American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

October 5, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016

Re: CMS-1734-P

Re: Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

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Dear Administrator Verma:

On behalf of our 42,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the Calendar Year (CY) 2021 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:*** The Centers for Medicare & Medicaid Services (CMS) is proposing to implement a policy, finalized in the CY 2020 PFS and QPP final rule, that would increase the office and outpatient evaluation and management (E/M) services and add a new add-on code for complexity for these services (GPC1X) in CY 2021. To preserve budget neutrality, CMS is proposing to reduce the conversion factor by 10.6 percent in 2021 from $36.09 to $32.26 —dropping it to one of the lowest levels it has been in 25 years. CMS estimates that emergency physicians and other health care practitioners practicing under the specialty designation of emergency medicine will experience a -6 percent reduction to their reimbursement in 2021. **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.**

- ***Emergency Medicine Payment Reduction:*** ACEP lays out the specific impact that a -6 percent reduction would have on patients' access to emergency care, highlighting how the novel coronavirus (COVID-19) public health emergency (PHE) will exacerbate the effects of such a reduction.
  We specifically make the following three policy recommendations:
  - To account for the additional expenses that hospital-based clinicians must absorb when treating patients during the COVID-19 PHE, ACEP strongly urges CMS to **implement a 20 percent COVID-19 professional services claims-based payment adjustment.**
  - ACEP urges CMS to **delay the implementation of the add-on code for complexity (GPC1X) to CY 2022 or later** or to possibly consider eliminating the code altogether**.**
  - ACEP recommends that CMS and the Department of Health and Human Services (HHS) utilize its 1135 waiver authority under the COVID-19 PHE to **waive the budget neutrality requirement for all of CY 2021.**
- ***Valuation of Emergency Department Evaluation and Management Codes for CY 2021*: ACEP thanks CMS for proposing to accept our recommended work relative value unit (RVU) values for Emergency Department (ED) Evaluation and Management (E/M) codes 99283, 99284, and 99285 in CY 2021 and urges CMS to finalize the proposal as proposed.**
- ***Telehealth Services:*** ACEP for years has strongly supported the delivery of telehealth services by board-certified emergency physicians. We lay out our previous requests for CMS to add the ED E/M codes on the list of Medicare approved telehealth services. With respect to CMS' specific proposals, ACEP recommends that:
  - **CMS add the ED E/M codes levels 1-3 (CPT codes 99281-99283) permanently to the list of approved Medicare telehealth services.** CMS should add these services on a Category 2 basis, as ACEP continues to believe that these services add significant clinical value. We do appreciate that CMS has proposed to add these codes temporarily on a Category 3 basis. Since the HHS Secretary, Alex Azar, recently announced that the PHE would be extended for 90 days past its current expiration date of October 23, 2020, we note that the codes added on a Category 3 basis would—under CMS' proposal—remain on the list of approved telehealth services until the end of CY 2021.
  - **CMS should consider adding higher-level ED E/M codes, the observation codes, and at least a subset of the remaining critical care codes to the list of approved telehealth services on a Category 3 basis**. Further, CMS should test the use of these high-level ED codes and critical care codes in Centers for Medicare & Medicaid Innovation (CMMI) models. ACEP does however appreciate CMS' rationale for not proposing to include these codes on the list of approved telehealth services past the end of the COVID-19 PHE.
- ***Physician Practice Expense Data Collection:*** While CMS is not proposing changes to the practice expense (PE) methodology or data collection process, ACEP believes that CMS should consider altering its PE methodology going forward to better account for uncompensated care costs due to the Emergency Medical Treatment and Labor Act (EMTALA).
- ***Scope of Practice:*** ACEP strongly opposes CMS' proposal to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests in addition to physicians.
- ***PFS Payment for Services of Teaching Physicians*:** ACEP supports extending the policy instituted during the COVID-19 PHE that allows teaching physicians to supervise residents remotely using telehealth equipment.

- *Medical Documentation Requirements:* In last year's rule, CMS finalized numerous changes to the medical record documentation requirements for physicians and other health care practitioners. ACEP continues to support these policy changes, as we believe that the additional flexibility will significantly reduce burden for teaching physicians.
- *Payment for Medication Assisted Treatment (MAT) in the ED:* **ACEP strongly supports CMS' proposal to pay for medication assisted treatment (MAT) delivered in the ED starting in 2021.**
- *Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs):* ACEP supports CMS' proposal to expand the definition of OUD treatment services to include opioid antagonist medications, such as naloxone. **However, ACEP strongly recommends that CMS introduce a proposal in next year's rule that would allow EDs to get reimbursed for administering naloxone and emergency physicians and other clinicians working in EDs to get compensated for the time that is spent counseling patients on the usage and indications for naloxone at home.**
- *Electronic Prescribing of Controlled Substances:* ACEP supports the proposal to delay the Electronic Prescribing of Controlled Substances (EPCS) requirement for Medicare Part D until at least 2022. We also encourage CMS to work closely with the Drug Enforcement Administration (DEA) on implementing the requirement. It is important to note that ACEP is responding separately to a request for information on how CMS should implement the requirement going forward.
- *Medicare Shared Savings Program***:** ACEP has heard that only a limited number of emergency physicians actually participate directly in the Medicare Shared Savings Program (MSSP). While emergency physicians could possibly be part of a larger physician group or hospital participating in the MSSP or another accountable care organization (ACO) model, emergency physicians do not play an active role in these initiatives. We are however concerned that CMS is imposing significant changes to the MSSP quality scoring methodology all in one year and believe that CMS should instead phase the changes in over time.

Quality Payment Program

- *MIPS Value Pathways (MVPs):* ACEP lays out overall concerns with the process CMS is proposing for developing and proposing MVPs. We also highlight issues with CMS' proposals on capturing the patient voice, incorporating population health measures into MVPs, promoting the use of digital performance measure data submission technologies, adding a criterion that denominators must be consistent across the measures, incorporating QCDR measures into MVPs, and meeting the Promoting Interoperability performance category requirements.
- *APM Performance Pathway (APP):* ACEP supports the concept of the APP as well as the flexibility it provides to alterative payment model (APM) participants. However, we note that not many of our members participate in an APM, including the MSSP. ACEP believes that one of the contributing factors leading to the paucity of emergency physicians actively participating in the MSSP and other APMs is that there are not many measures in these initiatives that are relevant to clinicians practicing in the ED setting. None of the six proposed APP measures directly relate to emergency medicine. Therefore, **we would like to recommend some measures to include in the APP measure set that are meaningful to emergency medicine**.
- *Quality Performance Category:* **ACEP opposes the addition of Quality Measure # 418 *Osteoporosis Management in Women Who Had a Fracture* to the Emergency Medicine specialty set**.
- *Cost Performance Category:* ACEP is disappointed that CMS is continuing to maintain the Medicare Spending Per Beneficiary (MSPB) measure and the Total Per Capita Cost measures. We

have repeatedly asked CMS to remove these measures from the MIPS program. We also encourage CMS to continue to develop episode-based cost measures that capture the clinical screening, diagnostic testing, and stabilization work done by emergency physicians before a patient is admitted into the hospital.

- ***Improvement Activities:*** CMS is proposing to modify two existing improvement activities and add the following new criterion for nominating new improvement activities: "include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible." ACEP supports the addition of this new criterion as long CMS still allows new improvement activities to be added even in situations when it is not possible to connect them to existing quality and cost measures.
- ***Promoting Interoperability***: Although most emergency physicians are deemed hospital-based clinicians and are therefore exempt from this performance category of MIPS, ACEP supports CMS' proposals to make the Query of Prescription Drug Monitoring Program (PDMP) measure optional again in 2021 and to add a new optional *Health Information Exchange Bi-Directional Exchange* measure.
- ***MIPS Final Scoring Methodology:***
    - **ACEP opposes CMS' proposal to develop performance period benchmarks for the CY 2021 MIPS performance period using the data submitted during the CY 2021 performance period rather than historic data**.
    - ACEP recommends that CMS, to the extent possible, use the 2018 performance year data (2020 benchmarks) for scoring purposes in the 2021 performance year. CMS should also not use 2021 performance to determine whether measures are topped out, but instead determine that status for each measure prior to the start of the CY 2021 performance period.
    - ACEP supports CMS' proposal to increase flexibility in the Quality category scoring methodology by expanding the list of reasons that a quality measure may be impacted during the performance period, and revising when CMS would allow scoring of the measure with clinicians are unable to report a full 12 months-worth of data. ACEP requests that CMS add some examples specific to hospital-based clinicians to this list.
    - Calculating the Final Score
        - ACEP supports CMS' proposal to modify the complex patient bonus for the 2022 MIPS payment year (2020 performance period) in response to the COVID-19 PHE by doubling the number of complex bonus points that a clinician receives.
        - CMS proposes to increase the Cost category to 20 percent in 2021 and to 30 percent by 2022. CMS proposes to make corresponding decreases to the Quality category weight (the Quality category weight would be 40 percent in 2021 and 30 percent in 2022). ACEP recognizes that cost category is required by law to reach this percentage by 2022, but we remain concerned about the lack of available cost measures that are meaningful and attributable to emergency physicians.
        - CMS is proposing to increase the performance threshold from 45 points in 2020 to 50 points in 2021. ACEP believes that the current proposal represents a reasonable increase in the performance threshold for 2021. **However, we caution the agency against increasing the performance thresholds above 60 points in 2022, given the downstream effects of our continued response to the COVID-19 PHE.**
        - ACEP supports CMS' proposal to maintain the additional performance threshold at 85 points for the 2021 MIPS performance period and encourages CMS not to increase this threshold going forward.

- *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.**
    - CMS proposes to codify requirements that, beginning with the 2023 MIPS payment year as condition of approval, each QCDR must conduct annual data validation audits and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits. ACEP understands that most of the requirements outlined here are already in place. However, many of the requirements do not have clearly delineated guidelines. CMS should provide very specific information for what they expect for these audits.
    - Over the last couple of years, CMS has been proposing increased testing requirements for QCDR measures. ACEP understands the rationale behind these requirements but do believe they would add significant costs to the QCDR measure development process. At a certain point, the costs of measure development will outweigh the benefit of operating QCDRs. All in all, **CMS is inherently making it impossible for small organizations to run QCDRs and develop new measures.**
    - CMS includes proposals around duplicative measures. ACEP supports these proposals and we look forward to continuing to work with CMS and other entities to harmonize emergency medicine quality measures and eliminate any duplicative measures.
- *Physician Compare***:** ACEP continues to be concerned that all the quality measures reported by clinicians are included in the Physician Compare rating. 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.
- *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 an Qualifying APM participant (QP) is expiring in 2024 and the QP threshold is extremely high (the QP payment amount threshold is increasing to 75 percent and the QP patient count threshold is increasing to 50 percent

The Physician Fee Schedule

In this proposed rule, the Centers for Medicare & Medicaid Services (CMS) proposes to implement a policy, finalized in the CY 2020 PFS and QPP final rule, that would increase the office and outpatient evaluation and management (E/M) services and add a new add-on code for complexity for these services (GPC1X) in CY 2021. According to the American Medical Association (AMA), this policy alone is protected to increase spending by nearly $10 billion (the office and outpatient E/M increases represent $5.6 billion and the additional add-on code for complexity represents another $3.3 billion). Along with some other proposals included in the rule, PFS spending is projected to increase by $10.2 billion. 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. Therefore, to preserve budget neutrality, CMS is proposing to reduce the conversion factor by 10.6 percent in 2021 from $36.09 to $32.26 —dropping it to one of the lowest levels it has been in 25 years. As discussed in detail below, such a reduction to the conversion factor will have a devastating impact on access to care—potentially impacting the ability for our most vulnerable to receive services during a global pandemic.

