

September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016

Re: CMS-1751-P

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

Dear Administrator Brooks-LaSure:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the Calendar Year (CY) 2022 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule, as many of the proposed policies have a significant impact on our members and the patients we serve.

Summary of Comments

Physician Fee Schedule

- **Overview:** In this proposed rule, the Centers for Medicare & Medicaid Services (CMS) proposes a physician fee schedule (PFS) conversion factor of \$33.58, a decrease of \$1.31 from the CY 2021 PFS conversion factor of \$34.89. The conversion factor reflects the expiration of a 3.75 percent bump up that Congress added to the conversion factor in 2021. Emergency medicine clinicians will experience this across-board reduction to their reimbursement in 2022. ***This cut to emergency medicine, if finalized, would jeopardize the nation's critically-needed safety net. ACEP requests that CMS do everything within its authority to mitigate the reduction.***
- **Evaluation and Management Services: Split or Shared Services:** CMS is proposing a number of refinements to current policies for split or shared evaluation and management (E/M) visits, critical care services, and services furnished by teaching physicians.
 - **Emergency Department (ED) Services:** CMS lists activities that can count when time is used to select E/M visit level when performed and regardless of

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whether or not they involve direct patient contact—and then seeks comments on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) ED visits, since those visits also have a unique construct. ***Given that time is not a component of ED E/M services, ACEP believes that the proposed list needs to be refined to remove time-based activities and to better represent medical decision making (MDM) as the driving force determining the substantive portion of an ED visit.***

- ***Critical Care:***
 - ***Time:*** CMS is proposing to require practitioners to document in the medical record the total time that critical care services were provided by each reporting practitioner, but not specifically documenting start and stop times. ACEP agrees with this proposal, as it reflects the evolution of team-based care.
 - ***More than One EM visit on the Same Date:*** CMS clarifies in the rule that if more than one E/M visit is provided on the same day, to the same patient, by the same physician, or by more than one physician in the same specialty in the same group, only one E/M service may be reported unless the E/M services are for unrelated problems. ACEP asks that CMS consider allowing the reporting of a critical care service when an E/M service is completed and the patient later becomes unstable.
 - ***Interaction between Critical Care and Procedures:*** ***ACEP is opposed to CMS' proposal to bundle critical care into separately billable procedures. ACEP believes that CMS should not the finalize the proposal and continue to separately reimburse critical care along with procedures that do not contain critical care as part of a global surgical package.***
- ***Teaching Physicians:*** ***ACEP would like to see the use of telehealth for the supervision of residents adopted permanently in all cases and not restricted to residency training sites outside of OMB Metropolitan Statistical Areas.***
- ***Telehealth Services:*** ACEP for years has strongly supported the delivery of telehealth services by board-certified emergency physicians. During the COVID-19 public health emergency (PHE), CMS has taken numerous steps to expand the use of telehealth under Medicare. With the pandemic still ongoing, ACEP:
 - ***Strongly supports CMS' proposal to extend the period that codes are temporarily on the list of approved telehealth services on a Category 3 basis through the end of calendar year (CY) 2023.***
 - Does not support CMS' proposal to limit Medicare telehealth coverage for certain services (listed in Table 11 in the proposed rule) to the end of the PHE instead of including them in Category 3 and allowing them to remain on the approved list of telehealth services for a longer period of time. We specifically request that Initial Observation and Observation Discharge Day Management (CPT 99218 – 99220; CPT 99234- 99236) be added to Category 3.
 - Supports the statutory provision to eliminate the geographic restrictions and to add the home as an originating site for telehealth services when used for the treatment of a mental health disorder. ***However, ACEP is concerned with CMS' proposal to require that patients must have an in-person visit with their treating physician or a physician from the same practice every six months.***

ACEP also would like to comment on the process for adding new telehealth services to the list of approved telehealth services. Specifically, we are concerned that the Category 2 criterion is unreasonable and makes it extremely difficult to add services to the list of approved telehealth services.

- **[Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting](#)**: CMS is soliciting comments about PHE-related costs that could be accounted for by establishing new payment rates for new services to inform future rulemaking. Given lessons learned during the COVID-19 PHE and other infectious disease outbreaks, CMS should consider reimbursing for certain direct and indirect activities that physicians typically take on during these pandemics or other extreme circumstances.
- **[Physician Assistant \(PA\) Services](#)**: CMS is proposing to implement a provision of the Consolidated Appropriations Act that allows Medicare to pay PAs directly for their services. Currently, Medicare only can pay the employer of the PA and PAs cannot bill Medicare directly. While ACEP understands that CMS is required by statute to implement this provision of the law, *we have strong concerns with this policy, as we believe it could lead to PAs providing unsupervised care in the ED. ACEP strongly believes that PA and nurse practitioners (NPs) should not perform independent unsupervised care in the ED. This holds true regardless of state laws or hospital regulations. In the case of rural and underserved areas, supervision may require telehealth services or real-time off-site emergency physician consultation.*
- **[Appropriate Use Criteria Program](#)**: *ACEP strongly supports the proposed implementation delay to 2023. Overall, we believe that the program is unnecessary and could harm patient care in the ED by postponing vital treatment.* We request that CMS work with Congress to repeal this program.
- **[Electronic Prescribing of Controlled Substances](#)**: *ACEP supports the proposal to delay the Electronic Prescribing of Controlled Substances (EPCS) requirement for Medicare Part D until 2023.* ACEP also supports the proposed exceptions but notes that we have had issues getting buprenorphine prescriptions filled through electronic prescribing. Many pharmacies do not carry buprenorphine, and others carry a limited supply of certain buprenorphine products (particularly of the generics). Buprenorphine is an extremely valuable tool in the ED to help start patients on the path towards recovery. *Given the effectiveness of buprenorphine in treating patients with opioid use disorder and the issues some physicians have experienced with electronically prescribing this medication, we believe that buprenorphine prescriptions should be an additional exception to the EPCS requirement. We also strongly support the CMS proposal not to impose penalties on physicians for non-compliance with the EPCS requirement. CMS' proposed compliance actions are definitely an appropriate level of enforcement and should be finalized.*
- **[Chronic Pain Management](#)**: CMS is soliciting comments on whether the agency should create separate coding and payment for chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate. ACEP appreciates CMS' discussion in the rule to develop payment systems to better support management of patients' pain. However, as emergency physicians, we mostly treat patients with acute pain, and believe that any new payment policies CMS implements should not be limited to management of chronic pain but should also focus on improving support for acute pain. Patient outcomes will be improved, and overall Medicare spending could

decrease, if CMS provides physicians with the resources they need to help prevent patients from developing chronic pain, rather than only paying for treatment after patients' medical diagnoses and treatments become more complicated.

- **Medicare Shared Savings Program**: While emergency physicians could possibly be part of a larger physician group or hospital participating in the Medicare Shared Savings Program (MSSP) or another accountable care organization (ACO) model, emergency physicians do not play an active role in these initiatives. We do however appreciate that CMS' proposals that will hopefully alleviate some of the quality reporting burden.

Quality Payment Program

- **Health Equity Data Collection Request for Information**: ACEP provides some insights from the emergency medicine perspective regarding CMS' questions related to the future potential stratification of quality measure results by race and ethnicity and how to improve demographic data collection. We also discuss some interventions that are currently being employed in the ED to help identify barriers to health such as transportation and access to food and housing
- **MIPS Value Pathways (MVPs)**:
 - ***Emergency-Medicine Focused MVP: ACEP strongly supports the adoption of the emergency medicine-focused MVP, the "Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP" in 2023.*** ACEP had proposed this MVP to CMS for consideration and believe that it will help improve quality of care, reduce costs, and transition emergency physicians to alternative payment models (APMs)—as it aligns with ACEP's proposed APM, the Acute Unscheduled Care Model (AUCM).
 - ***MIPS Sunset Date:*** CMS is seeking comment on sunsetting the traditional MIPS program after the 2027 performance year and fully transitioning to reporting through MVPs. ACEP cannot comment on whether the end of 2027 is an appropriate sunset date for traditional MIPS—but in general we believe that MVP reporting should be voluntary for the foreseeable future. It is difficult to know what the landscape of MIPS reporting will look like at that point in time. In all, we want to ensure a level playing field, where all clinicians have the opportunity to participate in MVPs.
 - ***MVP Participation Registration:*** ACEP supports the proposed voluntary participation in MVPs and understands the need to have a registration process. ***However, we would like to clarify whether a clinician or group who elects to participate in an MVP can still report measures outside that MVP in traditional MIPS—and if so, whether CMS would use the highest scores in each performance category to determine a clinician or group's total performance score.***
 - ***Qualified Clinical Data Registries (QCDRs):*** QCDRs, such as ACEP's own Clinical Emergency Data Registry (CEDR), will be required to support MVPs starting in 2023. ***ACEP supports this proposal, as there are a number of CEDR measures included in the proposed emergency-medicine-focused MVP.*** However, we do ask that CMS clarify a couple of QCDR requirements, including whether a QCDR would be responsible for validating an MVP Participant's performance on population health measures and/or providing "enhanced" performance feedback, including performance data comparing the performance of similar clinicians who report on the same MVP.
 - ***Population-based Measures:*** ACEP continues to not support the use of administrative claims-based

measures in all MVPs.

- *Subgroup Reporting:* ACEP is concerned about how CMS defines subgroups and do not think that subgroup composition should be based on specialty, geographic location, size, or any other factors. ACEP also strongly urges CMS to maintain the subgroup option as a voluntary participation pathway in MIPS and we do not support requiring multispecialty groups to form single specialty subgroups in order to participate in MVPs starting in 2025.
- *MVP Scoring:* CMS is proposing that the scoring methodology for MVPs will align with that used for traditional MIPS. ***ACEP does NOT support this proposal and believes that there should be some additional incentives for initially participating in an MVP over traditional MIPS.***
- **Quality Performance Category:**
 - *Quality Benchmark:* Due to the COVID-19 pandemic, CMS is proposing to change how it establishes quality benchmarks. Since CMS held clinicians harmless if they were unable to report data from 2020, CMS believes that 2020 data may be unreliable. Therefore, CMS intends to develop performance period benchmarks for the CY 2022 MIPS performance period using the data submitted during the CY 2022 performance period or a different baseline period. ACEP does NOT support using data submitted during 2022 to set benchmarks for that performance period. ***ACEP recommends that CMS, to the extent possible, use the 2019 performance year data for scoring purposes in the 2022 performance year.***
 - *Data Completeness:* CMS is proposing to maintain the current data completeness threshold (the percentage of applicable patients on which providers must report on for a particular measure) at 70 percent for the 2022 performance period but is proposing to increase the data completeness threshold to 80 percent for the 2023 performance period. ***ACEP opposes the proposed increase in the threshold for 2023.***
 - *Scoring Rules for Measures Without a Benchmark or That Do Not Meet Case Minimums:* CMS is proposing to change its existing policy to award three points to measures without a benchmark or that do not meet the case minimum. CMS is instead proposing to establish a five-point floor for the first two performance periods for new measures. Thus, except for new measures in the first two performance periods, measures without a benchmark or that do not meet the case minimum will receive 0 points (except when reported by small practices—small practices will still receive 3 points for reporting these measures). ***ACEP opposes this proposal since groups of all sizes—not just smaller groups—sometimes cannot make the case minimum for certain measures.***
 - *Bonus Points:* ***ACEP opposes the proposal to eliminate bonus points for reporting high-priority and outcome measures as well as measures that meet end-to-end electronic reporting criteria.***
- **Cost Performance Category:** ACEP encourages CMS to continue to develop episodes that capture the clinical screening, diagnostic testing, and stabilization work done by emergency physicians before a patient is admitted into the hospital. CMS' contractor, Acumen, has convened a workgroup to develop an emergency medicine episode-based cost measure. ACEP is pleased that three ACEP members are now participating in it—including as the chair of the workgroup. ACEP has concerns with creating a separate process for externally developing measures outside of the current Acumen process. It is unclear what input outside stakeholders could provide and how other cost measure developers would

demonstrate that they have the right clinical and methodological input during the measure development process.

