Reporting it as a bonus also means ECs do not have to report the exclusion.

These Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures would be optional and available for bonus points beginning with the CY22 performance period/CY24 MIPS payment year. A MIPS-eligible clinician may earn five bonus points if they report a “yes” response for either the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure. But if an EC does not report the registry reporting measures, they do not have to report an exclusion.

#### Improvement Activities (IA) Category

**CMS Finalized Policy:** This final rule adds seven new activities, modifies 15, and removes six. There are two new activities, “Create and implement an anti-racism plan” (IA\_AHE\_8) and “Implement food insecurity and nutrition risk identification and treatment protocols” (IA\_AHE\_9), as well as several modifications to other IAs that are intended to address health equity and social drivers of health. Others are intended to address clinician well-being, emergency preparedness, and PPE management.



Groups that report IAs must be performed by at least 50 percent of the National Provider Identifier's (NPIs) billing under the group's or virtual group's tax identification number (TIN), and the NPIs must perform the same activity during any continuous 90-day period during the same performance period.

The final rule also made some changes to the process of nominating new IAs during the PHE. CMS also finalized two additional criteria for new IAs, requiring that they are not duplicative of other IAs, and that they "drive improvements that go beyond purely common clinical practices."

**ACP Comments:** ACP agrees that new IAs should not be duplicative of existing options. However, ACP continues to be concerned that the criteria to "drive improvements that go beyond purely common clinical practices" is unrealistic. ACP believes the current weighting system is sufficient to help physicians prioritize high weighted activities that go beyond standard clinical activities. **The College is also pleased to see IAs that address disparities, as well as patient and family engagement.**

### Cost Performance Category

**CMS Finalized Policy:** CMS is adding five new episode-based measures, including two chronic condition episodes (asthma/chronic obstructive pulmonary disease, diabetes), two procedural episodes (colon and rectal resection (COPD), melanoma resection), and one acute inpatient medical condition episode (sepsis). This adds to the two global or population-based measures and 18 episode-based measures. For performance period 2022, the cost performance category weight is set at 30 percent.

In addition to the current process, CMS finalized a process for stakeholders to develop cost measures outside the current measure development process, where all cost measures are developed by CMS' measure development contractor.

**ACP Comments:** As stated in our comments on the CY22 MPFS proposed rule, **ACP continues to have specific concerns, including attributing costs at the group practice level or higher, not attributing the same costs to multiple clinicians/groups, and risk adjusting for social determinants of health.** 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 eQMs. We continue to urge CMS whenever possible to make technical improvements to measures, as opposed to removing them.

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

**CMS Finalized Policy:** CMS finalized that individual MIPS-eligible clinicians who are participants in MIPS APMs may report through the APP at the individual level. Additionally, CMS finalized that groups and APM entities may report through the APP on behalf of constituent MIPS-eligible clinicians.

Regarding CMS' proposal to allow MIPS-eligible clinicians to report the APP as a subgroup beginning with the PY23, CMS is finalizing this with the modification that multispecialty groups will be required to form subgroups in order to report MVPs beginning in the CY26 performance period/2028 MIPS payment year, instead of the CY25 performance period/2027 MIPS payment year, as proposed.

**ACP Comments:** As stated in ACP's comments on the proposed rule, the College supports efforts to promote consistency across the QPP and to offer clinicians flexible reporting options, which reduces burden. **The College supports 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.** 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 continue to emphasize the rigidity of the design of the new APP, particularly concerning quality measurement, and how this may inadvertently create more administrative burden.**

#### Complex Patient Bonus

**CMS Finalized Policy:** CMS finalized their proposal on formulas for the complex patient bonus with two separate components (medical complexity and social complexity) and an overall cap of 10 bonus points beginning with the 2022 MIPS performance year.

**ACP Comments: The College supports the finalized formulas for the complex patient bonus and the introduction of the five- to seven-point floor to incentivize new measures.** ACP encourages CMS to continue to support the reporting bonuses in future reporting years. However, ACP is critical of CMS making the complex patient bonus a more tedious by adding the social complexity component and by removing the high-priority measure and e-prescribing bonuses. Adding complexity often means adding administrative burden and especially in the context of the ongoing PHE, this is not in the best interest of the patient or physicians.

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

**CMS Finalized Policy:** In the final rule, CMS finalized extending the availability of the CMS Web Interface collection type for an additional three years (though PY24) for Accountable Care Organizations (ACOs) to prepare for reporting electronic clinical quality measures (eCQM)/MIPS clinical quality measures (MIPS CQM) under the Alternative Payment Model (APM) Performance Pathway (APP). For performance years 2022-2024, CMS will allow ACOs to report either the 10 CMS Web Interface measures and administer Consumer Assessment of Healthcare Providers and Systems (CAHPS) or report the three Alternative Payment Model Performance Pathway (APP) eCQMs/MIPS CQMs and administer CAHPS. Beginning with the 2025 performance period and subsequent years, ACOs must report the three APP eCQM/MIPS CQMs.