Along with these potential reductions, physicians must continue to deal with annual updates to Medicare payments that do not cover the increased cost due to inflation of providing care. The annual updates also do not take into account the two percent sequestration reduction that continues to apply year after year. 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 2020 Medicare Trustees Report, which was released on April 22, 2020, acknowledges that updates for physician reimbursement are not sufficient. The Trustees believe that, absent a change in the delivery system, the availability and quality of care that Medicare beneficiaries receive will fall over time.[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 particular physician specialties including emergency medicine to continue providing care.

With respect to the impact on emergency medicine, we do note that CMS is proposing to increase the work RVUs for the emergency department (ED) E/M codes, levels 3, 4, and 5 (CPT codes 99283, 99284, and 99285). As discussed in the "Valuation of Emergency Department Evaluation and Management Codes for CY 2021" section below, this proposal, if finalized, would increase emergency medicine reimbursement by approximately 3 percent, offsetting some of the reduction to the conversion factor. In all, after taking into account the increase in the ED E/M work RVUs and other technical adjustments, CMS estimates that emergency physicians and other health care practitioners practicing under the specialty designation of **emergency medicine will experience a -6 percent reduction to their reimbursement in 2021**. **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.** The specific impact of this cut and our policy recommendations are found in the "Emergency Medicine Payment Reduction" section below.

[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 2020 Medicare Trustees Report is available at: https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.

Emergency Medicine Payment Reduction

Impact of the Emergency Payment Reduction

A -6 percent reduction to Medicare reimbursement for emergency physicians and other emergency medicine health care professionals would have rippling effects across the health care system and have a detrimental impact on access to care. Based on an assessment of Medicare claims data and a qualitative analysis of the current health landscape in the face of the novel coronavirus (COVID-19) public health emergency (PHE), we believe that there would be four overarching impacts of this reduction:

- ***Some emergency medicine group practices will close, as they have already been significantly impacted by the COVID-19 pandemic.*** EDs across the country have experienced a significant reduction in volume since the COVID-19 pandemic began. The Centers for Disease Control and Prevention (CDC) estimated a 42 percent drop in the number of ED visits from March 29 to April 25, 2020 compared to the same weeks in 2019.[3] Anecdotally, we have heard from some EDs that report even higher drops in volume, in the range of 50 to 60 percent. From a recent survey of nearly 200 ACEP members, 64 percent of respondents stated that their ED volumes dropped between 25 to 50 percent and 30 percent of respondents stated that their ED volumes dropped over 50 percent. While ED volumes are starting to pick back up, this initial reduction in ED volume was caused in part by government's call to stay at home during the first stages of the pandemic, which in turn led to fewer accidents and other traumatic injuries. Although having fewer accidents and injuries is definitely a good phenomenon, unfortunately, we have also seen that individuals that needed to seek immediate care for medical emergencies either delayed care or avoided care altogether due to a fear of being exposed to COVID-19 while in the ED. According to a survey conducted by the CDC, 40.9 percent of nearly 5,000 U.S. adult respondents reported having delayed or avoided any medical care in June of this year, **including urgent or emergency care (12.0 percent)** and routine care (31.5 percent), because of concerns about COVID-19. Groups of persons among whom urgent or emergency care avoidance exceeded 20 percent and among whom any care avoidance exceeded 50 percent included adults aged 18–24 years (30.9 percent for urgent or emergency care; 57.2 percent for any care), unpaid caregivers for adults (29.8 percent; 64.3 percent), Hispanic adults (24.6 percent; 55.5 percent), persons with disabilities (22.8 percent; 60.3 percent), persons with two or more selected underlying medical conditions (22.7 percent; 54.7 percent), and students (22.7 percent; 50.3 percent).[4]

  It has also 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 personal protective equipment (PPE), and taking on other new administrative costs (such as triaging and treating patients with potential COVID symptoms in ways that limit possible exposure to the disease). All of these additional costs are weighing

[3] Centers for Disease Control and Prevention. *The Morbidity and Mortality Weekly Report. Impact of the COVID-19 Pandemic on Emergency Department Visits — United States, January 1, 2019–May 30, 2020*. June 3. 2020. https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6923e1-H.pdf.

[4] Centers for Disease Control and Prevention. *Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns — United States, June 2020*. September 11, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6936a4-H.pdf.

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 actually do increase in their area. Thus, with less revenue from ED volume reductions, emergency physician groups are struggling to meet these coverage requirements. In that same ACEP survey cited above, a fifth of respondents said that their group has laid off a physician, nearly a third said that their group had furloughed a physician, and **over half stated that their group has cut their pay for the same work.**

While emergency physicians have received some financial support from federal programs, such as the Provider Relief Fund, for many groups these resources have only covered a small fraction of their overall lost revenues and decreased expenses due to COVID-19. We have repeatedly requested that $3.6 billion be specifically allocated from the Provider Relief Fund towards emergency medicine groups and to the emergency physicians who practice within them.[5] However, we estimate that emergency physician groups have thus far received only 7 to 15 percent of this $3.6 billion need. We do note that HHS just announced a third general distribution from the Provider Relief Fund, but we are unsure how much will wind up being allocated to emergency physicians and emergency physician group practices.

Looking forward, many emergency physicians are already very concerned about the viability of their groups—even without this looming 6 percent 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.** We need American's health care safety net to be fully functional both now and in the future as our country reopens. 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.**

- ***Hospital closures could increase due to COVID-19, which on top of cuts to frontline clinicians will create significant access issues.*** Some of our members expect their hospital partners to declare bankruptcy in the next 6 months. While hospital closures are caused by many factors, studies suggest that our members have cause for concern. One recent study, conducted by the Center for Healthcare Quality and Payment Reform (CHQPR), found that over 800 rural hospitals – or 40 percent of all rural hospitals in the country – are at risk of closing in the near future.[6] According to the Kaiser Family Foundation, hospital closures are caused by financial distress, poor economic conditions, a high Medicare and Medicaid share of patients, and Medicare payment cuts.[7] When a hospital closes, mortality rates and readmission rates increase at hospitals near to where the hospital closed, particularly at high-occupancy bystander hospitals that are sensitive to changes in the availability of emergency care in

[5] ACEP has written four letters to the Secretary of the Department of Health and Human Services (HHS) regarding the allocation of the Provider Relief Fund. On March 27, 2020, ACEP sent a letter asking that HHS prioritize funding for frontline health care workers, especially emergency physicians, who are risking their lives combating the virus and are at the highest risk of being exposed to COVID-19 and missing work. On April 3, 2020, ACEP sent a follow-up letter specifically requesting $3.6 billion to support emergency physician practices. On April 14, 2020, ACEP sent another letter reiterating our previous requests and expressing our questions and concerns about the initial $30 billion wave of funding and the associated terms and conditions that health care providers must agree to keep their share of the funds. Finally on June 1, 2020, ACEP wrote a letter asking that HHS reserve a portion of the $75 billion that Congress provided in the Paycheck Protection Program and Health Care Enhancement Act to cover the remaining balance of the $3.6 billion request.

[6] Miller, Harold. *Saving Rural Hospitals and Sustaining Rural Healthcare*. The Center for Healthcare Quality and Payment Reform (CHQPR). Sept. 2020. http://www.chqpr.org/downloads/Saving_Rural_Hospitals.pdf.

[7] Kaiser Family Foundation. *A Look at Rural Hospital Closures and Implications for Access to Care: Three Case Studies*. July 2016. http://files.kff.org/attachment/issue-brief-a-look-at-rural-hospital-closures-and-implications-for-access-to-care.

neighboring communities.[8] In other words, access to emergency care decreases especially for time-sensitive cases. Patient outcomes also decline with hospital closures, with one study indicating that inpatient mortality increases for time sensitive conditions such as stroke and acute myocardial infarction patients (4.4 percent increase in inpatient mortality), and within these diagnoses Medicaid patients and racial minorities had the highest mortality increases (11.3 percent and 12.6 percent, respectively).[9] Finally, hospital closures cause long-term staffing and recruitment issues, limiting patient access and choice in the surrounding area.

- ***Emergency physicians who work in hospitals with a higher proportion of Medicare patients would fare worse.*** Looking at Medicare claims data, the hospitals with the highest share of Medicare patients tend to be mid-sized community hospitals. Since emergency physicians who work at these hospitals see a high proportion of Medicare patients, they may be hit hardest by the Medicare payment reduction. We estimate that emergency physicians in these hospitals would lose hundreds of thousands of dollars in revenue in aggregate if they experience a 6 percent cut to Medicare reimbursement in 2021.[10] Such a reduction would likely impact the ability of emergency physicians to serve these communities.

- ***The Safety net could crumble at a time when it is needed the most.*** Emergency physicians are critically needed to maintaining access to care in the future, as demand for services and acuity of patients are likely to increase. While many individuals avoided emergency care during the pandemic, others who put off non-emergent services or surgeries are seeing their conditions worsen over time. Thus, what may not have been an emergency if treated right away could turn into a highly critical case. With sicker more acutely ill patients needing treatment, we need to have a strong safety-net in place to ensure that all of them receive timely care.

Policy Recommendation # 1: Professional Services Claims-based Payment Enhancement

As described above, emergency physicians have taken on numerous additional costs treating patients during the COVID-19 PHE—and these expenses have not been sufficiently covered by existing federal resources, such as the Provider Relief Fund. In order to appropriately recognize this enhanced, non-separately reimbursable work performed by emergency physicians and other front-line clinicians, ACEP believes that **CMS should provide a 20 percent reimbursement enhancement for professional claims (without regard to specialty designation).** This additional payment would apply to all ICD-10 codes submitted with dates-of-service during the PHE that meet the criteria established for COVID-19 testing and treatment coverage under the Health Resources and Services Administration (HRSA) COVID-19 Uninsured Program.[11]

The payment would direct resources to the health care professionals who are performing patient care services where they are required to engage in enhanced direct and indirect work to effectively treat COVID-19 patients which includes activities associated with managing a pandemic.