- **Improvement Activities:** ACEP has no concerns with the proposals that CMS is making related to the Improvement Activities category but would like to reiterate our support for allowing clinicians to report on one set of measures and receive credit in multiple categories of MIPS, as it will help reduce the burden of reporting for physicians and also link elements of the program together into one cohesive function.
- **Promoting Interoperability:** Although most emergency physicians are deemed hospital-based clinicians and are therefore exempt from this performance category of MIPS, ACEP supports CMS' proposal to maintain the 90-day performance period for the Promoting Interoperability category for CY 2022. We also support CMS' proposal to maintain the Prescription Drug Monitoring Program (PDMP) Query measure as optional.
- **Complex Patient Bonus:** ACEP supports CMS' proposal to double the complex patient bonus in 2021 to 10 points to account for the increased complexity of caring for patients during the COVID-19 pandemic. Starting in 2022, CMS is proposing to refine its methodology for defining higher-risk patients for the purposes of allotting the complex patient bonus. ACEP does not support the proposal to limit the complex patient bonus to clinicians who have a median or higher value for one or both of the two risk indicators (Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients that is dually eligible for Medicare and Medicaid).
- **Facility-Based Scoring Option:** ACEP supports the change CMS is proposing related to the facility-based scoring option methodology, as we believe this option should NEVER, even unintentionally, hurt clinicians. We recommend that CMS adopt it immediately starting in the 2021 performance period.
- **MIPS Final Scoring Methodology:**
 - ***Performance Threshold:*** CMS is proposing to set the threshold at 75 points in 2022 (the mean score during the 2017 performance period), a significant increase from the 2021 threshold of 60 points. There is also an additional bonus for exceptional performance. CMS is proposing to set that exceptional bonus threshold at 89 points. ACEP opposes increasing the performance thresholds that high in 2022, given the downstream effects of our continued response to the COVID-19 PHE. ***CMS should consider using the 1135 waiver authority it has under the PHE or its Extreme and Uncontrollable Circumstances Exception policy to waive the statutory requirement of using the mean or median of performance of a prior use to establish the threshold, and instead keep the performance threshold at 60 points and the exceptional performance category at 85 points in 2022.***
 - ***Category Weighting:*** ACEP recognizes that Cost category weighting is required by law to reach 30 percent in 2022. However, given the unprecedented and significant disruptions to the health care system and MIPS due to the COVID-19 PHE, we urge CMS to use its waiver authority or Extreme and Uncontrollable Circumstances Exception policy to maintain the weight of the Cost Performance Category at 20 percent.
- **Qualified Clinical Data Registries (QCDRs):** ACEP owns and operates its own QCDR, the Clinical Emergency Data Registry (CEDR). ***We believe that CMS should continue to refine the QCDR***

option under MIPS to streamline the self-nomination process, and provide better incentives for organizations, including medical associations such as ours, to continue to invest in their QCDRs and develop new, meaningful measures for specialists to use for MIPS reporting and other clinical and research purposes.

- **Public Reporting:** ACEP continues to be concerned that all quality measures reported by clinicians are included in the Compare rating. Under MIPS, clinicians have an incentive to report more than the six required measures since CMS will count the six with the highest scores. While CMS does not penalize clinicians who want to do extra and report on more than six measures, the Compare website provides the inverse incentive by counting and publicly reporting on every measure a clinician reports in their rating. Therefore, if clinicians report more than six measures and do poorly on one measure, their MIPS score will not be impacted, but their Compare rating will be.
- **Advanced APMs:** While many emergency physicians are ready to take on downside risk and participate in Advanced APMs, there simply are not any opportunities to do so. ACEP developed a physician-focused payment model (PFPM) called the Acute Unscheduled Care Model (AUCM). We look forward to continuing to work with CMS and HHS to improve emergency patient care through the implementation of the model. ACEP is especially concerned about the lack of Advanced APM options given that the five percent payment bonus for being a Qualifying APM participant (QP) is expiring in 2024.

The Physician Fee Schedule

Overview

In this proposed rule, the Centers for Medicare & Medicaid Services (CMS) proposes a physician fee schedule (PFS) conversion factor of \$33.58, a decrease of \$1.31 from the CY 2021 PFS conversion factor of \$34.89. The conversion factor reflects the expiration of a 3.75 percent bump up that Congress added to the conversion factor in 2021. These reductions stem from CMS' decision to increase the office and outpatient evaluation and management (E/M) services in 2021. As required by law, CMS must preserve budget neutrality in cases where relative value unit (RVU) changes may cause PFS spending to increase or decrease by more than \$20 million.

Physicians must continue to deal with annual updates to Medicare payments that do not cover the increased costs due to inflation of providing care. Along with the 3.75 percent across the board reduction, the two percent sequestration reduction continues to apply year after year. Furthermore, there is another “Pay-Go” sequester of 4 percent that is scheduled to begin at the start of 2022—making the total overall projected cut starting January 1 at 9.75 percent. In short, Medicare payment to physicians is simply inadequate. An analysis conducted by ACEP found that ***Medicare payments have decreased by 53 percent when comparing Medicare payments to inflation*** between the start of the Resourced-based Relative Value Scale (RBRVS) in 1992 and 2016.¹ Even the 2021 Medicare Trustees Report, which was just released on August 31, 2021, acknowledges that updates for physician reimbursement are not sufficient. The Trustees believe that, absent a change in the delivery system, access to Medicare-participating physicians will become a significant issue in the long term.² Given the fact that annual updates to physician payments are already not keeping up with the cost of providing physician services, adding large-scale payment reductions would make it even more difficult for a number of physician specialties including emergency medicine to continue providing care.

Emergency medicine clinicians will experience this across-the-board reduction to their reimbursement in 2022. This cut to emergency medicine, if finalized, would jeopardize the nation's critically-needed safety net, and we request that CMS do everything within its authority to mitigate the reduction.

A -3.75 percent reduction to Medicare reimbursement for emergency physicians and other emergency medicine health care professionals on top of the pending sequestration cuts would have rippling effects across the health care system and have a detrimental impact on access to care. During the COVID-19 public health emergency (PHE), it has been more expensive than usual to provide appropriate care to the patients who do come to the ED. Most emergency physicians are not employed by hospitals, but rather work for independent groups that contract with the hospital to provide emergency services in the ED. The majority of hospitals have not provided any financial support to these independent groups during the COVID-19 pandemic to help the groups cover any losses or increased expenses. Instead, the groups have had to incur additional expenses for treatment, such as developing and implementing protocols for alternative sites of care, enhancing telehealth capabilities, purchasing their own personal protective equipment (PPE), and taking on other new administrative costs due

¹ The ACEP analysis is available at: <https://www.acep.org/globalassets/uploads/uploaded-files/acep/advocacy/state-issues/medicare-versus-inflation.pdf>.

² The 2021 Medicare Trustees Report is available at: <https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf>.

to staffing shortages (such as taking over nursing functions including as triaging, treating, and performing nurse discharge responsibilities for patients with potential COVID symptoms in ways that limit possible exposure to the disease). All of these additional costs are weighing down on group practices as they try to maintain the minimum staffing levels necessary to serve patients night and day in the ED and prepare for surge staffing when COVID-19 cases increase in their area, as has been the case in many parts of the country this summer and fall due to the delta variant's spread.

Looking forward, many emergency physicians are already very concerned about the viability of their groups—even without this looming payment reduction. ***At a time when emergency physicians are risking their lives to combat this disease, they should NOT also be worrying about staying in business and keeping the ED doors open.*** For the safety and wellbeing of the American public, ***EVERY emergency physician and emergency physician group must be supported and protected during this difficult time.***

Given the potential impact of this payment reduction on emergency medicine and the safety net, compounded by the PHE, we do believe that CMS has an obligation to health care professionals and patients to do everything in its power to eliminate the reduction. While we understand that Congress has the authority to waive budget neutrality under most circumstances, we want to reiterate organized medicine's previous request³ that ***CMS and the Department of Health and Human Services (HHS) utilize its 1135 waiver authority under the COVID-19 PHE to waive this requirement for all of CY 2022.***

Evaluation and Management Services: Split or Shared Services

Emergency Department (ED)

CMS is proposing to continue its current policy allowing billing of certain “split” or “shared” E/M visits by a physician when the visit is performed in part by both a physician and a non-physician practitioner (NPP) who are in the same group and the physician performs a substantive portion of the visit. CMS is limiting split or shared visits in the institutional setting to E/M codes only, not procedures.

ACEP first would like to state that unlike an office or other outpatient visit, time is not a component of ED services. In fact, CMS has continued to reiterate its desire to harmonize with the Current Procedural Terminology (CPT) and formalize the adoption of the prefatory language as well as medical decision making (MDM) components for level assignment.⁴ The CPT specifically maintains that time is **not** a descriptive component for the ED levels of E/M services because ED services are typically provided on a variable intensity basis, often involving multiple encounters with several patients over an extended period of time. Therefore, it is often difficult to provide accurate estimates of the time spent face-to-face with the patient. We ask that the cognitive work as described by the MDM elements listed in the proposed rule be considered as the measure of the substantive portion rather than the time involved in providing those substantive portions for ED services.

In the rule, CMS lists activities that can count when time is used to select E/M visit level when performed and regardless of whether or not they involve direct patient contact—and then seeks comments on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) ED visits, since those visits also have a unique construct.

³ American Medical Association and Other Specialty Societies Letter to HHS Secretary. July 1, 2020. <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FE-M-Sign-on-letter-to-HHS-Budget-Neutrality.pdf>.

⁴ 85 Fed. Reg. 84,549 (December 28, 2020).

Given that time is not a component of ED E/M services, *ACEP believes that the proposed list needs to be refined to remove time-based activities and to better represent MDM as the driving force determining the substantive portion of an ED visit. Therefore, we recommend the following refined list:*

- Obtaining and/or reviewing separately obtained history.
- Performing and/or reviewing a medically appropriate examination and/or evaluation.
- Formulation of a differential diagnosis.
- Reviewing and amending (as appropriate) clinical information in the electronic or other health record.
- Ordering medications, tests, or procedures.
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver.
- Consulting with other health care professionals as appropriate.
- Counseling and educating the patient/family/caregiver.
- Formulating and instituting a final treatment plan.
- Determining appropriate disposition.

Practitioners would not count the following activities:

- The performance of other services that are reported separately.
- Teaching that is general and not limited to discussion that is required for the management of a specific patient

Creation of Modifier

CMS is proposing to create a modifier to describe split (or shared) visits and proposing to require that the modifier must be appended to claims for split (or shared) visits, whether the physician or NPP bills for the visit. ACEP opposes this proposal. We DO NOT believe that CMS should require a modifier to be reported for split or shared visits, as such a requirement would add a level of administrative burden that the new E/M coding structure and guidelines were designed to avoid. There is an American Medical Association (AMA) joint CPT and Relative Value Scale (RVS) Update Committee (RUC) workgroup on documentation guideline revision for E/M services. CMS should instead work with the AMA/CPT workgroup to clarify how to report split/shared services in the CPT Guidelines.