For PY 2022 and 2023, CMS has established an incentive for the quality performance standard for ACOs that report the eCQMs/MIPS CQMs. CMS will add several codes (include CPT codes 99441-99445, until they are no longer payable under the MPFS) to the list of primary care services used to assign patients to the ACO.

CMS finalized lowering the repayment mechanism amounts and modification of the methodology used for the annual repayment amount recalculation to use more recent data.

CMS finalized freezing the quality performance standard at the 30<sup>th</sup> percentile for MIPS Quality Performance Category scores for an additional year (PY 2023). CMS will increase the quality performance standard to the 40<sup>th</sup> percentile beginning with PY 2024.

CMS finalized policies impacting the Shared Savings Program application process by modifying the prior participation disclosure requirement. The disclosure is required only at the request of CMS during the application process.

**ACP Comments:** ACP appreciates CMS finalizing the phasing out of the Web Interface as a reporting option. However, ACP maintains strong reservations about the alignment of ACO and MIPS quality standards. In our comments on the MPFS proposed rule, ACP expressed concern over the feasibility of reporting eQDM and all-payer data starting in 2023. The College is happy with CMS’ decision to postpone these requirements to PY 2024. **ACP continues to encourage CMS to work collaboratively with the ACO, vendor, and medical community to resolve these barriers.**

**Medicare Diabetes Prevention Program (MDPP) PHE Permanent Exceptions**

**CMS Finalized Policy:** CMS finalized the proposal to continue the waiver of the enrollment application fee beginning on January 1, 2022. Also, CMS will redistribute all the ongoing maintenance sessions to certain core and core payment sessions over one year instead of two and will maintain the current payment for five percent weight loss goal the same while increasing the payment for attendance.

**TABLE 39: MDPP Payment Structure**

Payment Description	Current	Proposed	Final
<b>Core Sessions (Months 1-6)</b>			
Attend 1 Core Session or Bridge Payment	\$26	\$26	\$35
Attend 4 Core Sessions	\$52	\$78	\$105
Attend 9 Core Sessions	\$95	\$130	\$175
<b>Core Maintenance (CM) Sessions (Months 7-12)</b>			
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	\$15	\$52	\$75
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 1 (Months 7-9)	\$63	\$106	\$93
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 2 (Months 10-12)	\$15	\$52	\$75
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 2 (Months 10-12)	\$63	\$106	\$93
5% WL Achieved from baseline weight	\$169	\$189	\$169
9% WL Achieved from baseline weight	\$26	\$26	\$35
<b>Ongoing Maintenance Sessions (Months 13-24)</b>			
Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)	\$52		
Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)	\$52		
Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)	\$53		
Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months 22-24)	\$53		
<b>Subtotal Maximum Payment – Attendance Only</b>	<b>\$203</b>	<b>\$338</b>	<b>\$455</b>
<b>Total Maximum Payment*</b>	<b>\$704</b>	<b>\$661</b>	<b>\$705</b>

**ACP Comments:** ACP applauds CMS’ extension of the waiver for “provider’ enrollment application fees after the PHE as a way to increase participation. We also appreciate the Agency reducing the emphasis on weight loss by increasing the payment for attendance.

**Advanced Alternative Payment Models (APMs)**

**CMS Finalized Policy:** CMS finalized that qualifying APM participants (QPs) for the year receive a five percent lump sum incentive payment through CY24, or a differential payment update under the MPFS beginning with PY26. Determination of the Advanced APM five percent bonus takes place at the facility/APM entity level or at the individual eligible clinical level.

CMS did not finalize any rules impacting the timeline of incentive payments for APM participation beyond the MACRA 2024 deadline.

**ACP Comments:** ACP is disappointed in CMS’ decision to not extend incentive payments for APM participation, which would have further encouraged future APM participation beyond the MACRA 2024 deadline. ACP continues to strongly oppose CMS’ new approach for distributing Advanced APM incentive payments that prioritizes payment year TINs, which minimizes the clinical care team model and moves further from actions completed during the performance year. ACP is not supportive of CMS’

decision to make no changes to timing of incentive payments to earlier in the payment year, which would have lessened the window for NPI-TIN changes to occur.

### **Conclusion**

Thank you for this opportunity to comment on CMS' finalized policy regarding changes to the Physician Fee Schedule, Quality Payment Program, and other federal programs for CY22 and beyond. ACP is confident these recommended changes would improve the strength of these policies and help promote access to affordable care for Medicare patients, while dually supporting physicians in their ability to deliver innovative care and protect the integrity of the Medicare trust funds. The College appreciates the opportunity to offer our feedback and looks forward to continuing to work with CMS to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Director, Regulatory Affairs for the American College of Physicians, at [boutland@acponline.org](mailto:boutland@acponline.org) or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "William Fox". The signature is fluid and cursive, with the first name "William" and the last name "Fox" clearly distinguishable.

William Fox, MD, FACP  
Chair, Medical Practice and Quality Committee  
American College of Physicians