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[8] Hsai R. and Shen Y. *Emergency Department Closures And Openings: Spillover Effects On Patient Outcomes In Bystander Hospitals*. Health Affairs VOL. 38, No. 9 September 2019. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00125.

[9] Gujral K. and Basu A. *Impact of Rural and Urban Hospital Closures on Inpatient Mortality*. The National Bureau of Econiv Research. NBER Working Paper No. 26182. August 2019, Revised in June 2020. https://www.nber.org/papers/w26182.

[10] 2020 Analysis of Medicare claims data conducted by Health Management Associates.

[11] HRSA Uninsured Program Website. Claims Reimbursement. https://coviduninsuredclaim.linkhealth.com/billing-codes.html.

- Examples of such direct activities include:
    - Following new infection control protocols, including donning and doffing personal protective equipment (PPE);
    - Increased time for patient/family communication and communicating between provider service lines;
    - Expanded cleaning protocols necessitating slower turnaround time on bed space;
    - Increased time for conducting procedures and interventions for patients with known or suspected COVID-19 infection; and
    - Follow up for patients under investigation.

- Examples of such indirect activities include:
    - Monitoring the flow of new research and information;
    - Studying constantly changing treatment and management protocols;
    - Reconciling and adjudicating incongruous or conflicting findings such as understanding asymptomatic transmission during this pandemic or any other;
    - Supervising other physician specialties that were deployed to assist in the care of COVID-19 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 ICU and ventilator capacity;
    - 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;
    - Triage education ongoing for COVID-19 split flow;
    - Management of other work processes not associated with direct patient care but that is required and necessary to effectively manage a pandemic; 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;
    - Alternative housing for providers isolating from their families; and
    - Capturing and reporting COVID-19 related data.

By setting the payment enhancement at 20 percent, the policy would then be consistent with (a) the level set for Modifier ~22 (for enhanced *procedural* services) and (b) the 20 percent MS-DRG weight increase under the Inpatient Prospective Payment System (IPPS) for hospital admissions for patients with a COVID-19 diagnoses. The enhancement could be administered via the usual claims process. The payments for such activities should be retroactive to include services provided during the entirety of the declared PHE.

ACEP strongly urges CMS to implement this COVID-19 professional services claims-based payment

enhancement as quickly as possible to address the ongoing needs of the COVID-19 pandemic. Recognizing that there are often limited rulemaking vehicles in which to implement policies, we therefore **recommend that CMS issue this policy as an Interim Final Rule with Comment** (as it did its previous PHE policies) packaged inside the CY 2021 PFS and QPP final rule.

Policy Recommendation # 2: Delay the Implementation of the Add-on Code for Complexity

To mitigate the budget neutrality adjustment in CY 2021, **ACEP also strongly recommends that CMS delay the implementation of the add-on code for complexity (GPC1X) until CY 2022 or later.** CMS could also consider eliminating the code altogether. As discussed earlier, this code within itself will have a $3.3 billion re-distributional impact. Not implementing the add-on code for complexity in CY 2021 would decrease the overall reduction to emergency medicine by a couple of percentage points.

Beyond emergency medicine, delaying the implementation of the add-on code or potentially eliminating it altogether would also establish a fairer and more equitable payment structure for other specialties that do not bill office and outpatient E/M codes. While ACEP supports an increase in payment for primary care and other office-based visits, other physician specialties do not need to experience significant payment reductions for CMS to still achieve its overall goal.

Policy Recommendation # 3: Use PHE Waiver Authority to Waive Budget Neutrality Requirement

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 request[12] 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 2021.**

Valuation of Emergency Department Evaluation and Management Codes for CY 2021

Background

Every year, CMS re-values codes that have been identified as potentially misvalued. In the CY 2018 PFS final rule, CMS finalized a proposal to nominate CPT codes 99281-99285 as potentially misvalued based on information suggesting that the work relative value units (RVUs) for ED visits may not appropriately reflect the full resources involved in delivering these services. CMS specifically agreed with commenters, including ACEP, that these services might be "potentially misvalued given the increased acuity of the patient population and the heterogeneity of the sites where emergency department visits are furnished."[13] In the past, ACEP has argued that there has been an increase in intensity in reported ED services as a whole, due in part to successful attempts to guide non-emergency patients to other sites of service, as well as the increasing complexity of transition or coordination of care under episode-based or accountable care organization (ACO) models. As

[12] 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.

[13] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program Proposed Rule, 82 Fed. Reg. 53018 (November 15, 2017).

well, practice intensity has increased in EDs because EDs are treating older and sicker Medicare beneficiaries with multiple chronic conditions, and therefore emergency physicians must utilize more sophisticated diagnosis methods to manage the problems of these more-challenged beneficiaries.[14] Therefore, we welcomed the opportunity for the AMA Relative Value Scale (RVS) Update Committee (RUC) to propose new values for the codes.

The five ED E/M codes were surveyed and reviewed for the April 2018 RUC meeting. For CY 2020, CMS proposed and finalized the RUC-recommended work RVUs of 0.48 for CPT code 99281, 0.93 for CPT code 99282, 1.42 for 99283, 2.60 for 99284, and 3.80 for CPT code 99285.

In our comments on the CY 2020 PFS and QPP proposed rule, ACEP stated that we were extremely pleased that CMS agreed with the RUC recommendations for work RVUs for the ED E/M codes in CY 2020. However, we also urged CMS to finalize an additional increase in the ED codes in CY 2021 to maintain the relative value between the new patient office and outpatient codes CMS established for CY 2021 and the ED E/M codes. Specifically, we requested the following:

- That 99283 be raised to match the new proposed work RVU of 99203 to be **1.60**.
- That 99284 be raised to maintain historic relativity to 99204 by 6.9 percent to **2.74.**
- To maintain historic relativity to 99205, CMS would need to raise the code by 10.41 percent to **4.20.**
    - However, although the crosswalk suggests a higher work RVU for 99285, we asked instead for **4.00**, which was the survey median in the 2018 presentation to the RUC based on those that regularly provide the service.

Our proposal was in line with previous statements from the RUC. In fact, the RUC has three times (1997, 2007, and 2018) recommended that the ED E/M codes should be the same value as the new patient Office or Other Outpatient E/M codes for levels 1 through 3 and that levels 4 and 5 should be higher. Further, we argued that it would be reasonable and consistent with CMS' stated policy goals to increase ED E/M codes 99283, 99284, and 99285. CMS had already modified the ED E/M code values in CY 2020 to align them with the office and outpatient E/M code values, and since the office and outpatient E/M values were going to increase the very next year, it would make absolute sense for CMS to make corresponding changes to the ED E/M codes. In other words, if CMS did not take action, the agency would be making an appropriate valuation of emergency physician services in one year (based on an extensive RUC process), and then completely reversing course the following year. In the end, the ED E/M codes and emergency physician payments would be undervalued once again. This would undermine the RUC's recommendation that the ED E/M payments should be more appropriately valued.

CMS Proposal

Based upon our comments and rationale we presented in the CY 2020 PFS and QPP proposed rule as well as follow-up conversations and correspondence with CMS, the agency is proposing to accept our recommended work RVU values for ED E/M codes 99283, 99284, and 99285:

[14] Gonzalez Morganti, Kristy, Sebastian Bauhoff, Janice C. Blanchard, Mahshid Abir, Neema Iyer, Alexandria Smith, Joseph Vesely, Edward N. Okeke, and Arthur L. Kellermann, The Evolving Role of Emergency Departments in the United States. Santa Monica, CA: RAND Corporation, 2013. https://www.rand.org/pubs/research_reports/RR280.html.

Code	2020 RVWs	2021 RVWs
99283	1.42	1.60
99284	2.60	2.74
99285	3.80	4.00

ACEP thanks CMS for supporting our rationale and proposing our recommended values. We strongly urge the agency to finalize the increases as proposed.

As mentioned previously, CMS estimates that the proposed increases will bump up emergency medicine reimbursement by 3 percent, **which is absolutely critical to help offset a portion of the significant budget neutrality adjustment to the conversion factor.**

Telehealth Services

Background

Previous Request

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. Before delving into the specific regulatory changes and waivers CMS temporarily put into place during the pandemic and the proposals included in this proposed rule, it is important to note that ACEP for years has strongly supported the delivery of telehealth services by board-certified emergency physicians. On December 31, 2019, prior to the HHS Secretary declaring a PHE due to COVID-19, ACEP formally requested that CMS consider in this proposed rule to add the following CPT codes to the list of approved telehealth services:

- The five ED E/M Codes
    - 99281 through 99285
- ED Observation Services
    - 99217 through 99220
    - 99224 through 99236; and
    - 99234 through 99236

ACEP had requested that these services be added to the list of approved telehealth services on previous occasions to the December 31, 2019 request. In CMS' response to our first request in the CY 2017 PFS Final Rule, highlighted below, CMS discussed the unique nature of these services and why they are distinct from services currently on the list of approved telehealth services:

"The current request to add the emergency department E/M services stated that the codes are similar to outpatient visit codes (CPT codes 99201–99215) that have been on the telehealth list since CY 2002. As we noted in the CY 2005 PFS final rule, while the acuity of some patients in the emergency department might be the same as in a physician's office; we believe that, in general, more acutely ill patients are more likely to be seen in the emergency department, and that difference is part of the reason there are separate codes describing evaluation and management visits in the Emergency Department setting. The practice of emergency medicine often

requires frequent and fast-paced patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants. This work is distinctly different from the pace, intensity, and acuity associated with visits that occur in the office or outpatient setting. Therefore, we did not propose to add these services to the list of approved telehealth services on a category one basis.

The requester did not provide any studies supporting the clinical benefit of managing emergency department patients with telehealth which is necessary for us to consider these codes on a category two basis. Therefore, we did not propose to add these services to the list of approved telehealth services on a category two basis. Many requesters of additions to the telehealth list urged us to consider the potential value of telehealth for providing beneficiaries access to needed expertise. We note that if clinical guidance or advice is needed in the emergency department setting, a consultation may be requested from an appropriate source, including consultations that are currently included on the list of telehealth services."[15]

Given this response, we asked CMS in our December 31, 2019 request to consider adding these codes under a Category 2 basis. The Category 2 standard requires that "the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient."[16]

In our request, ACEP stated that we believed that results from innovative emergency telehealth initiatives suggested that having the ability to provide ED E/M services remotely to Medicare beneficiaries will improve care and lower costs across the country, in both urban and rural areas. Different types of emergency care models have already been tested, from "direct-to-consumer" models to models that involve a hub that connects emergency physicians to EDs in remote locations or allows emergency physicians to provide consultations for specific clinical conditions. In general, studies have shown that physicians and patients are extremely satisfied with the care being provided through these models, and costs have decreased due to avoided ED visits and inpatient admissions.