Critical Care Policies

Time

The exception to the split or shared services rule in the ED is when reporting critical care, which *is* a time-based code regardless of site of service. CMS is proposing to allow split (or shared) visit billing in critical care because the agency believes the practice of medicine has evolved towards a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by clinicians in the same group in the facility setting. CMS is proposing to require practitioners to document in the medical record the total time that critical care services were provided by each reporting practitioner, but not specifically documenting start and stop times. ACEP agrees with this proposal, as it reflects the evolution of team-based care.

More than One EM visit on the Same Date

CMS clarifies in the rule that if more than one E/M visit is provided on the same day, to the same patient, by the same physician, or by more than one physician in the same specialty in the same group, only one E/M service may be reported unless the E/M services are for unrelated problems. Instead of billing separately, CMS notes that physicians should select a level of service representative of the combined visits and submit the appropriate code for that level.

ACEP requests that CMS reconsider this proposal, as it does not follow the CPT guidance for critical care which allows a separately identifiable E/M service to be reported on the day of a critical care code. Occasionally patients in the ED or on the inpatient floor who are initially stable become critically ill after a full ED E/M service has been provided, completed, and documented. For instance, a fully evaluated chest pain patient awaiting an inpatient bed develops a life-threatening arrhythmia which requires critical care services. Since critical care is a time-based code, it can easily be differentiated from any other E/M service provided on the same day, much like separately reported procedures during critical care are deducted from critical care time. If an emergency physician were to report both critical care and a procedure, the time spent providing the procedure would have to be deducted from the critical care clock as per current coding requirements. ***ACEP asks that CMS consider allowing the reporting of a critical care service when an E/M service is completed and the patient later becomes unstable.***

Interaction between Critical Care and Procedures

ACEP is opposed to CMS' proposal to bundle critical care into separately billable procedures. There are a few exceptions for codes that have critical care included as part of the global surgical package, such as code 48150 (pancreatectomy, proximal subtotal with total duodenectomy, partial gastrectomy, choledochoenterostomy and gastrojejunostomy (Whipple-type procedure); with pancreatojejunostomy), which includes two units of CPT code 99291 in the global period. The CPT critical care preamble is clear about naming procedures that are bundled into critical care.

The following services⁵ are included in "critical care clock time" when performed during the critical period by the same physician(s) providing critical care and should not be reported separately:

1. the interpretation of cardiac output measurements (CPT 93561, 93562)
2. pulse oximetry (CPT 94760, 94761, 94762)
3. chest x-rays, professional component (CPT 71045, 71046)
4. blood gases, and collection and interpretation of physiologic (e.g., ECGs, blood pressures, hematologic data)
5. gastric intubation (CPT 43752, 43753)
6. transcutaneous pacing (CPT 92953)
7. ventilator management (CPT 94002-94004, 94660, 94662)
8. and vascular access procedures (CPT 36000, 36410, 36415, 36591, 36600)

Any other services performed that are not included in this list should be reported separately.

ACEP notes that it would be rare for an emergency physician to provide the full global service for procedures associated with critical care, such as follow up visits, and therefore there is no redundancy between the critical care and the procedure itself. Based on current coding conventions for many substantial procedures, emergency physicians generally append a 54 modifier⁶ to the claim to communicate that intent, which would also avoid any double counting of the work involved. For instance, there could be a situation where a patient presents to

⁵ The services can also be found in the 2021 CPT book, pages 31 and 32,

⁶ A 54 modifier is defined in CPT 2021 Appendix A Modifiers, page 878.

the ED after a rollover motor vehicle accident with a sustained head injury requiring critical care, but also a wrist fracture requiring immediate reduction. In this scenario, the emergency physician would stop the critical care clock for the time spent while reducing the wrist fracture and append -54 to indicate none of the follow-up global visits would be provided.

Importantly, emergency physicians generally provide critical care in situations when a patient presents as unstable due to an injury or illness that is not directly caused by performing a procedure (e.g., the Whipple example above). In other words, the emergency physician's critical care work is cognitively distinct from the work of the procedure. CMS should also consider a second example of a patient with an allergic reaction to a wasp sting, incurred while pruning their rose bushes, presenting in anaphylactic shock, who once stabilized also requires a laceration repair for a wound incurred when trying to avoid being stung. The laceration repair, even if a 10-day global code, would certainly be separately identifiable from the critical care service. ***Thus, in all, ACEP believes that CMS should not finalize the proposal and continue to separately reimburse critical care along with procedures that do not contain critical care as part of a global surgical package.***

Teaching Physicians

CMS clarifies that Medicare will not pay teaching physicians for shared services unless the physician exercises full, personal control over the portion of the case for which the physician is seeking payment. ACEP commends the decision to allow teaching physicians to use audio/video real-time communications technology to supervise residents during the pandemic and include the total time considered for visit level selection.

Since a teaching physician is still required to review resident physicians' interpretations and services, and ACGME has strict limits concerning direct supervision by interactive telecommunications technology that exclude high-risk, surgical, interventional, and other complex procedures including endoscopies and anesthesia, ACEP believes that the appropriate level of patient care and teaching physician direction will be maintained under this CMS decision. Moreover, adding another mechanism through which to supervise residents will increase the ability to provide residents with timely feedback while considering patient, resident, and teaching physician safety by decreasing unnecessary exposure during COVID-19 and future public health emergencies. ***ACEP would like to see the use of telehealth for the supervision of residents adopted permanently in all cases and not restricted to residency training sites outside of OMB Metropolitan Statistical Areas.***

Telehealth Services

Telehealth Background

ACEP for years has strongly supported the delivery of telehealth services by board-certified emergency physicians. During the COVID-19 PHE, CMS has taken numerous steps to expand the use of telehealth under Medicare, and many have argued that our nation will never go back to a "pre-COVID" world where telehealth services were rarely performed or accessible. While CMS has made substantial changes to telehealth policies, there are a few that particularly impact emergency medicine. The most significant policy, which impacted all telehealth services, has been CMS' use of its 1135 waiver authority to temporarily waive the originating site and geographic restrictions, allowing health care practitioners to provide telehealth services to patients regardless of where the clinicians or the patients are allocated—in both urban and rural areas. Further, CMS clarified that medical screening exams (MSEs), a requirement under the Emergency Medical Treatment and Labor Act (EMTALA), could be performed via telehealth. Finally, CMS temporarily added all five ED E/M codes, some observation codes, and critical care codes to the list of approved Medicare telehealth services on a Category 3

basis. Current policy dictates that these codes will remain on the list of approved telehealth services through the end of the calendar year in which the PHE ends.

These policies have been critically needed as emergency physicians continue to respond to the pandemic. Being able to perform MSEs via telehealth has helped protect emergency physicians from unnecessary exposure to the virus and has helped preserve the supply of personal protective equipment. Further, having the ED E/M codes on the approved list of Medicare telehealth services has helped provide an appropriate and sustainable reimbursement mechanism for emergency telehealth programs during the pandemic.

Telehealth Proposals

CMS is proposing to extend the amount of time that codes in Category 3 would remain on the list of telehealth services from the end of the calendar year in which the PHE ends to the end of CY 2023. This will allow CMS more time to collect more information regarding utilization of these services during the pandemic and provide stakeholders the opportunity to continue to develop support for the permanent addition of these services to the list of approved telehealth services. CMS also continues to maintain a separate list of services (found in Table 11 of the proposed rule) that the agency temporarily added to the list of approved telehealth services but does NOT include in Category 3. These services will therefore be automatically removed from the list of approved telehealth services at the end of the COVID-19 PHE.

In addition, CMS is implementing a provision of the Consolidated Appropriations Act that removed the geographic restrictions and added the home as originating site for telehealth services when used for the treatment of a mental health disorder. CMS is proposing to require that that patients with mental health disorders receive an in-person service six months prior to the telehealth service and another in-person service six months afterwards as well.

ACEP Comments on CMS Telehealth Proposals

Extending Category 3 Timeline

ACEP strongly supports CMS' proposal to extend the amount of time Category 3 codes will remain on the list of approved telehealth services. Thus far, studies on the use of emergency telehealth services during the pandemic have focused more on HOW telehealth has been utilized rather than on the actual clinical benefit of these services.⁷ Researchers are just now beginning to collect data on the effectiveness of telehealth during the pandemic. The data elements that researchers could examine include:

- Outcome of telehealth interaction
 - In-person visit afterward
 - Patient went to the ED based upon the recommendation of the telehealth clinician.
 - Patient went to the ED on their own.
 - In person visit not needed afterward
 - Number of avoided in-person ED visits
 - Potential cost savings
 - Impact on ED referrals and consults

⁷ Jaffee et al. "Telehealth use in emergency care during coronavirus disease 2019: a systematic review," JACEP Open, May 2021. <https://onlinelibrary.wiley.com/doi/10.1002/emp2.12443>.

- Impact on hospital admission rate
- Number of unexpected in-person visits needed within 3 days of telehealth visit.
- Number of unexpected admissions within 3 days for same complaint/related to initial telehealth visit.
- Number of telehealth visits per capita compared to in person visits.
- Annual patient healthcare expenditures of telehealth patients versus non-telehealth patients.
 - Stratify regarding ranges of the number of annual telehealth visits.
- Impact on ED volume
- Diagnosis codes for telehealth visits.

It will take some time to collect these data elements and make a compelling case to CMS on whether all or some of the emergency medicine codes that are temporarily on the approved list of telehealth services on a Category 3 basis should be added to the list permanently on a Category 2 basis. Perhaps even more importantly, it will be difficult to assess the full impact that emergency telehealth services could have on Medicare patients in a post-pandemic world until after the virus is no longer such a significant focus of emergency care in so much of our country.

We also note that we are attempting to get some emergency codes added to “Appendix P” in CPT. The AMA annually updates the CPT codes, policies, and appendices which describe correct coding processes. Appendix P in CPT addresses telehealth services and list codes that are approved by CPT for telehealth coverage. We find ourselves in a real “catch 22” situation in which codes cannot be added to Appendix P unless they are reimbursed. However, they cannot be reported (and thereby reimbursed) because they're not in Appendix P. Extending the time that codes remain on the list of the approved telehealth services on a Category 3 basis through 2023 will also allow us time to advocate through the CPT process for inclusion of the codes in Appendix P.

Codes Listed in Table 11

ACEP does not support CMS’ proposal to limit Medicare telehealth coverage for certain services listed in Table 11 to the end of the PHE instead of allowing them to remain on the approved list of telehealth services for a longer period of time by including them in Category 3. Like those services covered under Category 3, these services have only been on the list of approved telehealth services during the duration of the PHE. If these services even have a chance of being considered for permanent addition to the list of approved telehealth services on a Category 2 basis, CMS should allow more time beyond the PHE to gather evidence about the clinical benefit of these services when delivered via telehealth.

We specifically request that Initial Observation and Observation Discharge Day Management (CPT 99218-99220; CPT 99234-99236) be added to Category 3. Other observation codes—Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224- 99226)—are already in Category 3. ***It is clinically inconsistent to include the “Subsequent Observation and Observation Discharge Day Management” codes but not include the “Initial Observation and Observation Discharge Day Management codes” in Category 3.*** The COVID pandemic has allowed physicians to maximize staffing of ED observation units through the use of dedicated “observationists” covering several observation units via telehealth during “virtual rounds.” Through these virtual rounds, providing both initial observation and subsequent observation services via telehealth has become part of the continuum of care delivered in many EDs across the country.

Segmenting these observation services going forward would result in a fragmentation of practice patterns and clinical workflow. It would be extremely confusing, and possibly disruptive to patient care, to have two sets of policies for patients in an observation unit—and it would significantly increase the administrative burden on clinicians as they scramble to try to determine which patient has to wait for an in-person evaluation versus who can be seen right away by telehealth during virtual rounds.