Some successful programs that we noted in our request included:

- Emory University Hospital has just completed a successful pilot study focusing on care delivered in their emergency department observation units (EDOUs). Most U.S. hospitals do not have protocol-driven EDOUs despite their documented benefits. The observational study took place in Emory's academic hospital 8-bed EDOU. During a six-day period, the ED attending supervising the EDOU participated in morning patient rounds entirely via a telehealth device which an advanced practice provider (APP) carted into patient rooms. Immediately after, the same ED attending physician re-examined all patients in person to determine if tele-rounding missed any clinical details. The study found that there were no patient history or examination findings that were missed due to telehealth. The goal of this project, once fully established, would be to use telehealth to oversee remote observation units across numerous hospitals.

- The University of Mississippi Medical Center (UMMC) in Jackson, Mississippi provides emergency medicine specialist expertise to advance practitioners in approximately 20 to 30 rural EDs throughout

[15] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements Final Rule, 81 Fed. Reg. 80196 (November 15, 2016).

[16] CMS Medicare Telehealth webpage: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Criteria.

the state of Mississippi. Many of these EDs may have closed without the UMMC program providing emergency physician back-up and support to the mid-level providers on-site. Since the program's inception, over 500,000 patients have had access to board certified emergency medicine specialists without ever leaving their small community. UMMC was recognized by the Health Resources and Services Administration in 2017 as a Center of Excellence in Telehealth for its work and accomplishments in telehealth.

- Avera Health based in Sioux Falls, SD provides telehealth services through a program called eCARE to approximately 440 unique health care facilities in 25 states; 200 of which are rural hospitals. The model centers around a telehealth hub which is staffed 24 hours a day by an interdisciplinary team of physicians, nurses, pharmacists, and social workers. During an eCARE shift, clinicians only see patients via telehealth and are attuned to the specific needs of the rural facilities. Started in 2009, eCARE has provided instant access to board-certified emergency physicians and critical care nurses who operate as a part of the rural emergency team. The eCARE emergency team can expedite care, bring in specialists, assist with patient codes, call in support staff, and arrange transfers or whatever else is needed during a critical emergency case. Results to date include:
    - $49,841 in average annual savings to hospitals, because of better staffing options[17]
    - Potential to result in net savings of $3,823 per avoided Emergency transfer[18]
    - $117,406 decrease in total ED costs[19]
    - $30 million saved in avoided transfers

- In the remote international port in the Aleutian Islands in Alaska, Iliuliuk Family and Health Services has partnered with emergency physicians and critical care doctors at Anchorage Hospital, more than 800 miles away, to respond to emergencies. While the volume of cases is low, there are occasionally high-acuity emergent cases. Using satellite technology, primary care physicians can consult with emergency physicians in Anchorage to stabilize patients and prevent the need to have them transported to a hospital that is hundreds of miles away.

In summary, we stated that these emergency telehealth initiatives have proven to be successful and add clinical benefit to patients and that we strongly believed that emergency telehealth services, if provided to Medicare beneficiaries, would yield similar positive results.

COVID-19 PHE Policies

ACEP recognizes that the COVID-19 PHE has changed the landscape of telehealth from what is was when we made our formal request at the end of 2019. 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, was 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

[17] MacKinney AC, Ward MM, Ullrich F, Ayyagari P, Bell AL, Mueller KJ. The Business Case for Tele-emergency. Telemed J E Health. 2015 Dec;21(12):1005-11. http://www.ncbi.nlm.nih.gov/pubmed/26226603.

[18] Natafgi N, Shane D, Ullrich F, MacKinney C, Bell A, Ward M. (2017). Using Tele-Emergency to Avoid Patient Transfers in Rural Emergency Departments: An Assessment of Costs and Benefits. Journal of Telemedicine and Telecare. March 7, 2017. doi: https://doi.org/10.1177/1357633X176965854.

[19] Ward M, Merchant AS, Carter KD, Zhu X, Ullrich F, Wittrock A, Bell A. (2018) "Use of Telemedicine For ED Physician Coverage In Critical Access Hospitals Increased After CMS Policy Clarification." Health Affairs (Millwood). 2018, 12, 37. doi: 10.1377/hlthaff.2018.051032.

where the clinicians or the patients are allocated—in both urban and rural areas. Further, CMS temporarily allowed medical screening exams (MSEs), a requirement under Emergency Medical Treatment and Labor Act (EMTALA), to be performed via telehealth. Finally, CMS temporarily added all five ED E/M codes, the observation codes, and critical care codes to the list of approved Medicare telehealth services.

CMS ED E/M Telehealth Proposals

Code Proposals

In the proposed rule, CMS breaks out the codes that it temporarily added to the list of approved telehealth services during the COVID-19 PHE into three buckets:

- BUCKET 1: Codes that CMS is proposing to be included on the list of approved telehealth services permanently.

- BUCKET 2: Codes that CMS is proposing to be included on the list of approved telehealth services for the remainder of the calendar year in which the PHE ends (i.e. if the PHE ends in January 2021, the codes would remain on the list until December 31, 2021). CMS is adding these codes through a newly established category for evaluating whether telehealth codes should be added to the list of approved telehealth services: "Category 3."

- BUCKET 3: Codes that CMS is proposing to be removed from the list of approved telehealth services once the PHE ends.

CMS is proposing to only include in Bucket 1 those codes that are similar to office-based codes which are already permanently on the list of approved telehealth services. **However, CMS is proposing to add the ED E/M codes levels 1-3 (CPT codes 99281-99283) to the list of approved telehealth services on a Category 3 basis (Bucket 2).** CMS states in the rule that it believes that these codes have the potential to add clinical benefit outside of the PHE and could therefore be added to the list permanently. However, CMS is looking for additional information from the public that would supplement its clinical assessment of these codes. While CMS recognized that formal analyses may not be available during the pandemic, it is looking for comments on the following:

- By whom and for whom are the services being delivered via telehealth during the PHE;
- What safeguards are being employed to maintain safety and clinical effectiveness of services delivered via telehealth;
- What specific health outcomes data are being or are capable of being gathered to demonstrate clinical benefit;
- How is technology being used to facilitate the acquisition of clinical information that would otherwise be obtained by a hands-on physical examination if the service was furnished in person
- Whether patient outcomes are improved by the addition of one or more services to the Medicare telehealth services list,
- Whether the permanent addition of specific, individual services or categories of services to the Medicare telehealth services list supports quick responses to the spread of infectious disease or other emergent circumstances that may require widespread use of telehealth; and

- What is the impact on the health care workforce of the inclusion of one or more services or categories of services on the Medicare telehealth services list.

CMS proposes to place ED E/M codes levels 4 and 5 (CPT codes 99284 and 99285) as well as hospital, intensive care unit, emergency care, and observation stays and critical care services (CPT codes 99217-99220; 99221-99226; 99484-99485, 99468-99472, 99475- 99476, 99477- 99480, and 99291-99292) in Bucket 3. CMS is concerned that these services cannot truly be performed be met via two-way, audio/video telecommunications technology, due to the characteristics of patients who receive the services, the clinical complexity involved, the urgency for care, and the need for complex decision-making. Although CMS is proposing not to add these codes to the list of approved services past the end of the PHE, it is seeking comment on whether any of these codes should be shifted to bucket 2 and added temporarily on a Category 3 basis.

ACEP Comments on CMS Telehealth Proposals

ED E/M Codes Levels 1-3

ACEP believes that CMS should have specifically addressed our December 31, 2019 request for the ED E/M codes and observation codes to be added to the list of approved Medicare telehealth services in the proposed rule. Historically, CMS has always responded to requests for additions to the list of approved Medicare telehealth services in the PFS proposed rule, and we thought CMS should have at least acknowledged that request in the rule.

Nevertheless, we wish to provide comments on the specific proposals included in the proposed rule. Consistent with our request from 2019, **ACEP strongly urges CMS to add the ED E/M codes levels 1-3 (CPT codes 99281-99283) permanently to the list of approved Medicare telehealth services.** CMS should add these services on a Category 2 basis, as we continue to believe that these services add significant clinical value. We also believe that these ED E/M codes best reflect the services that emergency physicians typically render, regardless of whether these services are delivered in-person or remotely via telehealth.

We do appreciate that CMS has proposed to add these codes temporarily on a Category 3 basis. Since the HHS Secretary, Alex Azar, recently announced that the PHE would be extended for 90 days past its current expiration date of October 23, 2020, we note that the codes added on a Category 3 basis would—under CMS' proposal—remain on the list of approved telehealth services until the end of CY 2021.

In making our request for CMS to add these codes on a Category 2 basis, please find our responses to CMS' specific questions:

By whom and for whom are the services being delivered via telehealth during the PHE

During the COVID-19 PHE, emergency physicians provided telehealth services in the following three different clinical situations, all of which added clinical value to patients:

1. ***Preventing Medicare Beneficiaries from making unnecessary visits to the ED.*** Medicare beneficiaries who had urgent medical needs, but were unsure if they were having a medical emergency, were able to contact their EDs and have a telehealth visit with an emergency physician to assess whether the patient could stay at home, go to a urgent care clinic, or visit the ED. While previously Medicare beneficiaries had the opportunity to go to the ED if needed, this type of telehealth visit has now

provided Medicare beneficiaries with a safe way of getting their condition evaluated before making that decision. Emergency physicians are trained in rapid diagnosis and evaluation of patients with acute conditions, so they are most capable of providing these type of telehealth services. In many cases, we are able to provide treatment to patients with minor illnesses and injuries completely via telehealth.

2. ***Providing MSEs to Patients who came to the ED.*** As alluded to above, CMS released guidance stating that physicians (or other qualified medical persons) can perform MSEs via telehealth and where appropriate meet the MSE requirement without an in-person examination. Hospitals are temporarily allowed to set up alternative locations "on campus" for patients to receive an MSE other than in the ED. For example, patients presenting with possible symptoms of COVID-19 and meeting certain criteria (i.e. vital sign parameters) can be sent to a negative-pressure tent, where they are seen by an in-person nurse and a physician via telehealth (video and audio) who determines if the patient can be discharged from the tent or needs to be seen in the ED. After completing this process, a low percentage of patients need ED evaluation.

3. ***Ensure appropriate follow-up care after ED discharges:*** Emergency physician groups have set up systems and protocols to follow-up with patients once they are discharged from the ED, ensuring that patients are taking their medications appropriately or are seeing their primary care physician or specialist if needed. These follow-up services have helped enhance care coordination efforts and avoid trips back to the ED or inpatient admissions. In addition, for patients under investigation for COVID-19, the treating ED group has been able to follow up with the patient to make sure their COVID symptoms are not progressing. Some groups have sent patients home with portable pulse oximeters and followed up to check their general status and oxygen levels.

<u>What safeguards are being employed to maintain safety and clinical effectiveness of services delivered via telehealth</u>

Being able to provide **emergency services via telehealth has helped preserve PPE and reduce unnecessary exposure to COVID-19.** Emergency physicians are at an increased risk of contracting COVID-19 due to frequent and close physical interactions among patients and other health care workers. Having the ability to provide telehealth services has reduced face-to-face contact, without compromising care. Medicare beneficiaries and other patients have been able to safely receive services either from their home, the ED, or an alternative location within the hospital. Through tele-triage systems and medical screening exams, beneficiaries are able to receive timely care in the right setting.

EDs across the country have also integrated their telehealth programs into their existing quality improvement initiatives, setting targets and metrics to ensure that the quality of care that is delivered is maintained and improved over time.

<u>What specific health outcomes data are being or are capable of being gathered to demonstrate clinical benefit</u>

ACEP expects to see improved health outcomes due to the proliferation of emergency telehealth services. For example, telehealth has the potential to improve care coordination and limit avoidable trips to the ED or hospital. Further, it allows for screening examinations that do not need to be done in person, thereby reducing the chance of exposure to COVID-19. Finally, it improves access to care for beneficiaries, a clear clinical benefit, by connecting patients with clinicians from any location in a timely manner.

Some EDs have been able to track data that could be used to evaluate clinical outcomes, such as monitoring whether a patient required an additional medical visit after the telehealth visit and determining the percentage of patients who avoided an ED or urgent care visit for the illness or injury.

How is technology being used to facilitate the acquisition of clinical information that would otherwise be obtained by a hands-on physical examination if the service was furnished in person

Emergency telehealth programs have used technology to help ascertain key clinical information from patients, ensuring that emergency physicians are able to rapidly diagnose patients during a telehealth encounter. Emergency physicians are able to provide examinations using video communications systems and have found to be able to provide key elements of the physical exam. It also is useful to have blood pressure, heart rate, and pulse ox measured, if available, but those tools are only really needed for higher acuity patients. Wireless medical telemetry systems (WMTSs), such as VIOS, GE Healthcare, Edan, Medeia, and Phillips, can be used for real-time monitoring of patients.

Whether patient outcomes are improved by the addition of one or more services to the Medicare telehealth services list

Yes, we believe that adding the ED E/M codes to the list of approved telehealth services will improve patient outcomes, especially through increased access to timely emergency care. We also think that outcomes can be improved by allowing patients to receive services in the appropriate care setting and helping them avoid unnecessary trips to the ED or to the hospital. Evidence suggests that increased use of emergency telehealth can result in overall cost savings to the system by diverting patients from expensive care settings and by averting transfers to inpatient facilities.

Whether the permanent addition of specific, individual services or categories of services to the Medicare telehealth services list supports quick responses to the spread of infectious disease or other emergent circumstances that may require widespread use of telehealth

As stated above, all the policies that CMS enacted to expand the use of emergency telehealth services during the COVID-19 PHE have protected both clinicians and patients and have saved lives. Having the ED E/M codes levels 1-3 on the list of approved telehealth services permanently would allow EDs that have stood up telehealth programs during the COVID-19 PHE to continue providing these services and be even more ready to respond to the next disaster.

What is the impact on the health care workforce of the inclusion of one or more services or categories of services on the Medicare telehealth services list

Being able to provide the ED E/M services via telehealth has truly helped address unprecedented staffing challenges during the PHE. Older physicians, or those who are quarantined but asymptomatic, immunocompromised, pregnant, or have underlying medical conditions, have been able to continue to work with minimal to no exposure and also minimize the impact to staffing issues during this critical time. Physicians and other health care practitioners whose clinics are closed, retired physicians, surgeons with canceled elective surgeries, resident physicians, locums, volunteer physicians, and those physicians from areas that are only mildly affected have all provided services.

Going forward, being able to provide emergency telehealth services can help address workforce issues and shortages of board-certified emergency physicians in rural areas. According to a comprehensive report from the Emergency Medicine Residency Association (EMRA),[20] around 80 percent of new physicians start working in areas that already have a high supply, leaving rural areas perpetually underserved.[21] While 21 percent of the U.S. population lives in rural areas, only 12 percent of emergency physicians practice there. Not only is the density of emergency physicians lowest in rural settings (10.3 urban vs. 5.3 large rural vs. 2.5 small rural), but also the percentage of emergency physicians with residency training in emergency medicine is lower as well. Rural physicians who identify as having emergency medicine as a specialty are less likely to have formal emergency medicine training (31 percent vs. 57 percent), be board certified (43 percent vs. 59 percent) or to have graduated in the past 5 years (8 percent vs. 19 percent).[22]

Importantly, new data show that while 64 percent of all emergency medicine practitioners in urban counties are emergency physicians, only 45 percent of practitioners in rural counties are. Rural counties make up the difference largely with non-emergency trained physicians: non-emergency physicians make up 12 percent of emergency medicine clinicians in urban counties, but more than 28 percent of EM clinicians in rural counties. The percentage of emergency medicine clinicians who are advanced practice providers is relatively similar between urban and rural counties at 24.1 percent and 26.8 percent, respectively.[23]

ED E/M codes can also be used in demonstrations like the Emergency Triage, Treat, and Transport (ET3) Model where a paramedic or emergency medical services (EMS) technician is onsite with a Medicare beneficiary but can connect with a board-certified emergency physician who is able to treat the beneficiary remotely via telehealth. This kind of approach, if done appropriately, certainly helps address staffing issues and ensures the patients get timely care. Under current ET3 rules, physicians providing telehealth services to beneficiaries can only bill codes on the list of approved telehealth services. ED E/M codes best represent the nature and intensity of services being delivered under this model.

ED E/M codes levels 4 and 5 (CPT codes 99284 and 99285) as well as hospital, intensive care unit, emergency care, and observation stays and critical care services (CPT codes 99217-99220; 99221-99226; 99484-99485, 99468-99472, 99475-99476, 99477- 99480, and 99291-99292)

ACEP understands CMS' rationale for not proposing to include these higher-level ED visit codes and other critical care codes on the list of approved telehealth services going forward past the end of the PHE. We note that under current Medicare telehealth rules, physicians in the ED can bill office and outpatient E/M codes levels 1 through 5 when performing telehealth services using place of service (POS) code 02. There are many situations where it is appropriate for emergency physicians to provide telehealth services to patients where they could use a higher-level office and outpatient E/M code. However, as we stated earlier in the "Valuation of Emergency Department Evaluation and Management Codes for CY 2021," we believe that ED E/M codes 4 and 5 reflect services that are delivered to sicker, more critical patients than those who typically present to the office and outpatient setting for non-emergent or urgent care. That is why we agree with CMS' proposal to set

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[20] Emergency Medicine Residency Association. *Emergency Medicine Advocacy Handbook*. https://www.emra.org/books/advocacy-handbook/advhbook/.

[21] Goodman DC. Twenty-year trends in regional variations in the U.S. physician work- force. *Health Aff (Millwood)*. 2004;Suppl Web Exclusives:VAR90-VAR97.

[22] Hall MK, Burns K, Carius M, Erickson M, Hall J, Venkatesh A. State of the National Emergency Department Workforce: Who Provides Care Where? *Ann Emerg Med*. 2018;72(3):302-307.

[23] Health Resources & Services Administration. National Health Service Corps Loan Repayment Information. https://nhsc.hrsa.gov/loan-repayment/index.html.

the work RVU values for the ED E/M codes 4 and 5 at higher levels than the respective office and outpatient E/M codes for new patients. In other words, CMS' proposal to not include these services on the list of approved telehealth services past the end of the pandemic aligns with its overarching view that these codes represent care delivered to sicker patients where higher intensity interventions and treatment are required.

Nevertheless, we do believe there are certain cases where it is appropriate to provide higher level and critical care to patients via telehealth. Patients in rural EDs can be co-managed by emergency physicians in tertiary care EDs, thus saving expensive patient transports (including by helicopter). Board-certified emergency physicians with extensive critical care and trauma experience can provide medical guidance and collaborative care to patients being treated in rural EDs or at rural hospitals (including critical access hospitals) by a non-specialized ED clinician. Effective telehealth collaboration for high-level cases (which would yield ED E/M codes of level 4 or 5) could facilitate clinical collaboration and decrease unnecessary transfers. In fact, one study found significant cost savings from averted transfers across a cohort of ED telehealth programs in rural areas. Averted transfers saved on average $2,673 in avoidable transport costs per patient, with 63.6 percent of these cost savings accruing to public insurance.[24]

In addition, as discussed above, there is a shortage of rural board-certified emergency physicians that is continuing to grow. Thus, eventually more and more critical care services may need to be delivered via telehealth over time to ensure that patients receive timely and necessary care. **CMS should therefore consider adding the ED E/M codes, the observation codes and at least a subset of the remaining critical care codes to the list of approved telehealth services on a Category 3 basis.** Further, CMS should test the use of these high-level ED codes and critical care codes in Centers for Medicare & Medicaid Innovation (CMMI) models, including the ET3 model mentioned above. Testing the ability to bill for these codes in CMMI models may demonstrate clinical effectiveness and may eventually give CMS the information it needs to add these codes to the list of approved telehealth services on a Category 2 basis.

Audio-only Codes

CMS is not proposing to continue to include telephone codes (audio-only) on the list of approved telehealth services past the PHE. CMS states that it does not have the authority to waive the requirement that telehealth services include both an audio and visual requirement. However, CMS is seeking comment on whether the agency should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. CMS is also seeking comment on whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE or if it should be PFS payment policy permanently.

ACEP believes that the temporarily addition of audio-only codes to the approved list of telehealth services has served as a viable way of connecting beneficiaries who may not have access to two-way audio and visual devices to their physicians during the COVID-19 PHE. However, we understand that current legislative restrictions prevent the agency from adding these codes permanently to the list of approved telehealth services, and therefore recommend that CMS defer to Congress on this issue.

[24] Ward MM, Carter KD, Ullrich F, et al. "Averted Transfers in Rural Emergency Departments Using Telemedicine: Rates and Costs Across Six Network." *Telemed J E Health.* 2020;10.1089/tmj.2020.0080. https://pubmed.ncbi.nlm.nih.gov/32835620/.

Direct Supervision

Many services under the PFS can be delivered by auxiliary personnel under the direct supervision of a physician. In these cases, the supervision requirements necessitate the presence of the physician in a particular location, usually in the same location as the beneficiary when the service is provided. During the PHE, CMS is temporarily modifying the direct supervision requirement to allow for the virtual presence of the supervising physician using interactive audio/video real-time communications technology. In the rule, CMS is proposing to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021. CMS is soliciting input on circumstances where the flexibility to use interactive audio/video real-time communications technology to provide virtual direct supervision could still be needed and appropriate.