ACEP believes that there is also potential for cost savings and improvements in quality of care if all observation services can be delivered via telehealth. Protocol-driven ED observation units have been shown to lower the cost of care for payors, with fewer admissions, fewer readmissions, and improved patient satisfaction.^{8 9} Further, this model of care can reduce costs for hospitals, decrease observation length of stays, and improve inpatient bed utilization—which is extremely beneficial for rural hospitals.¹⁰

Additional studies are underway to demonstrate the clinical benefits of remote observation services relative to traditional in-person inpatient care. Prematurely removing the Initial Observation and Observation Discharge Day Management codes from the list of approved telehealth services could jeopardize the ability to follow through with this important work to assess the clinical effectiveness of virtual observation services.

Mental Health Services

ACEP strongly supports the statutory provision to eliminate the geographic restrictions and to add the home as an originating site for telehealth services when used for the treatment of a mental health disorder. As emergency physicians, we see every day the end result of so many in our country having difficulty accessing mental health services. In many cases, when people with mental health disorders come to the ED, there are no places where they can be safely discharged or transferred. Therefore, unfortunately, boarding of psychiatric patients in EDs is extremely prevalent, and many times psychiatric services are not provided to these patients while they are being boarded. Due to its loud and chaotic nature, the ED environment can exacerbate any underlying conditions—and boarded patients tend to have higher rates of psychotic and personality disorders and are more likely to require physical restraints and seclusions.¹¹ For some individuals, the ability to receive telehealth services at home could be a much better alternative than seeking mental treatment at the ED.

We are concerned, however, with CMS' proposal to require that patients must have an in-person visit with their treating physician or a physician from the same practice every six months. We believe that this length of time is arbitrary and may not be an appropriate interval in particular cases. Physicians are in the position to determine when in-person treatment is necessary for their patients, which could be a longer or shorter interval than every six months. The Consolidated Appropriations Act gives CMS the autonomy to determine appropriate follow-up periods for in-person visits, and CMS should take advantage of this flexibility and give physicians the discretion to decide when in-person care may be necessary for their patients.

⁸ Ross MA, Hockenberry JM, Mutter R, Wheatley M, Pitts S. Protocol-Driven Emergency Department Observation Units Offer Savings, Shorter Stays, And Reduced Admissions. *Health Affairs*. 2013 Dec; 32(12):2149-2156.

⁹ Hockenberry JM, Mutter R, Barrett M, Parlato J, Ross MA Factors associated with prolonged observation services stays and the impact of long stays on patient cost. *Health Services Research*. 2014 Dec;49(3):893-909.

¹⁰ Perry M, Franks N, Pitts SR, Moran TP, Osborne A, Peterson D, Ross MA, The impact of emergency department observation units on a health system, *Am J of Emerg Med*. 2021 Volume 48; 231-237. <https://doi.org/10.1016/j.ajem.2021.04.079>

¹¹ Nordstrom, K; Berlin, J; Nash, Sara Siris; Shah, Sejal B.; Schmelzer, Naomi, A; Worley, Linda L.M. “Boarding of Mentally Ill Patients in Emergency Departments: American Psychiatric Association Resource Document.” *West J Emerg Med*. 2019 Sep; 20(5): 690–695. Published online 2019 Jul 22. doi: [10.5811/westjem.2019.6.42422](https://doi.org/10.5811/westjem.2019.6.42422).

Category 2 Criterion

ACEP also would like to comment on the current process for adding new telehealth services to the list of approved telehealth services. Specifically, we are concerned that the Category 2 criterion is unreasonable and makes it extremely difficult to add services to the list of approved telehealth services. The specific definition of Category 2 is below:

Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests will include an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. Requestors should submit evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient. The evidence submitted should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit will not include minor or incidental benefits. Some examples of clinical benefit include the following:

- *Ability to diagnose a medical condition in a patient population without access to clinically appropriate in person diagnostic services.*
- *Treatment option for a patient population without access to clinically appropriate in person treatment options.*
- *Reduced rate of complications.*
- *Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).*
- *Decreased number of future hospitalizations or physician visits.*
- *More rapid beneficial resolution of the disease process treatment.*
- *Decreased pain, bleeding, or other quantifiable symptom.*
- *Reduced recovery time.*

Having to produce ample data and evidence to show that providing certain services adds clinical value is a time-consuming and costly endeavor. It could also take years to gather this amount of evidence. ACEP also believes that CMS should not need to look at whether the act of providing a service via telehealth adds additional clinical value. Telehealth is simply a means in which health care providers deliver services—an extremely useful tool that providers can employ to expand access to care. In other words, if a physician provides a specific high-quality service to a patient, we should expect it to be as effective and add as much clinical value regardless of whether it was delivered in-person or via telehealth. We should not have to prove that providing a service via telehealth adds even *more* clinical value than conducting the service in-person. Rather, we should only be required to demonstrate that a service delivered via telehealth is ***as clinically effective*** as the service would have been if it were performed in-person. Therefore, ACEP suggests that CMS consider revising its Category 2 criterion in future rulemaking.

Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting

CMS is soliciting comments about PHE-related costs that could be accounted for by establishing new payment rates for new services to inform future rulemaking. As described above, emergency physicians have taken on numerous additional costs treating patients during the COVID-19 PHE. Medicare payment systems currently do not include permanent mechanisms to reimburse these critical activities, which are associated with managing infectious disease outbreaks. As a result, physicians struggle under the current funding mechanisms that are not intended to resource providers for these unanticipated events. In addition, supplemental funding that hospitals

may receive to cover their increased expenses during a pandemic do not generally flow to the independent physician groups that hospitals often contract with to staff the EDs. Given lessons learned during the COVID-19 PHE and other infectious disease outbreaks, CMS should consider reimbursing for certain direct and indirect activities that physicians typically take on during these pandemics or other extreme circumstances.

Examples of direct clinician activities include:

- Donning and doffing personal protective equipment (PPE) and following new infection control protocols;
- Expanded cleaning protocols necessitating slower turnaround time on bed space;
- Educating, engaging and enrolling patients in research and investigational initiatives, including as clinical trials, expanded access programs (EAPs), and compassionate use (CU); and
- Follow-up for persons under investigation.

Examples of indirect clinician activities include:

- Monitoring the flow of new research and information, and triaging education to effectively manage the pandemic;
- Studying constantly changing treatment and management protocols;
- Reconciling and adjudicating incongruous or conflicting findings such as understanding asymptomatic transmission during a pandemic;
- Supervising other physician specialties deployed to assist in the care of outbreak patients;
- Leading, managing, and advising groups of staff dedicated to evaluating, implementing, and interpreting testing platforms, exposure management, PPE procurement, and associated activities during a pandemic, including contingency functioning related to supplies staff and limited physical capacity;
- Daily contingency planning related to hospital capacity and supply availability;
- Setting up and operating remote locations such as tents and triage areas;
- Creating and managing protocols for isolation of infected or exposed patients and staff;
- Crafting visitor and staffing policies; and
- Providing emotional support for staff.

Other activities may include:

- Planning to safely resume elective procedures, including developing protocols for distancing, testing, sanitation, hygiene and availability and distribution of personal protective equipment
- Advising local schools on safe reopening;
- Collaborating with state and local health departments on public messaging to reduce transmission;
- Providing advice and preparing alternative housing for providers isolating from their families; and
- Capturing and reporting outbreak related data.

We encourage CMS to implement a permanent mechanism to reimburse clinicians for these critical activities associated with managing infectious disease outbreaks. Under our proposal, CMS would automatically initiate payment to clinicians under the PFS for services associated with these unanticipated events, within certain parameters, when they occur. Such a policy would promote certainty for both physicians and CMS for future outbreaks—physicians could anticipate receiving additional resources, while CMS would have an established pathway for channeling of those resources.

In order to effectuate such a payment mechanism, we believe that CMS should create a modifier that physicians could append to current E/M codes. The use of a modifier would provide CMS with two appropriate, useful safeguards (1) CMS could set documentation requirements regarding the existence of the

outbreak (2) CMS could set documentation requirements to justify the enhanced services that were provided during the outbreak.

There are other mechanisms that could achieve the same policy goals, but we would add that a mechanism such as a modifier to represent this work would allow CMS to more narrowly tailor the directing of resources based on cases where the enhanced care is delivered in a way that supports program integrity. We also add that a payment modifier would ensure that physicians, regardless of specialty designation, are receiving reimbursement commensurate with the atypical activities associated with treating patients during an outbreak or pandemic.

ACEP also notes that the CPT Editorial Panel created a CPT code 99072 to account for the additional supplies, materials, and clinical staff time during a PHE to capture the items that are above and beyond and atypical of routine office visit E/M. However, this CPT code does not capture the myriad of activities and tasks that are required of a front-line physician during a pandemic. Currently this code is considered bundled and not separately payable under the PFS. Even if CMS were to assign a value to this code, it still would not meet the needs of the physician community as it would not account for specific services provided during a pandemic.

Physician Assistant (PA) Services

CMS is implementing a provision of the Consolidated Appropriations Act that allows Medicare to pay PAs directly for their services. Currently, Medicare only can pay the employer of the PA and PAs cannot bill Medicare directly.

While ACEP understands that CMS is required by statute to implement this provision of the law, ***we have strong concerns with this policy, as we believe it could lead to PAs providing unsupervised care in the ED. ACEP strongly believes that PA and nurse practitioners (NPs) should not perform independent unsupervised care in the ED. This holds true regardless of state laws or hospital regulations. In the case of rural and underserved areas, supervision may require telehealth services or real-time off-site emergency physician consultation.*** Each supervising physician should retain the right to determine his/her degree of involvement in the care of patients provided by PAs in accordance with the defined PA scope of practice, state laws and regulations, and specific supervisory or collaborative agreement.

We are also concerned about CMS' overall position regarding care delivered by non-physician practitioners. When making any policy choices, CMS should rely on fact-based resources, including a thorough review of the education and training of nonphysician health care professionals and the impact on the overall cost and quality of care. CMS should review the true impact of state scope of practice laws on access to care across the country.

As the most highly educated and trained health care professionals, we believe that physicians should lead the health care team. There is a vast difference in the education and training of physicians versus other health care professionals, including PAs. The well-proven pathways of education and training for physicians include medical school and residency, and years of caring for patients under the expert guidance of medical faculty. Physicians complete 10,000-16,000 hours of clinical education and training during their four years of medical school and three-to-seven years of residency training. Physician assistant programs are two-years in length and require only 2,000 hours of clinical care -- it is very important to note that these PA programs do not include a residency requirement. The difference does not stop there, as physicians are also required to pass a series of comprehensive examinations prior to licensure as well as further examinations for specialty board certification. By contrast physician assistants must pass a single 300-question multiple choice exam. We encourage CMS to

take a close look at the stark differences in education and training as outlined above, which clearly demonstrates the education and training of PAs are not commensurate with physicians.

Comparison of Training Requirements		
	Physicians	Physician Assistants
Clinical education	4 years	2 years
Residency training	3 – 7 years	--None--
Clinical care training (including during medical school for physicians)	10,000-16,000 hours	2,000 hours
Examinations	<u>21 hours, 820 questions:</u> - USMLE I: 8 hours, 280 questions - USMLE II: 9 hours, 315 questions - Specialty board: 4 hours 225 questions	5 hours, 300 questions

Medicare patients are some of the most medically vulnerable patients in our population, often suffering from multiple chronic conditions or other complex medical needs and account for nearly 20 percent of ED encounters each year.¹² As such, they deserve care led by physicians - the most highly educated, trained and skilled health care professionals. Patients agree and overwhelmingly want physicians leading their health care team. In fact, an AMA survey found that four out of five patients prefer a physician to lead their health care team and 86 percent of patients say patients with one or more chronic conditions benefit when a physician leads their health care team.¹³ Further, according to an August 2021 public opinion survey from ACEP and Morning Consult, nearly 80 percent of adults trust a physician to deliver their medical care in an emergency, compared to a nurse practitioner (9 percent), physician assistant (7 percent) or nurse (5 percent).¹⁴

Supporting physician-led health care teams is also aligned with most state scope of practice laws. For example, over 40 states require physician supervision of or collaboration with PAs. Most states require physician supervision of or collaboration with nurse anesthetists, and 35 states require some physician supervision of or collaboration with nurse practitioners, including populous states like California, Florida, New York and Texas. These states represent more than 85 percent of the U.S. population. Moreover, despite multiple attempts, in the last five years no state has enacted legislation to allow nurse practitioners full-immediate independent practice.