ACEP believes this policy has been helpful during the PHE and would therefore be supportive of continuing such a policy past the end of the pandemic. Doing so would extend the reach of board-certified emergency physicians to areas of the country where there may not be any such physicians available. We believe that it is essential to have board-certified emergency physicians directly supervise all care delivered in EDs, and telehealth represents a viable tool to accomplish this goal.

Physician Practice Expense Data Collection

CMS provides a brief update on a January 2020 convened Technical Expert Panel (TEP) and analyses performed by the RAND Corporation. While CMS is not proposing changes to the practice expense (PE) methodology or data collection process, we believe that CMS should consider altering its PE methodology going forward to better account for uncompensated care costs due to the Emergency Medical Treatment and Labor Act (EMTALA). EMTALA guarantees that that patients receive emergency medical care regardless of their insurance status or ability to pay. Emergency physicians or other qualified health professionals must screen patients presenting at the ED to determine if an emergency medical condition is present. If an emergency medical condition is found, EDs are required to either stabilize the patient prior to transfer, or to obtain a certification that the transfer is appropriate. Although health care practitioners are required to screen and stabilize patients, insurer payment for that treatment is not guaranteed. Emergency physicians therefore have a higher proportion of uncompensated care than other specialists.

Unfortunately, the cost to emergency physicians of having to absorb uncompensated care is not adequately reflected in the PE component of the ED E/M codes. The first step to incorporating these costs into the PE values for these codes would be to conduct a survey and collect data. Such a survey on uncompensated costs has not been done in 20 years. In 2000, the last time such a survey was administered, emergency medicine physicians attributed 61.0 percent of the bad debt they incurred to EMTALA, or $138,300 per year. This data should be updated and used to set more appropriate PE values that truly reflect the cost of delivering emergency services.

Scope of Practice

CMS is proposing to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests in addition to physicians. CMS granted this flexibility during the COVID-19 PHE and is now proposing to extend it permanently. CMS is concerned about ensuring an adequate workforce in areas where there are shortages and seeks information about states that have scope of practice laws in place.

ACEP opposes this proposal. In general, ACEP believes that NPs and PAs should not provide unsupervised ED care. 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 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 and other health care professionals, including APRNs and 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. By comparison nurse practitioners, the largest category of APRNs, must complete only 500-720 hours of clinical training after two-three years of graduate-level education. Physician assistant programs are two-years in length and require 2,000 hours of clinical care. Neither nurse practitioner nor PA programs include a residency requirement. The difference does not stop there as physicians are required to pass a series of comprehensive examinations prior to licensure as well as further examinations for specialty board certification. By contrast nurse practitioners must pass a single test consisting of 150-200 multiple choice questions. Similarly, 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 nurse practitioners and PAs are not commensurate with physicians.

Medicare patients are some of the most medically vulnerable patients in our population, often suffering from multiple chronic conditions or other complex medical needs. As such they deserve care led by physicians - the most highly educated, trained and skilled health care professionals. We cannot and should not allow anything less. Patients agree and overwhelmingly want physicians leading their health care team. In fact, 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.

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 physician assistants. Most states require physician supervision of or collaboration with nurse anesthetists, one type of APRN, 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's clear nurse practitioners and primary care physicians tend to work in the same large urban areas. This occurs regardless of the level of autonomy granted to nurse practitioners at the state level.

Finally, we caution against positioning scope of practice as an administrative burden. Doing so obfuscates the very real administrative burdens facing physicians and other health care professionals every day, where every hour they spend providing clinical care to their patients requires two hours of administrative tasks**. 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, not based on politics. Patients – and in this case Medicare patients – deserve nothing less.

PFS Payment for Services of Teaching Physicians

CMS is seeking comment on whether to permanently or at least temporarily extend the policy instituted during the COVID-19 PHE that allows teaching physicians to supervise residents remotely using telehealth equipment. ACEP supports this proposal as this expands the ability of board-certified emergency physicians to train the next generation of emergency physicians.

Medical Documentation Requirements

In last year's rule, CMS finalized numerous changes to the medical record documentation requirements for physicians and other health care practitioners. In this proposed rule, CMS is clarifying that physicians and other health care practitioners, including therapists, can review and verify documentation entered into the medical record by members of the medical team for their own services that are paid under the PFS. ACEP continues to support the policy that CMS finalized in last year's rule, as we believe that this broad flexibility will significantly reduce burden for teaching physicians.

Payment for Medication Assisted Treatment (MAT) in the ED

CMS is proposing to pay for medication assisted treatment (MAT) delivered in the ED starting in 2021. Specifically, CMS is proposing to create an add-on code to be billed with E/M visit codes used in the ED setting. This code would include payment for assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services. The add on code would have a work RVU value of 1.30.

ACEP strongly supports the addition of the new add-on code and urges CMS to finalize the proposal as proposed. We have seen great results with utilizing buprenorphine to help start patients on the path towards recovery. Initiating MAT in the ED helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and decreases overdose deaths.[25] In addition, the available data demonstrate that patients with opioid use disorder (OUD) who are started on 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).[26]

25 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.

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

Substantially increased participation in MAT, after ED buprenorphine initiation has been replicated in additional studies.[27][28][29]

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.[30] 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.[31] 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.

As CMS implements the new code, we do request that CMS provide additional guidance to clarify whether all of the discrete actions listed in the code must actually be completed by the clinician that bills the service. As CMS states in the rule, the code is designed to reimburse for "assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services." We note that the "initiation" of the service for patients will involve a transition of care to other clinicians outside the ED. Thus, we believe it will be particularly helpful for CMS to clarify what "follow-up" is required of the ED clinician who bills the service given that post-initiation care is administered by the practitioner outside the ED to whom the ED clinician would have transitioned the patient care.

Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

In the CY 2020 PFS and QPP final rule, CMS implemented a new Medicare benefit for the treatment of OUD furnished by Opioid Treatment Programs (OTPs). In doing so, CMS established new codes describing the bundled payments for certain episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. In this proposed rule, CMS is proposing several refinements to the new benefit. One of the new proposals is to expand the definition of OUD treatment services to include opioid antagonist medications, such as naloxone.

ACEP supports the proposal but believes that **at least some of these services should also be reimbursed for when delivered in the ED in addition to OTPs, such as the administration of naloxone.** We agree with CMS that naloxone is truly a life-saving drug, which when used properly can immediately reverse opioid overdose. This medication can be administered intravenously, intramuscularly, or intranasally and is effective within minutes. Victims of opioid overdose often completely stop breathing and without respiratory support death is imminent. However, after the prompt administration of naloxone, the victim begins to breathe again

[27] 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.

[28] 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.

[29] Edwards F, Wicelinski R, Gallagher N, et al. Treating Opioid Withdrawal with Buprenorphine in a Community Hospital Emergency Department: An Outreach Program. Ann Emerg Med. 2020 Jan;75(1):49-56.

[30] 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.

[31] 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.

and may quickly become fully conscious, rescued from the edge of death. Naloxone has been utilized in hospitals and by fire and emergency medical services (EMS) personnel for decades. The CDC has advocated for increasing naloxone administration by EMS personnel in an effort to reduce even more opioid-related deaths.[32]

While there has been a movement to increase prompt access to naloxone for opioid overdose victims over the last several years, the price of naloxone in nearly all forms of packaging has been steadily climbing in this country. These rising prices have affected the ability of emergency medical services providers to obtain enough naloxone to treat all the overdose cases they see. In addition, the cost of naloxone products which laypersons can obtain may in some cases be the highest of all, limiting their ability to provide immediate treatment to members of their communities.

ED "take home naloxone programs" (THNP) also need to be far more prevalent. Research shows that patients who receive a prescription for naloxone are more likely to enter a treatment program, report decreased drug use and demonstrate a greater willingness to undergo screening for HIV and hepatitis C.[33]A secondary effect has also been noted, in which 28 percent of take-home naloxone kit recipients report training a friend or family member how to use the antidote within three months of receiving the prescription.[34] Dispensing naloxone to high-risk patients from the ED is one of the most efficient ways to get naloxone into the hands of individuals at the highest risk of opioid overdose. However, hospitals face regulatory and administrative barriers to dispensing naloxone, the greatest barrier being an inability to bill for or recuperate costs of naloxone that is dispensed. As a result, most EDs with THNPs are either grant-funded or hospital funded. Hospitals will dispense naloxone as long as there is a grant or other program which provides the naloxone kits to be dispensed. Once the grant-funded supply runs out, then suddenly the ED (or inpatient unit) no longer has naloxone to dispense, until the next grant comes along. Then the clinicians may stop ordering it, because they cannot keep track of when it is available and when it is not.

The CDC can also take a leading role in making every hospital a distribution point for naloxone. Take-home naloxone programs could be much more rapidly, and broadly, implemented if hospitals/EDs were simply permitted to bill insurers, including Medicare, for dispensing naloxone products (rather having to rely on a grant-funded naloxone distribution program).

ACEP strongly recommends that CMS introduce a proposal in next year's rule that would allow EDs to get reimbursed for administering naloxone, and emergency physicians and other clinicians working in EDs to get compensated for the time that is spent counseling patients on how to appropriately use naloxone at home. That way, EDs have a stable supply of naloxone that can be distributed to patients in need. This policy is especially needed now that the U.S. Food and Drug Administration (FDA) has officially recommended [35] that health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat OUD. The FDA also outlines circumstances where health care

[32] The Centers for Disease Control, "Expanding Naloxone use could reduce drug overdose deaths and save lives," 24 April, 2015, available at: https://www.cdc.gov/media/releases/2015/p0424-naloxone.html.

[33] Mcdonald R, Strang J. Are take-home naloxone programmes effective? Systematic review utilizing application of the Bradford Hill criteria. Addiction. 2016;111(7):1177-1187. doi:10.1111/add.13326.

[34] Strang J, Manning V, Mayet S, et al. Overdose training and take-home naloxone for opiate users: prospective cohort study of impact on knowledge and attitudes and subsequent management of overdoses. Addiction. 2008;103(10):1648-1657. doi:10.1111/j.1360 0443.2008.02314.)

[35] U.S Food and Drug Administration. *FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder.* 7-23-2020 Drug Safety Communication. https://www.fda.gov/media/140360/download.

professionals should consider prescribing naloxone, including to patients who are at increased risk of opioid overdose or household members, including children or other close contacts at risk for accidental ingestion or opioid overdose. Further, the FDA is requiring drug manufacturers for all opioid pain relievers and medicines to add new recommendations about naloxone to the prescribing information. According to the FDA, this will help ensure that health care professionals discuss the availability of naloxone and assess each patient's need for a naloxone prescription when opioid pain relievers or medicines to treat OUD are being prescribed or renewed.