A common argument for expanding the scope of practice of nonphysician professionals is it will increase access to care. However, in reviewing the actual practice locations of nurse practitioners and primary care physicians, it is clear nurse practitioners and primary care physicians tend to work in the same large urban areas. There are significant shortages of nurse practitioners in rural areas—the very problem with physician access that scope

¹² The Centers for Disease Control and Prevention. National Hospital Ambulatory Medical Care Survey: 2018 Emergency Department Summary Tables, https://www.cdc.gov/nchs/data/nhamcs/web_tables/2018-ed-web-tables-508.pdf.

¹³ The AMA's survey results are available at: <https://www.ama-assn.org/system/files/corp/media-browser/public/arc/plr-survey-2015.pdf>.

¹⁴ The ACEP and Morning Consult poll results are available here: <https://www.emergencyphysicians.org/article/access/poll-adults-view-247-access-to-the-er-essential-prefer-care-led-by-physicians-in-a-crisis>.

expansion has sought to address. This occurs regardless of the level of autonomy granted to nurse practitioners at the state level.

Overall, while all health care professionals play a critical role in providing care to patients, their skillsets are not interchangeable with that of fully trained physicians. The scope of practice of health care professionals should be commensurate with their level of education and training. Patients – and in this case Medicare patients in particular – deserve nothing less.

Appropriate Use Criteria Program

CMS proposes to delay the Appropriate Use Criteria (AUC) program date to January 1, 2023. The program has already been delayed several times, most recently to January 1, 2022.

As background, the AUC program, created by the Protecting Access to Medicare Act of 2014 (PAMA), will eventually require physicians ordering advanced imaging for Medicare beneficiaries to first consult appropriate use criteria through approved clinical decision support mechanisms in order for the furnishing provider of that advanced imaging to be able to receive payment. PAMA exempts emergency services defined as an “applicable imaging service ordered for an individual with an emergency medical condition” (as defined by EMTALA). ACEP sincerely appreciates that CMS clarified that exceptions granted for an individual with an emergency medical condition include instances where an emergency medical condition is suspected, but not yet confirmed. This may include, for example, instances of severe pain or severe allergic reactions. In these instances, the exception is applicable even if it is determined later that the patient did not, in fact, have an emergency medical condition.

ACEP strongly supports the proposed delay to 2023. Overall, we believe that the program is unnecessary and could harm patient care by postponing vital treatment. In many ways, the Merit-based Incentive Payment System (MIPS), through the Cost Category, achieves the same ultimate goal as the AUC program does—to manage the utilization of services. Thus, in effect, MIPS has replaced the need to have an AUC program in place. From the emergency medicine perspective, it makes much more sense for emergency physicians to spend their time focusing on improving quality and reducing costs through MIPS rather than having to constantly evaluate whether each Medicare beneficiary who needs advance imaging would qualify for this exception (and if the beneficiary does not qualify, having to use a clinical decision support tool and adhere to appropriate use criteria that are not applicable to the ED setting).

Further, some hospitals have not appropriately updated their systems to allow emergency physicians to claim the emergency medical condition exception. This has caused confusion and fear that emergency physicians, despite the noted exception, would still have to consult appropriate use criteria even during suspected or confirmed medical emergencies, wasting valuable time. ACEP has tried to educate both our members and hospitals about the emergency medical condition exception, but despite these efforts, we are still hearing these concerning reports. Eliminating the program completely is the only way to ensure that patients are protected and are able to receive immediate treatment when experiencing a suspected or confirmed medical emergency. We therefore request that CMS work with Congress to repeal this program.

Electronic Prescribing of Controlled Substances

CMS is implementing a provision of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, which requires electronic prescribing of controlled substances (EPCS) under Medicare Part D. In this rule, CMS is proposing to delay compliance of the EPCS requirement by another year, until January 1, 2023—but seeking comment on keeping the date at

January 1, 2022. CMS also proposes certain exemptions to the electronic prescribing of controlled substances (EPCS) requirement.

- When the prescriber and dispensing pharmacy are the same entity;
- For prescribers who issue 100 or fewer controlled substance prescriptions for Medicare Part D drugs per calendar year; and
- For prescribers in an area that is undergoing a disaster or who are granted a waiver due to extraordinary circumstances.

Further, CMS proposes to NOT institute any financial penalties during the first compliance year (January 1-December 31, 2023). During that first year, CMS' compliance actions will consist of sending letters to prescribers that it believes are violating the EPCS requirement. CMS will consider whether further compliance actions will be necessary and what those compliance actions will be in future rulemaking. CMS seeks comment on this proposal, including what penalties to possibly implement going forward.

ACEP supports the proposal to delay the EPCS requirement until 2023 and does not support keeping the current effective date of January 1, 2022—even with the addition of the proposed exceptions. With respect to the exceptions, while we agree with all those listed, we are disappointed that CMS did not consider factors unique to emergency medicine when establishing the final exceptions and requirements. As we stated in our comments on last year's rule¹⁵, the majority of ED visits fall outside of “business hours,” and some of our patients are not familiar with a regular pharmacy. Thus, many e-prescriptions are prone to “failure” - meaning, the pharmacy hours are not convenient for the patient, or the prescribed drug may not be in stock. This usually requires the patient to return to the ED or call the prescriber to cancel the original prescription and re-issue it to a new pharmacy. If the original prescriber's ED shift has ended, a new prescriber must be recruited. This is a limitation of e-prescribing protocols in general and not EPCS in particular, though the additional authentication for EPCS makes this even more cumbersome, and the nature of emergency medicine means this scenario is all too common. Additional state requirements for prescription drug monitoring program (PDMP) logins and checks, and the separate authentication requirements for PDMP, further complicate these scenarios.

Emergency physicians have also faced hurdles getting registered and implementing EPCS into our workflows. For example, when we purchase a new smartphone, we are required to visit the credentialing office of our facility and obtain a new help-desk ticket and a new credentialing of the CSP app. Then, that credential must be tied to the EHR for two-factor authentication for EPCS. Further, if we lose a smartphone, we have to re-enroll—and since that process takes time, often we cannot e-prescribe for days to weeks afterwards. These issues have only been exacerbated during the COVID-19 PHE.

In addition, we have had issues getting buprenorphine prescriptions filled through electronic prescribing. Many pharmacies do not carry buprenorphine, and others carry a limited supply of certain buprenorphine products (particularly of the generics). Thus, emergency physicians are constantly having to re-route e-prescriptions, creating a huge administrative burden and discouraging physicians who otherwise want to prescribe buprenorphine from doing so. Buprenorphine is an extremely valuable tool in the ED to help start patients on the path towards recovery. Initiating medication assisted treatment (MAT) in the ED helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and decreases overdose deaths.¹⁶ In addition, the available data demonstrate that patients with opioid use disorder (OUD) who are started on

¹⁵ ACEP's comments on the CY 2021 PFS and QPP proposed rule are available here: <https://www.acep.org/globalassets/new-pdfs/advocacy/acep-response-to-cy-2021-pfs-and-qpp-proposed-rule.pdf>.

¹⁶ Bao YP, Wang RJ, et al. Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. *Mol Psychiatry*. 2018 Jun 22.

buprenorphine in the ED -- and for whom there is a clinic to maintain treatment after treatment in the ED -- are twice as likely at 30 days to remain in treatment for OUD, than patients who receive a referral alone (78 percent of patients started on MAT in the ED remain in treatment at 30 days, compared to only 37 percent of those who receive a referral alone).¹⁷ substantially increased participation in MAT, after ED buprenorphine initiation has been replicated in additional studies.^{18,19}

Furthermore, studies of patients with OUD in California and elsewhere have demonstrated an instantaneous reduction in mortality after buprenorphine-assisted detoxification, justifying its use in the ED even when access to long-term maintenance and follow-up is not available.²⁰ Finally, a study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal found a greater than 50 percent reduction (17 percent versus 8 percent) in return-rate to the same ED for a drug-related visit within one month, compared to the return-visit rate after usual care.²¹ In all, research suggests that the sooner we can start patients on the right path, and keep them engaged in treatment, the more successful their recovery can be. ***Therefore, given the effectiveness of using buprenorphine to help treat OUD and the issues some physicians have experienced with electronically prescribing this medication, we believe that buprenorphine prescriptions should be an additional exception to the EPCS requirement.***

Finally, we strongly support the CMS proposal not to impose penalties on physicians for non-compliance with the EPCS requirement. CMS' proposed compliance actions are definitely an appropriate level of enforcement and should be finalized.

Chronic Pain Management

CMS is soliciting comments on whether the agency should create separate coding and payment for chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate. ACEP appreciates CMS' discussion in the rule to develop payment systems to better support management of patients' pain. However, as emergency physicians, we mostly treat patients with acute pain, and believe that any new payment policies CMS implements should not be limited to management of chronic pain but should also focus on providing support for acute pain. Patient outcomes will be improved, and overall Medicare spending could decrease if CMS provides physicians with the resources they need to help prevent patients from developing chronic pain, rather than only paying for treatment after patients' medical diagnoses and treatments become more severe.

In addition, to help with the management of acute pain, Medicare should work to significantly improve affordable access to the many different non-opioid options. ACEP is extremely supportive of the use of non-opioid alternatives for pain management. Innovative alternative treatments to opioids (ALTO) programs are being implemented in states such as New Jersey and Colorado and have dramatically and quickly reduced opioid

¹⁷ D'Onofrio G, O'Connor PG, Pantalon MV, et al, JAMA. 2015 Apr 28;313(16):1636-44.

¹⁸ Kaucher K, Caruso E, Sungar G, et al. Evaluation of an emergency department buprenorphine induction and medication-assisted treatment referral program. Am J Emerg Med. 2019 Jul 30.

¹⁹ Hu T, Snider-Adler M, Nijmeh L, Pyle A. Buprenorphine/naloxone induction in a Canadian emergency department with rapid access to community-based addictions providers. CJEM. 2019 Jul;21(4):492-498.

²⁰ Elizabeth Evans et al., "Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006-10," Addiction 110, no. 6 (June 2015): 996-1005.

²¹ Berg ML, Idrees U, Ding R, Nesbit SA, Liang HK, McCarthy ML. Evaluation of the use of buprenorphine for opioid withdrawal in an Emergency Department. Drug Alcohol Depend. 2007;86:239-244.

prescriptions in the ED. ALTO uses evidence-based protocols like nitrous oxide, nerve blocks, trigger point injections, and other non-opioid pain management tools to treat a patient's pain in the ED.

ACEP also wishes to reiterate some feedback on CMS' opioid prescribing policies in Medicare Part D that have previously been finalized.²² We continue to have concerns that CMS' policies, especially the opioid-related safety edits finalized in 2019, do not adequately take into account the unique nature of care provided in EDs. Emergency physicians operate in shifts, and therefore it may be logistically challenging for a patient or pharmacist to immediately reach out to the physician who treated the patient. We had recommended that CMS create a more flexible policy for opioids prescribed by emergency physicians in EDs to account for situations when a pharmacy or sponsor is unable to reach the emergency physician who ordered the prescription. The care coordination safety edits require the pharmacist to contact the prescriber to override the edit. If the pharmacy cannot reach the prescriber, the beneficiary, a representative of the beneficiary, or the prescriber can request an expedited coverage determination, which must be resolved within 24 hours. However, an expedited determination process still usually involves a supporting statement from the prescriber that the drug is necessary. Thus, this safety edit imposes a burden on both the beneficiary and the prescriber. Medicare Part D plan policies such as these, related on the duration of prescriptions, dose changes, and other restrictive barriers to obtaining properly prescribed pain medications has limited access to pain care.

Medicare Shared Savings Program

CMS proposes numerous changes to the Medicare Shared Savings Program (MSSP). First, CMS is proposing to continue allowing accountable care organizations (ACOs) to report quality measures via the CMS Web Interface collection type for an additional two years, thereby delaying the transition to electronic reporting through the Alternative Payment Model (APM) Performance Pathway (APP). CMS is also proposing to freeze the quality performance standard that ACOs need to meet to share in savings for an additional year through 2023. Overall, ACEP supports these two changes to the program, as they may reduce overall reporting burden. However, we note that although emergency physicians could possibly be part of a larger physician group or hospital participating in the MSSP or another ACO model, many do not play an active role in these initiatives.

The Quality Payment Program

Health Equity Data Collection Request for Information

In the proposed rule, CMS states that the agency is committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies. CMS is attempting to “expand its efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity.”²³ It is therefore seeking comment potential future expansions of the CMS Disparity Methods, including: (1) future potential stratification of quality measure results by race and ethnicity, and (2) improving demographic data collection.

²² ACEP's comments can be found at: <https://www.acep.org/globalassets/acep-response-to-2021-advance-notice.pdf>.

²³ 86 FR. 39346. (July 23, 2021)

Future Potential Stratification of Quality Measure Results by Race and Ethnicity

CMS does not have a means of collecting data about race and ethnicity, and through the work of contractors, has developed two algorithms to indirectly estimate the race and ethnicity of Medicare beneficiaries. One methodology uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or API. In recent years, CMS has also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.²⁴

CMS is interested in learning more about the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

ACEP believes that order to effectively stratify quality measure results by race and ethnicity, there must first be assurance that such data is accurate and collected in a way that allows for its meaningful use. Granular demographic data (e.g., specifying specific categories of Asian Americans) as related to race and ethnicity provides the degree of detail necessary to effectively understand differences and set meaningful policy.

We also think that quality measures should account for risk factors such as lack of access to food, housing, and/or transportation that affect patients' ability to adhere to treatment plans. As emergency physicians, we see patients from all backgrounds who have various social risk factors. Many interventions are being employed in the ED to help identify barriers to health such as transportation and access to food and housing. One such tool that ACEP supports to help manage care for patients with complex needs is the Collective Medical Technologies' (CMT) Edie™ (a.k.a. PreManage ED) software. Edie™ is an information exchange that provides critical information on patients, such as how many ED visits patients have had in the last year, where they presented, their drug history, other providers who are involved with the patients, and finally, whether there is a patient-specific care management plan that could guide treatment. The platform improves patient care by allowing emergency physicians to make more informed clinical decisions and better direct a patient's follow-up care. It also lowers health care costs through a reduction in redundant tests and through better case management that reduces hospital readmissions. Through an alliance with CMT, ACEP has seen this system mature in approximately 17 states. Washington state, in the first year alone, experienced a 24 percent decrease in opioid prescriptions written from emergency departments, a 14 percent reduction of super-utilizer visits, and state Medicaid savings of more than \$32 million.²⁵

Some EDs across the country are attempting to create care coordination and case management programs that help improve follow up appointment scheduling from the ED and target social interventions and primary medical care to high ED utilizers. One such program in Maryland applies mobile technology to use paramedics in a community health worker role to follow up on discharged patients at risk for readmission.²⁶ Many of these patients are Medicare beneficiaries. Another program in the East Bay, California has a help desk for health-related social needs with four integrated medical-legal partnerships, called Health Advocates, to help patients

²⁴ 86 FR. 39347. (July 23, 2021)

²⁵ <https://www.acepnow.com/article/emergency-department-information-exchange-can-help-coordinate-care-highest-utilizers/2/>

²⁶ For more information on the Maryland Mobile Integrated Health Care Programs, please go to <https://www.miemss.org/home/LinkClick.aspx?fileticket=w-K7gG-8teo%3D&tabid=56&portalid=0&mid=1964>

navigate housing and transportation challenges, immigration challenges, and benefit eligibility.²⁷ ACEP is continuing to explore other innovative ways our physicians can help coordinate care for high-risk patients, including through participation in alternative payment models.

With respect to the two algorithms CMS contractors developed to indirectly estimate the race and ethnicity of Medicare beneficiaries, ACEP believe that they seem to be a reasonable temporary approach to collecting demographic data. The risk of introducing bias by using such means, however, must be recognized as a potential factor that makes the data and subsequent analysis of such data less reliable. We also do not think that estimating an individual's race and ethnicity based on name and geography is appropriate. Women and children often take the names of their husband and father, respectively. Particularly for women, estimating one's race/ethnicity based on surname simply does not make sense. Such estimation would also be insufficient for adopted individuals who take their adoptive family's surname. Additionally, there are discrepancies in how individuals self-report their race on the U.S. Census questionnaire, which would be used in each of the algorithms contemplated by CMS. If CMS plans to use proxies for race and ethnicity data to help identify and address inequities in care delivery and health outcomes, it must incorporate robust mechanisms by which to check conclusions. Routine audits of such processes and conclusions would also be ideal, in order to discover and correct errors expeditiously.

Improving Demographic Data Collection

CMS is also soliciting comments on current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), language preference, tribal membership, and disability status).

In our experience, self-reporting of demographic data tends to remain the mainstay of hospital demographic collection practices. This process is limited by balancing the urgency of caring for acute medical conditions with efforts to collect accurate demographic data from the patient. In emergency medicine, patients are sometime incapacitated and unable to provide such data. Additionally, the approach to collecting such data must be done such that the patient feels safe in doing so, with no risk of unfair retribution or biased treatment as result of their answers.

Solid business plans must be used to incentivize hospitals to mitigate the impact of health inequities through robust demographic data collection. These plans must emphasize the estimated billions of dollars in costs and loss of productivity that results from health inequity. Additionally, the long-term impact of upstream investment in health equity and the impact of health equity initiatives on human resource recruitment, productivity, competitiveness, contract negotiations, and brand value must be magnified.

ACEP also wants to make sure that data are used appropriately and do not unintentionally exacerbate not exacerbate inequities or result in penalties to hospitals or physicians due to flawed risk adjustment models. For example, the Hospital Wide Readmission program has substantially increased penalties for hospitals that serve a disproportionate number of low-income patients.²⁸ In addition, there must be investment made to ensure that demographic data is as accurate as possible. CMS must provide adequate resources to help providers achieve better health outcomes for high-risk patient populations.

²⁷ For more information on the Health Advocates Program, please go to <http://www.levittcenter.org/ed-social-welfare-in-collabor/>.

²⁸ Zuckerman, R. et al., Effect of a Hospital-wide Measure on the Readmissions Reduction Program. *N Engl J Med* 2017; Oct. 19, 2017. 377:1551-1558 DOI: 10.1056/NEJMsa1701791.

MIPS Value Pathways (MVPs)

Emergency Medicine-focused MVP

ACEP developed and proposed an emergency medicine-focused MVP called the “Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP” to CMS for consideration. The MVP attempts to capture care to patients with the most common undifferentiated high-risk conditions that may occur within the ED, including chest pain, abdominal pain, headache, and back pain. ED disposition decisions for these conditions have considerable influence on healthcare quality and cost and prior work by ACEP has identified that the conditions have significant variation in admission decision rates. Opportunities for advancement also exist for headache and back pain within the ED, as prior work has identified significant clinician variation in opioid prescribing and imaging utilization for atraumatic back pain and headache. Given the opportunity for this MVP to improve emergency care and lower costs, CMS is proposing to include it in its first batch of MVPs that would start in 2023. ***ACEP strongly supports the inclusion of this MVP in the MIPS program.***

We also believe that participation in this MVP could help transition emergency physicians towards value-based care and help them eventually participate in APMs. While many emergency physicians are ready to participate in APMs, they do not have many opportunities to do so. In order to fill this gap in available emergency medicine APMs, ACEP developed the emergency medicine-specific alternative payment model (APM), the Acute Unscheduled Care Model (AUCM).²⁹ Structured as a bundled payment model, the AUCM would improve quality and reduce costs by allowing emergency physicians to accept some financial risk for the decisions they make around discharges for certain episodes of acute unscheduled care. Initial episodes focus on patients with the following symptoms: abdominal pain, altered mental status, chest pain, and syncope. In later years, the AUCM will be expanded to include all ED conditions that have national admission rates less than 90 percent, thereby also capturing headache and back pain. The AUCM would enhance the ability of emergency physicians to reduce inpatient admissions, and observation stays when appropriate through processes that support care coordination. Emergency physicians would become members of the continuum of care as the model focuses on ensuring follow-up, minimizing redundant post-ED services, and avoiding post-ED discharge safety events that lead to follow-up ED visits or inpatient admissions. The model also allows waivers to promote telehealth, care coordination, and home visit services after discharge to encourage risk sharing for the cost of care and better patient outcomes.

ACEP submitted the AUCM proposal to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for consideration. We presented the AUCM proposal before the PTAC on September 6, 2018. The PTAC recommended the AUCM to the Secretary of the U.S. Department of Health and Human Services (HHS) for full implementation.³⁰ The AUCM met all ten of the established criteria, and the PTAC gave one of the criteria (“Scope”) a “Deserves Priority Consideration” designation since the PTAC felt that the model filled an enormous gap in terms of available APMs to emergency physicians and groups. They did recognize the need for the development of cost measures to support the model. The PTAC submitted its report to the Secretary in October 2018. The HHS Secretary responded to the PTAC’s recommendation in September 2019, requesting the “the CMS Innovation Center... assess how key mechanisms of action in this model could operate as a component in a larger model dedicated to improving population health.”³¹

²⁹ More information about the AUCM can be found at: <https://www.acep.org/apm>.

³⁰ The PTAC’s report on the AUCM can be found at: https://aspe.hhs.gov/system/files/pdf/255726/ReportToTheSecretary_ACEP_10.20.18.pdf,

³¹ The HHS Secretary’s response to the PTAC’s AUCM recommendation can be found at: <https://downloads.cms.gov/files/ptac-hhsresponse-sep18-dec18.pdf>.

ACEP is still waiting for the CMS Innovation Center (CMMI) to act on the Secretary's request, and we look forward to working with the Center to improve emergency patient care through the implementation of the model. In the meantime, we believe that there is significant synergy between this proposed MVP and the AUCM. Thus, as stated previously, the overlap of measures within the proposed MVP and those already targeted by the AUCM will allow the MVP to serve as the vehicle needed to incrementally phase emergency clinicians into APMs.

MIPS Sunset Date

CMS is seeking comment on sunsetting the traditional MIPS program after the 2027 performance year and fully transitioning to reporting through MVPs. ACEP cannot comment on whether the end of 2027 is an appropriate sunset date for traditional MIPS—but in general we believe that MVP reporting should be voluntary for the foreseeable future. It is difficult to know what the landscape of MIPS reporting will look like at that point in time. In all, we want to ensure a level playing field, where all clinicians have the opportunity to participate in MVPs. If MVPs are not available for all specialties at the time, then MVPs should remain optional for all clinicians. This would ensure that all clinicians have an equal opportunity to succeed in MIPS. CMS estimates that only 10 percent of eligible clinicians will participate in an MVP in 2023. It is hard to imagine that CMS can introduce enough MVPs to reach a 100 percent participation rate by the beginning of 2028.