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. To help inform CMS's implementation of this requirement, the agency recently issued a request for information (RFI). ACEP is responding to that RFI under separate cover. In this rule, CMS is proposing to require EPCS by January 1, 2022 (a delay of one year from the statutorily required date of January 1, 2021) to allow for sufficient time to implement feedback from the RFI and to help ensure that the agency is not burdening clinicians during the COVID–19 pandemic.

ACEP supports the proposal to delay this requirement until at least 2022. Further, as CMS implements the requirement, we believe that CMS must consider factors unique to emergency medicine. The majority of our 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 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 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.

Finally, we encourage CMS to work closely with the Drug Enforcement Administration (DEA) on implementing the EPCS requirement. The DEA recently reopened the Electronic Prescriptions for Controlled

Substances Interim Final Rule (IRF) for comments.[36] ACEP appreciated the opportunity to comment on this regulation[37], as a lot has changed since the IRF was first released ten years ago. Going forward, we believe it is important for the DEA and CMS to work together in order to ensure that the final implementation timeline adopted by CMS for Medicare prescriptions takes into account the DEA's timeframe for implementing new regulations. Sufficient time will need to be allotted between the DEA issuance of revised regulations and the imposition of new Medicare requirements for vendors to update their products to comply with the new DEA requirements and for medical practices to acquire and transition to the new technology.

Medicare Shared Savings Program

CMS proposes numerous changes to the Medicare Shared Savings Program (MSSP), including introducing a new set of quality reporting requirements and measures that accountable care organizations (ACOs) must follow. We have some comments on this new Alternative Payment Model (APM) Performance Pathway (APP) framework in the "APM Performance Pathway" section below. CMS is also proposing refinements to the list of codes that are used to assign beneficiaries to ACOs and altering the methodology for determining shared savings and shared losses based on ACO quality performance.

ACEP notes that overall, we have heard that only a limited number of emergency physicians actually participate directly in the MSSP. While emergency physicians could possibly be part of a larger physician group or hospital participating in the MSSP or another ACO model, emergency physicians do not play an active role in these initiatives.

We are however still concerned that CMS is imposing significant changes to the MSSP quality scoring methodology all in one year and believe that CMS should instead phase them in over time. We also oppose CMS' proposal to remove the pay-for-reporting year currently provided to those ACOs beginning an initial MSSP contract as well as for individual measures that are newly introduced to the measure set. Providing the pay-for-reporting year is critical to an ACO's success, and it encourages less experience organizations to form ACOs and participate in the program.

[36] Drug Enforcement Administration. Docket No. DEA-218I. "Electronic Prescriptions for Controlled Substances." https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0421_3.htm.

[37] ACEP's comments on the DEA IFC can be found at: https://www.acep.org/globalassets/new-pdfs/advocacy/acep-response-to-dea-electronic-prescribing-interim-final-rule.pdf.

The Quality Payment Program

MIPS Value Pathways (MVPs)

Over the past years, CMS has heard feedback, including from ACEP, that MIPS reporting should be streamlined and more meaningful to clinicians. Therefore, CMS proposed in the CY 2020 PFS and QPP rule to create the MIPS Value Pathways (MVPs), an approach that would allow clinicians to report on a uniform set of measures on a particular episode or condition in order to get MIPS credit. CMS previously indicated that it would propose the first set of MVPs in this rule, so that some MVPs could be implemented in 2021.

However, due to the COVID-19 pandemic, CMS did not propose any MVPs for 2021 in this year's rule. Rather, CMS is postponing MVPs to at least 2022 and is seeking comment on proposed revisions to the MVP guiding principles that CMS established in last year's rule.

Overall Concerns

In the rule, CMS lays out a process for stakeholders (including specialty societies such as ACEP) to submit their candidate MVPs for consideration by CMS. CMS will follow up with the stakeholder as needed and then may decide to propose and finalize the MVP through rulemaking. While we appreciate CMS' attempt to have outside stakeholders drive this process and do believe that input from specialty societies is critical, we also recognize the amount of time and resources that would be required to develop MVPs. CMS appears to be solely relying on stakeholders to fund the development of MVP concepts for their specialties and any new quality and cost measures associated with the MVP. Some specialty societies will not be able to put forth MVP concepts simply because they do not have the financial resources necessary to conduct this work. If CMS is committed to developing robust MVPs, we believe that it is CMS' responsibility to bear the cost of all quality and cost measure development and testing work. This is especially true of cost measures, where currently, there are no available episode-based cost measures that can be attributable to many specialists, including emergency physicians. Since emergency medicine does not have viable cost measures, we are also concerned about the potential in the short term to develop an emergency-medicine focused MVP that includes measures that link across the Quality, Cost, and Improvement Activity categories of MIPS.

Further, we do believe additional transparency in the MVP development process is needed. Under the proposed process, CMS could take a stakeholder submitted proposal, provide some feedback, and then include its own version of the proposal in a proposed rule. In other words, CMS could in theory include a completely altered proposal in the rule and state that it was developed "in partnership" with an external stakeholder. Should that occur, the stakeholder may even wind up opposing its own proposal since it does not reflect the intended proposal. That would be completely counter to CMS' goal of working in conjunction with stakeholders. Therefore, if CMS does propose any changes to a proposed MVP from what the stakeholder originally submitted, it must clearly describe all these changes in the proposed rule.

We are also are generally concerned about the timeline for finalizing new MVPs. Under CMS' proposed timeline, MVPs would be finalized in the PFS/QPP final rule each year, which typically is released in early November. The MVP would then "go live" the following calendar year, around two months later. This may not be enough time for clinicians to understand the reporting requirements associated with the MVP, alter the systems they use to report MIPS measures, and successfully start collecting data on January 1. We believe that CMS should provide more of a lead time for clinicians to understand the new MVP reporting requirements

before the MVPs are fully implemented, including granting a provisional one-year testing period for MVPs, where it would be easier for clinicians to meet MVP reporting requirements. This phase-in approach would provide more of an incentive to clinicians to participate in MVPs.

Finally, with respect to incentives for participating in MVPs, we believe that clinicians may in fact have a better chance of scoring higher under traditional MIPS than under an MVP. Currently, clinicians can report on as many quality measures as they so choose, and CMS picks the six that the clinician performs the best on when calculating the clinician's performance score. If clinicians are only allowed to report on a select few measures under MVPs, they may have less of a chance of receiving a high score. While we are not suggesting that CMS mandate that clinicians report more measures under MVPs, we do recommend that CMS refine their scoring approach so that clinicians have as much of an opportunity to do well under an MVP than they do under traditional MIPS. **CMS should therefore consider providing a scoring bonus to clinicians who voluntarily participate in an MVP in order to entice them to make the transition.**

Capturing the Patient Voice

CMS is proposing that stakeholders who are developing MVPs should include patients as a part of the MVP development process. While ACEP definitely supports the concept of getting the patient voice incorporated into MVPs, we believe that stakeholders should not be penalized if they are unsuccessfully able to connect with patients. There could be situations where patients are invited to participate, but for some reason are unable to provide feedback in a timely manner. Patients or patient groups could also request financial incentives to participate, which some stakeholders may not be able to afford. **Therefore, we recommend that CMS only require stakeholders to *invite* patients to participate in the MVP development process, and not actually *require* patients to participate.** In other words, as long as stakeholders make a good faith effort to get patients to participate, that should be sufficient. It is also unclear what level of patient engagement would be necessary and when during the MVP development process should stakeholders contact patients. CMS should clarify this in the final rule.

Finally, it is important to note that most emergency physicians are not employed by hospitals, but instead enter into contracts with hospitals to provide services in the ED. Hospitals normally only give business associate agreement (BAA) and data use agreement (DUA) rights for use of personal identifiable information (PII) for billing purposes and could refuse the right of clinicians to use the PII for MVP development purposes. Hospitals already conduct patient feedback efforts and many not support another organization contacting hospital patients to gather any kind of data not controlled by the hospital. In other words, it may be difficult for emergency physicians and other hospital-based clinicians to actually contact individual patients who are seen in the ED and engage them in the MVP development process.

Incorporating Population Health Measures into MVPs

ACEP does not support the use of population-health 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. As hospital-based clinicians, we are concerned about the measure reliability and applicability, case size, attribution, risk adjustment, application at the clinician or group level, and degree of actionable feedback for improvements. Further, many of the existing population claims measures have not been tested at the physician level and based on a retrospective analysis of claims and does 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.

In all, 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. Thus, we urge CMS to only apply these measures to MVPs in certain cases: where they are clinically relevant, easily attributed to a clinician, and are agreed upon by the specialty association that helped design the MVP.

Digital Reporting Measures

ACEP supports CMS' goal to promote the use of digital performance measure data submission technologies in MVPs and encourages the agency to finalize this proposal. In all, we believe it is appropriate to move away from claims-based reporting towards electronic reporting, and since MVPs represent the future of MIPS reporting, they should include measures that derive from data that are captured and can be transmitted electronically and via interoperable systems—including through clinical registries. However, it will be important for CMS to ensure the accuracy of the data that are reported through digital performance measure data submission technologies.

We also believe that CMS needs to better define "digital" technologies and the associated requirements that go along with reporting these measures. Measures associated with digital reporting should only encompass discrete data elements and should exclude narrative clinical notes. Further, non-clinical information should not be required to follow the electronic end-to-end requirements. This should include data elements not normally managed or used in clinical treatment, such as patient demographics (other than date of birth and gender) and billing data. Separating out this non-clinical information will enable clinicians to implement electronic calculations of the clinical measures without concern that some of the patient data, unrelated in any way to the clinical quality measure calculation, does not invalidate the electronic status of the measure. Finally, we think that true "electronic end-to-end" reporting should mean that all data elements that the clinicians enter into the EHR are not subject to any manual manipulation when they are transmitted to the quality measure reporting entity.

Consistent Denominators

ACEP does not support the proposed criterion that denominators must be consistent across the measures and activities within the MVP. Maintaining the denominator criteria across quality measures or all categories would greatly limit the applicability of MVPs to specialists and sub-specialists. Specialists most likely would not have enough patients who meet the denominator across all four MIPS categories. The criteria would also require physicians to report on all four categories for the full calendar year and eliminate the option for physicians to only report on Improvement Activities and Promoting Interoperability for 90 days. Having to report on Improvement Activities and Promoting Interoperability for more than 90 days would greatly increase administrative burden. However, we potentially would consider reporting on Improvement Activities and Promoting Interoperability for more than 90 days within an MVP if CMS modified the category requirements and moved away from treating the two categories as separate. Furthermore, the criteria would lead to significant work by measure developers to modify existing measures and/or create new ones to fit MVP requirements, which we believe is not necessary. It also would significantly delay the availability of MVPs because organizations would have to develop and propose new measures.