Further, since MVPs have not even been implemented yet, it is too early to judge whether they will achieve their ultimate goals of streamlining reporting, making reporting more meaningful to clinicians, and helping clinicians participate in APMs. ACEP notes that CMS has been trying to improve the MIPS program since its inception, and it would be detrimental to clinicians and to patient care if CMS were to prematurely sunset the program before the agency was certain that MVPs would be a better replacement. However, despite our uncertainty around whether the traditional MIPS program should sunset after 2027, we do want to reiterate our strong support for the emergency medicine-focused MVP and our belief that it will help improve care and lower costs.

MVP Participation Registration

CMS is proposing that if an individual or group would like to report through an MVP, the “MVP Participant” would need to register for the MVP between April 1 and November 30 of the performance year (i.e., for the first year, between April 1 and November 30, 2023). An MVP Participant would not be able to submit or make changes to the MVP it selects after the close of the registration period and would not be allowed to report on an MVP it did not register for.

ACEP supports the voluntary participation in MVPs and understands the need to have a registration process. ***However, we would like to clarify whether a clinician or group who selects to participate in an MVP can still report measures outside that MVP in traditional MIPS—and if so, whether CMS would use the highest scores in each performance category to determine a clinician or group's total performance score.*** CMS may want to consider allowing clinicians who register for an MVP to have this option of reporting measures in traditional MIPS in case they wind up unable to report certain measures in the MVP and need to report additional measures to have a chance of receiving a positive payment adjustment.

Qualified Clinical Data Registries (QCDRs)

QCDRs, such as ACEP's Clinical Emergency Data Registry (CEDR), will be required to support MVPs starting in 2023. ***ACEP supports this proposal, as there are a number of CEDR measures included in the proposed emergency-medicine-focused MVP.*** However, we do ask that CMS clarify a couple of QCDR requirements, including whether a QCDR would be responsible for validating an MVP Participant's performance on population health measures and/or providing "enhanced" performance feedback, including performance data comparing the performance of similar clinicians who report on the same MVP.

Population-based Measures

ACEP continues to not be supportive of the use of administrative claims-based measures in all MVPs.

Overall, we believe that measures that should be included in MVPs are those that have been developed by specialty societies to ensure they are meaningful to a physician's particular practice and patients, and measure things a physician can actually control. Many of the existing administrative claims measures have not been tested at the physician level and based on a retrospective analysis of claims and do not provide granular enough information for physicians to make improvements in practice. Physicians do not treat a population, but treat patients as individuals tailored to their specific needs. Therefore, at a minimum CMS must develop robust risk-adjustment models that account for social risk factors. To date, CMS' risk-adjustment methodologies do not appropriately adjust for such disparities. Overall, we do not believe that population-based measures will be appropriate in all MVPs and will measure meaningful improvements in quality and reductions in cost. If CMS is to continue going forward with the use of population-based measures, we commend that CMS demonstrates that each measure has a high level of reliability and are fully tested to ensure that the measure can appropriately be assigned to specific physicians or groups.

MVP Reporting Requirements

In the rule, CMS lays out the following proposed reporting requirements:

- MVP Participants will need to select one population health measure to be calculated on. Initially in 2023, there will be two options: the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate and the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions.
- MVP Participants would select four quality measures.
- MVP Participants would select two medium-weighted improvement activities OR one high-weighted improvement activity.
- CMS would calculate performance exclusively on the cost measures that are included in the MVP using administrative claims data.

ACEP appreciates CMS' attempt to streamline the reporting requirements and reduce burden through MVP participation. However, with respect to the quality requirements, we want to ensure that if clinicians do not meet the minimum cases for four measures, that they will be held harmless and scored only on the measures that are applicable to them. We therefore ask that CMS clarify this policy in the final rule.

MVP Subgroup Reporting

CMS is allowing subgroup reporting (i.e., a subset of individual clinicians within a group) of MVPs and is establishing requirements for subgroup registration and reporting. ACEP is concerned about how CMS defines subgroups and we do not think that subgroup composition should be based on specialty, geographic location, size, or any other factors. One reason not to constrain the composition of subgroups is that some MVPs are built around conditions. In addition, imposing such limitations will increase the cost and burden of creating a subgroup, thus reducing participation. Further, it is difficult to define a subgroup for clinicians who practice in multiple settings. For example, in rural areas, clinicians can cover the ED, observation unit, and the inpatient floor. If these clinicians have to choose a subgroup that delineates ED vs other settings, they may not have enough patients to meet the measure thresholds. Overall, we have concerns about ensuring that clinicians are placed in the most appropriate subgroup. There should also be a process for rectifying any unintentional mistakes made in the subgroup registration process.

ACEP also strongly urges CMS to maintain the subgroup option as a voluntary participation pathway in MIPS and we do not support requiring multispecialty groups to form single specialty subgroups in order to participate in MVPs starting in 2025.

MVP Scoring

CMS is proposing that the scoring methodology for MVPs will align with that used for traditional MIPS. ***ACEP does NOT support this proposal and believes that there should be some additional incentives for initially participating in an MVP over traditional MIPS.*** Although we hope that participating in the emergency-medicine MVP in 2023 will reduce administrative burden for emergency physicians and allow them to focus on specific quality measures and activities that improve the quality of care they deliver, we also think that many emergency physicians may be hesitant to make any changes to their reporting patterns. If CMS eliminates certain bonus points in traditional MIPS and increases the performance threshold to 75, physicians and groups would not want to take any chances and move to MVP where they could possibly receive a lower score.

Therefore, ACEP suggests that CMS include at least a five-point bonus for participating in an MVP initially. While we understand that CMS may receive pushback at a later date if and when the agency decides to eliminate such a bonus, we truly believe that an incentive is necessary to maximize participation in MVPs.

Quality Performance Category

Quality Benchmark

Due to the COVID-19 pandemic, CMS is proposing to change how it establishes quality benchmarks. Since CMS held clinicians harmless if they were unable to report data from 2020, CMS believes that 2020 data may be unreliable. Therefore, CMS intends to develop performance period benchmarks for the CY 2022 MIPS performance period using the data submitted during the CY 2022 performance period or a different baseline period. ACEP does NOT support using data submitted during 2022 to set benchmarks for that performance period. Under that approach, clinicians would not know the performance benchmarks for quality measures ahead of time, possibly making it more difficult for them to choose which measures they should report on that would give them the best chance of receiving a high-performance score. Clinicians could also unknowingly choose measures that are topped out, thereby reducing the number of points they are eligible to receive. ***ACEP***

therefore recommends that CMS, to the extent possible, use the 2019 performance year data for scoring purposes in the 2022 performance year. CMS should also not use 2022 performance to determine whether measures are topped out, but instead determine that status for each measure prior to the start of the CY 2022 performance period. That way, clinicians know what each measure’s performance benchmark is and which measures are topped out before the performance period begins, increasing the chance that they receive a high-performance score in 2022.

CMS is proposing to remove the “Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented” measure from the emergency medicine specialty set. While we do not oppose the deletion of this measure, we do note that the emergency medicine specialty set is thus decreasing, making it more difficult to meet the quality performance requirements.

Data Completeness

CMS is proposing to maintain the current data completeness threshold (the percentage of applicable patients on which providers must report on for a particular measure) at 70 percent for the 2022 performance period but is proposing to increase the data completeness threshold to 80 percent for the 2023 performance period.

ACEP opposes the proposed increase in the threshold for 2023. We believe that physicians and group practices are being held to an unreasonably high bar – higher than other quality programs, like the Medicare Part C and D Star ratings and certain hospital reporting programs that only require a sample of patients for each quality measure. In addition, some emergency physicians practice across multiple settings, yet their specific NPI/TIN remains the same. Since these different settings do not integrate data seamlessly, it is challenging for some emergency physicians to even reach the current 70 percent data completeness threshold. Until enough data and care can be integrated across settings, it is premature to continue to increase data completeness threshold.

Increasing the threshold would also increase administrative burden and overall cost of complying with MIPS requirements. Many of the MIPS requirements are increasing and with the introduction of MVPs and the continued shift to digital quality measures, adding additional reporting burdens may overwhelm physicians and their group practices. Physicians need stability in the program to focus on improvement and reduced burden to successfully transition to MVPs and digital quality measures.

Scoring Rules for Measures Without a Benchmark or That Do Not Meet Case Minimums

CMS is proposing to change its existing policy to award three points to measures without a benchmark or that do not meet the case minimum. CMS is eliminating this policy and instead proposing to establish a five-point floor for the first two performance periods for new measures. Thus, except for new measures in the first two performance periods, measures without a benchmark or that do not meet the case minimum will receive 0 points (except when reported by small practices—small practices will still receive 3 points for reporting these measures). ***ACEP opposes this proposal since groups of all sizes—not just smaller groups—sometimes cannot make the case minimum for certain measures.*** We do support providing 5 points for first two years of a measure but believe that CMS should reduce the number of points from 5 to 3, instead of 5 to 0, after two years. If clinicians receive 0 points for certain measures without a benchmark, it would discourage them from ever reporting the measure--thus making it challenging for the measure to ever receive a benchmark.

Bonus Points

CMS is proposing to eliminate bonus points for reporting high-priority and outcome measures as well measures that meet end-to-end electronic reporting criteria. ***ACEP opposes removing both sets of bonus points.*** With respect to high-priority and outcome measures, we think CMS should continue to provide rewards for reporting certain measures that are more meaningful to patient care. Eliminating this bonus also de-incentivizes third parties from developing high priority and outcome measures. Most outcome measures are related to primary care, and it is important to encourage the development of more specialty-based outcome measures.

ACEP also thinks it is critical to continue the bonus for end-to-end reporting. Reporting electronically is extremely costly and CMS should reward physicians for utilizing registries, leveraging electronic capture, and reporting outside of claims.

Quality Scoring Flexibilities

CMS is proposing to expand the list of reasons that a quality measure may be impacted during a performance period to include changes to codes (such as ICD-10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes, or inclusion of inactive or inaccurate codes; changes to clinical guidelines; or, measure specifications. Errors included in the final measure specifications can result in the suppression or truncation of a measure. ACEP appreciates the intent of this proposal to prevent clinicians' overall performance score from being negatively affected based on changes to measures. However, we believe that CMS needs a better way of addressing errors in measures besides suppressing or truncating the measure. Measure stewards need more flexibility to adjust measures with errors when appropriate. It takes a lot of time and resources to develop measures, and we need to do as much as possible to keep a measure in the program. If a measure with an error is suppressed immediately and there is no opportunity for the error to be fixed, it will incentivize measure stewards not to put forth corrections to CMS.

Cost Performance Category

ACEP encourages CMS to continue to develop episodes that capture the clinical screening, diagnostic testing, and stabilization work done by emergency physicians before a patient is admitted into the hospital. CMS' contractor, Acumen, has convened a workgroup to develop an emergency medicine episode-based cost measure. ACEP nominated a few individuals to serve on that workgroup and we are pleased that three ACEP members are now participating in it—including as the chair of the workgroup.

ACEP has concerns with creating a separate process for externally developing measures outside of the current Acumen process. It is unclear what input outside stakeholders could provide and how other cost measure developers would demonstrate that they have the right clinical and methodological input during the measure development process. Further, other cost measure developers may not have as much access to Medicare data as Acumen does. If substandard measures are added to the program that affect particular clinicians, it could significantly impact their score—particularly if the cost category weight is finalized at 30 percent.

Improvement Activities Performance Category

CMS is proposing a process for removing an improvement activity in cases where performing the activity raises possible patient safety concerns. CMS is also proposing new criteria for nominating a new improvement activity. Finally, CMS is proposing: the addition of seven new improvement activities, three of which are related to

promoting health equity; the modification of 15 current improvement activities; and the removal of six improvement activities.

ACEP has no concerns with these proposals, and especially appreciates CMS' focus on health equity. However, we would like to reiterate our support³² for allowing clinicians to report on one set of measures and receive credit in multiple categories of MIPS, as it will help reduce the burden of reporting for physicians and also link elements of the program together into one cohesive function. This concept could be easily implemented into CMS' MVP proposals. Rather than clinicians having to attest to improvement activities as part of their MVP reporting, CMS could identify which improvement activities clinicians are inherently performing as part of a particular MVP, and corresponding Improvement Activity credit should be automatic. Such an approach fosters a hybrid approach between MIPS and Advanced APMs and would reduce clinicians' reporting burden while preparing them to participate in APMs.

Promoting Interoperability

Although most emergency physicians are deemed hospital-based clinicians and are therefore exempt from the Promoting Interoperability performance category of MIPS, there are a few proposals for which ACEP would like to call out its support. First, ACEP supports CMS' proposal to maintain the 90-day performance period for the Promoting Interoperability category for CY 2022. Allowing physicians to choose any continuous 90-day period provides physicians the ability to select the performance period that best meets their needs—giving them flexibility to focus on patient care while still meeting CMS reporting requirements. We urge CMS to consider the long-term impact of the COVID-19 pandemic on physician medical practices, particularly those in small and rural settings, and to maintain the 90-day performance period in CY 2023.

ACEP also supports CMS' proposal to maintain the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure as optional as many physicians and health systems remain incapable of interconnecting their health information technology (health IT) with PDMP systems. We also support increasing the available bonus from five points to 10 points as this provides positive incentives to connect electronic health records (EHRs) to PDMPs without unduly burdening physicians who have little control over their EHR vendors' interoperability decisions.

Complex Patient Bonus

ACEP supports CMS' proposal to double the complex patient bonus in 2021 to 10 points to account for the increased complexity of caring for patients during the COVID-19 pandemic.

Starting in 2022, CMS is proposing to refine its methodology for defining higher-risk patients for the purposes of allotting the complex patient bonus. ACEP does not support the proposal to limit the complex patient bonus to clinicians who have a median or higher value for one or both of the two risk indicators (Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients that is dually eligible for Medicare and Medicaid). We believe CMS should proceed very cautiously before eliminating the distinction between clinicians who have relatively few complex patients and those who have larger numbers of such patients. If CMS finalizes its proposal, clinicians who are just below the median could be discouraged

³² Please see ACEP's comments on ACEP Comments on Reducing Administrative Burden Request for Information from August 2019 at: <https://www.acep.org/globalassets/sites/acep/media/advocacy/federal-advocacy-pdfs/acep-response-to-administrative-burden-request-for-information.pdf>.

from treating complex patients. This could impact access to care for those patients, leading to greater disparities and inequities in health outcomes.

Facility-based Scoring Option

Under the facility-based scoring option, clinicians who deliver 75 percent or more of their Medicare Part B services in an inpatient hospital, on-campus outpatient hospital, or ED setting will automatically receive the quality and cost performance score for their hospital through the Hospital Value-based Purchasing (HVBP) Program. Most emergency physicians qualify for this option. Clinicians who qualify for the option can still report quality measures through another submission mechanism (such as a QCDR) and receive a “traditional” MIPS score for quality. If they do so, CMS will automatically take the highest of the HVBP score and the traditional MIPS score. Some emergency physicians, especially those who work in small groups or practice in rural areas, rely on this option since they do not have the resources or technology necessary to meet all the MIPS quality and cost requirements.

CMS has heard from clinicians that in some cases, individuals and groups are receiving a lower score than they would otherwise receive outside of facility-based measurement. CMS is therefore proposing a new policy to determine the MIPS final score for clinicians and groups who are eligible for facility-based measurement. CMS is proposing that, starting in 2022, the MIPS Quality and Cost Category scores will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission. Under this proposed policy, CMS would calculate two final scores for clinicians and groups who are facility-based. One score would be based on the clinician or group’s performance and the weights of the performance categories if facility-based measurement did not apply, and the other would be based on the application of facility-based measurement.

ACEP supports this change, as we believe that the facility-based scoring option should NEVER, even unintentionally, hurt clinicians. However, we recommend that CMS adopt it immediately starting in the 2021 performance period.

MIPS Final Scoring Methodology

Calculating the Final Score

Performance Threshold

The performance threshold is the score that clinicians need to achieve to avoid a penalty and receive a bonus. For the first five years of the program (2017-2021), CMS had the discretion to set the performance threshold at any level it chose. CMS used this flexibility to set artificially low thresholds, making it easier for clinicians to avoid a penalty. However, starting in 2022, CMS is required by law to set the threshold at the mean or median of prior performance. CMS therefore is proposing to set the threshold at 75 points in 2022 (the mean score during the 2017 performance period), a significant increase from the 2021 threshold of 60 points. There is also an additional bonus for exceptional performance, and CMS is proposing to set that threshold at 89 points.

ACEP opposes increasing the performance thresholds that high in 2022, given the downstream effects of our continued response to the COVID-19 PHE. The pandemic has affected MIPS participation for the last two years, and it is unclear how COVID-19 will impact MIPS reporting in 2022. Thus, CMS may not want to significantly increase the performance threshold in case some clinicians are still dealing with the pandemic for

part of the year. Increasing the threshold above 60 points would also disadvantage small and rural practices who may not have the resources necessary to score as high as large and urban practice. ***CMS should consider using the 1135 waiver authority it has under the PHE or its Extreme and Uncontrollable Circumstances Exception policy to waive the statutory requirement of using the mean or median of performance of a prior use to establish the threshold, and instead keep the performance threshold at 60 points and the exceptional performance category at 85 points in 2022.***

Category Weights

CMS proposes to increase the Cost category to 30 percent by 2022. CMS proposes to make corresponding decreases to the Quality category weight (the Quality category weight would be 30 percent in 2022). ACEP recognizes that the Cost category is required by law to reach this percentage in 2022. ***However, given the unprecedented and significant disruptions to the health care system and MIPS due to the COVID-19 PHE, we urge CMS to use its waiver authority or Extreme and Uncontrollable Circumstances Exception policy to maintain the weight of the Cost Performance Category at 20 percent.***

Qualified Clinical Data Registries (QCDRs)

QCDRs are third-party intermediaries that help clinicians report under MIPS. As stated above, ACEP has its own QCDR called the Clinical Emergency Data Registry (CEDR). CMS has separate policies governing QCDRs and the approval of QCDR measures. In general, ACEP believes that CMS should do more to promote the use of clinical data registries. One major ongoing issue for specialists is not being able to report on measures that are meaningful to them. Emergency physicians have experienced this problem in the past, and that is specifically why ACEP developed its QCDR, CEDR. Through CEDR, ACEP reduces the burden for our members and makes MIPS reporting a meaningful experience for them. We strive to make reporting as integrated with our members' clinical workflow as possible and constantly work on improving their experiences and refining and updating our measures so that they find value in reporting them. We have found that if our members can report on measures that are truly clinically relevant, they become more engaged in the process of quality improvement. For each measure we develop, a Technical Expert Panel comprised of clinical, measurement, and informatics experts in the field of emergency medicine is assembled, and several criteria are considered when designing a measure, including each measure's impact on emergency medicine, as well as whether the measures are scientifically acceptable, actionable at the specified level of measurement, feasible, reliable, and valid. Through our work and partnership with CMS, ***we are proud to have been a certified QCDR and have helped tens of thousands of emergency physicians participate successfully in MIPS.***

QCDRs have proven to be an excellent way to collect data and report quality measures. QCDR measure owners invest significant resources into measure development, data collection, and validation. Additionally, QCDR measure owners develop these measures for use beyond MIPS reporting (e.g., research, guideline development, quality improvement, etc.). Section 1848(q)(5)(B)(ii)(I) of the Social Security Act, as added by Section 101 of the Medicare Access and CHIP Reauthorization Act (MACRA), requires HHS to encourage the use of QCDRs to report quality measures under MIPS. This is why we strongly believe, in line with this statutory requirement, that ***CMS should continue to refine the QCDR option under MIPS to streamline the self-nomination process, and provide better incentives for organizations, including medical associations such as ours, to continue to invest in their QCDRs and develop new, meaningful measures for specialists to use for MIPS reporting and other clinical and research purposes. Conversely, CMS should refrain from finalizing proposals that would impose significant and unreasonable burdens on QCDRs.***

While there are no significant QCDR proposals in this year's rule, based on our principles highlighted above, CMS should reconsider its requirements regarding data validation and targeted audits and "fully-tested" measures. These requirements are extremely burdensome and costly and are pushing some organizations to remove their clinical registries from the MIPS program. Further, they are creating additional, unnecessary work for clinicians as well. For example, to comply with the requirements around data validation audits, QCDRs are requesting individual clinicians and groups to conduct their own audits. These individual audits are just being used for QCDR's data validation audits and for no other purpose—they are not even used by CMS for auditing purposes. Clinicians and groups are therefore spending their valuable time conducting an audit just to help QCDRs "check a box" that they have completed a data validation audit. All in all, CMS should reevaluate these requirements and develop more reasonable standards that effectively ensure that QCDR measures are appropriately tested and that data from QCDRs are valid, but that do not cause undue burden both on QCDRs and clinicians.

Public Reporting

ACEP continues to be concerned that all quality measures reported by clinicians are included in the Compare rating. Under MIPS, clinicians have an incentive to report more than the six required measures since CMS will count the six with the highest scores. While CMS does not penalize clinicians who want to do extra and report on more than six measures, the Compare website provides the inverse incentive by counting and publicly reporting on every measure a clinician reports in their rating. Therefore, if clinicians report more than six measures and do poorly on one measure, their MIPS score will not be impacted, but their Compare rating will be. Clinicians should not be penalized for submitting CMS more data than what is required. Besides the impact on clinicians, we believe CMS should strive to get as complete data as possible to improve quality and patient safety and therefore should want to incentivize clinicians to report on as many measures as possible.

We are also concerned that clinicians will only report on measures they perform well on due to the disincentive to report more than six measures. Due to this disincentive, CMS is only seeing a small subset of performance for any measure, and a subset that will be skewed to high performance. This may cause CMS to judge these measures to be "topped out" when in fact the majority of clinicians are not reporting on those measures due to the continuing need for improvement. It is in CMS' interest for the health of patients to encourage physicians to continue to improve in those areas, rather than drop the measure for reporting. Dropping measures unnecessarily also increases physician burden (having to retool reporting systems) and increases costs to CMS (having to both develop and review new measures) as well as to measure stewards.

Advanced APMs

While many emergency physicians are ready to take on downside risk and participate in Advanced APMs, there simply are not any opportunities to do so. As referenced earlier, ACEP developed the AUCM, which was recommended by the PTAC and endorsed by the former HHS Secretary. However, CMMI has yet to take action on the model.

We are especially concerned about the lack of Advanced APM options given that the five percent payment bonus for being Qualifying APM participant (QP) is expiring in 2024. Therefore, most emergency physicians will never have the opportunity to receive a 5 percent bonus because they do not have a viable Advanced APM option. We therefore encourage CMMI to introduce more Advanced APMs targeted at specialists.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory and External Affairs at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink that reads "Mark Rosenberg". The signature is written in a cursive style with a large, prominent "M" and "R".

Mark S. Rosenberg, DO, MBA, FACEP
ACEP President