Incorporating QCDR Measures into MVPs

Overall, ACEP strongly supports CMS' proposal to incorporate QCDRs into the overall MVP approach and continue to make them a viable mechanism for reporting. Currently, QCDRs can be used to report both MIPS and QCDR measures, and we agree that QCDRs should be a mechanism for reporting any new type of measure or activity that is developed or that could be applied to an MVP. We also agree that QCDR measures themselves should be integrated into new MVPs. Since QCDR measures are developed by QCDRs, many of which are specialty societies, they tend to be more meaningful to clinicians and more aligned with how clinicians provide patient care.

However, CMS also proposes that in order for a QCDR measure to be considered for inclusion in an MVP for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested. Further, only QCDR measures that were previously approved can be included in an MVP proposal since the self-nomination process for QCDR measures ends after the PFS and QPP proposed rule is typically released. **ACEP does not support this proposal**. We believe that CMS should provide QCDRs with more flexibility to develop new measures that could be incorporated into MVPs. As stakeholders try to create MVP proposals, CMS should not be stifling innovation, but instead should be incentivizing stakeholders to develop new measures if needed. Therefore, we request that if a stakeholder develops and proposes an MVP that includes new QCDR measures, **CMS should allow provisional approval of these QCDR measures until the QCDR can meet the testing requirements.** Special consideration should be given to scoring of the provisional measures so that they do not adversely affect clinicians that use them in their attempt to improve the quality of care delivered.

Promoting Interoperability

CMS states that MVPs must include the full set of Promoting Interoperability measures. CMS should clarify how the Promoting Interoperability Category requirements would be integrated into MVPs targeted at hospital-based clinicians. **Since hospital-based clinicians are currently exempt from the Promoting Interoperability requirements, we do not think they need to meet similar requirements in an MVP**. CMS should specifically clarify that the Promoting Interoperability hospital-based clinician exemption applies to MVPs.

APM Performance Pathway

CMS is proposing a new, complementary pathway to MVPs that will be available for clinicians who participate in APMs and who must still report in MIPS. As CMS transitions to the APP, CMS is proposing to eliminate the CMS Web Interface as a collection type and submission type beginning with the 2021 performance period.

ACEP supports the concept of the APP as well as the flexibility it provides to APM participants. Under CMS' proposal, MIPS APM participants could report APP measures and have the option of reporting outside the APP for purposes of being scored under MIPS. MSSP participants must report APP measures, but like other APM participants, also have the flexibility to report other measures. In all, APM participants can report multiple different measures through different mechanisms, and CMS will use the highest scores to determine ach APM participant's MIPS payment adjustment. Such an approach encourages emergency physicians and other clinicians who are in an APM to report through QCDRs or what other mechanisms they believe will help them improve their quality performance and receive a high score in MIPS.

While we do support the overall concept, as previously noted, not many of our members participate in an APM, including the MSSP. ACEP believes that one of the contributing factors leading to the paucity of emergency physicians actively participating in the MSSP and other APMs is that there are not many measures in these initiatives that are relevant to clinicians practicing in the ED setting. None of the six proposed APP measures directly relate to emergency medicine. Therefore, we would like to recommend that CMS include some measures that are meaningful to emergency medicine in the APP measure set.

Found below is a list of emergency medicine-related QPP measures that could be applicable to the APMs and that CMS may want to consider adding to the APP measure set. These measures, many of which are used by ACEP's Qualified Clinical Data Registry (QCDR), the Clinical Data Emergency Registry (CEDR), focus on the appropriate use of certain treatments.

Adding these QPP measures to the QPP measure set and to APM measure sets themselves would make participation in APMs more consequential to many emergency physicians, as it would allow them to report on quality measures that have a direct impact on the patients they serve.

ID	DESCRIPTION	NATIONAL QUALITY STRATEGY (NQS) DOMAIN
QPP65	Appropriate Treatment for Children with Upper Respiratory Infection (URI)	Efficiency and Cost Reduction
QPP66	Appropriate Testing for Children with Pharyngitis	Efficiency and Cost Reduction
QPP116	Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis	Efficiency and Cost Reduction
QPP317	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Community/Population Health
QPP331	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse)	Efficiency and Cost Reduction
QPP415	Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older	Efficiency & Cost Reduction
QPP416	Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years	Efficiency & Cost Reduction

Quality Performance Category

CMS is proposing a total of 206 quality measures for the 2021 performance period. This includes substantive changes to 112 existing MIPS quality measures, changes to specialty sets (including adding one measure and removing one measure from the emergency medicine specialty set), the removal of 14 quality measures, and the addition of two new administrative claims outcome quality measures.

Overall, ACEP believes that yearly program changes increase administrative burden, add to the complexity and cost of the program, and run counter to the Patients Over Paperwork initiative. Practices invest time and resources to implement quality measures into practice and update their systems. Removing measures forces a practice to pick new measures to satisfy MIPS requirements which increases the burden and the chance of not earning an incentive payment

We also specifically oppose the addition of Quality Measure # 418 *Osteoporosis Management in Women Who Had a Fracture* to the Emergency Medicine specialty set. This is a chronic condition measure that requires longitudinal care and retrospective data. It is not an accurate reflection of emergency care and should not be attributable to the emergency physician which only provides acute care management.

Consumer Assessment of Health Providers (CAHPS) for MIPS Survey

CMS is not proposing any fundamental changes to the established submission criteria for the CAHPS for MIPS Survey, but is proposing to expand telehealth codes used in beneficiary assignment. We appreciate CMS maintaining participation in the CAHPS for MIPS survey as a voluntary reporting option for groups in this category, but request again that CMS instead recognize a broader range of CAHPS and other non-CAHPS experience of care and patient-reported outcomes measures and surveys (including those that are offered by QCDRs), under the Improvement Activities category rather than the Quality category.

We remind CMS that ACEP offers a patient engagement module for all participants of CEDR, and we believe this module is superior to the Emergency Department Patient Experiences with Care (EDPEC) Survey that CMS just finished developing in July 2020. Most current vendors that would administer the EDPEC Survey do not survey a large enough sample size to allow for statistically valid individual physician attribution, and we believe strongly that performance improvement cannot be accomplished without the capability to give individual clinicians feedback and resultant skills training to improve physician-patient communication.

Cost Performance Category

ACEP is disappointed that CMS is continuing to maintain the Medicare Spending Per Beneficiary (MSPB) measure and the Total Per Capita Cost measures. We have repeatedly asked CMS to remove these measures from the MIPS program. **These measures are still not meaningful or relevant to emergency physicians.** They were developed for hospital-level accountability and are inappropriate for emergency physician practices, which do not have Medicare patient populations that are large enough or heterogeneous enough to produce an accurate picture of their resource use. Further, even with the recent risk adjustment changes finalized in last year's rule, the measures are still insufficiently adjusted for risk, which punishes physicians repeatedly for caring for the most vulnerable patients with high cost, multiple chronic conditions. ACEP has met with CMS on multiple occasions to discuss the inappropriateness of holding emergency physicians, who provide outpatient

services, accountable for patients admitted to inpatient status for seven days and discharged to skilled nursing facilities.

Episode-based Measures

CMS is not proposing any new cost measures this year but is proposing to include telehealth services in the current cost measure calculations, as applicable**. We encourage 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. ACEP has previously been told in discussions with CMS staff that many emergency physicians would not meet any currently used attribution thresholds**.

Improvement Activities Performance Category

CMS is proposing to modify two existing improvement activities and add the following new criterion for nominating new improvement activities: "include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible." ACEP supports the addition of this new criterion as long CMS still allows new improvement activities to be added even in situations when it is not possible to connect them to existing quality and cost measures.

Promoting Interoperability

Query of Prescription Drug Monitoring Program (PDMP) Measure

In last year's rule, CMS had finalized that the Query of PDMP measure would be optional and available for bonus points for CY 2019 but required in CY 2020. CMS is now proposing to make the Query of PDMP measure optional again in CY 2021 and eligible for five bonus points for the Electronic Prescribing objective. While ACEP believes that PDMPs play an important role in identifying high-risk patients, we agree that CMS should move slowly to allow sufficient time for PDMPs to become fully integrated into clinicians' EHRs and their workflow. We support effective and interoperable PDMPs that push prescription data to emergency physicians, rather than requiring them to separately sign into and pull the data from the PDMP. Currently, not all states have optimally functional PDMPs, resulting in highly variable usability and trustworthiness. Some states have not made commitments to make their PDMPs state-of-the-art, and as a result, they are cumbersome, may not contain real-time data, and the information can be unreliable. In addition, patients may cross state lines for care, and not all states are part of InterConnect, which shares interstate information about dispensed prescriptions.

ACEP appreciates that CMS is making this measure optional again in CY 2021. Going forward, we believe that under only certain conditions would it be appropriate for CMS to require a hospital or CAH to query a PDMP for at least one Schedule II opioid that is electronically prescribed. These conditions include having the Office of the National Coordinator (ONC) for Health Information Technology consider adopting new EHR certification criteria that require EHRs to integrate PDMPs into their existing capabilities. Furthermore, CMS should require all PDMPs to be interoperable and to include certain standards, such as privacy and security protocols that protect patient sensitive information.

Health Information Exchange Measure

In order to incentivize MIPS eligible clinicians to engage in bi-directional exchange through a health information exchange (HIE), CMS proposes to add the following new measure to the Promoting Interoperability category beginning with the performance period in 2021: *Health Information Exchange Bi-Directional Exchange measure.* CMS proposes to add this new measure to the HIE objective as an optional alternative to the two existing measures: the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. Clinicians. ACEP supports the movement to exchange more data through HIEs and therefore concurs with the addition of this measure. We also encourage CMS to finalize its proposal to make this simply an attestation measure.

MIPS Final Scoring Methodology

Quality Benchmarks

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 2019, CMS believes that 2019 data may be unreliable. Therefore, CMS intends to develop performance period benchmarks for the CY 2021 MIPS performance period using the data submitted during the CY 2021 performance period rather than historic data from 2019. Tied to this proposal, CMS is adjusting its policy for topped out measures. CMS proposes to apply the 7 measures achievement point cap to measures that meet the following two criteria.

1. Measures have been topped out for 2 or more periods based on the published 2020 MIPS performance period historic benchmarks (which are based on submissions for the 2018 MIPS performance period).
2. Measures remain topped out after the 2021 MIPS performance period benchmarks have been calculated.

ACEP understands the rationale behind these proposals but believe that CMS should pursue an alternative approach. Under the proposals, 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 possibly 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 2018 performance year data (2020 benchmarks) for scoring purposes in the 2021 performance year.** CMS should also not use 2021 performance to determine whether measures are topped out, but instead determine that status for each measure prior to the start of the CY 2021 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 2021.

With respect to topped out measures, we would like to reiterate previously expressed concerns that **the current topped out process leads to high administrative costs and burden because of the need to frequently implement new processes in order to report new measures.** In addition, it penalizes clinicians who focus on improving their performance on certain quality measures over time and, in some cases, forces them to switch to new measures that may be less meaningful to their clinical practice. Finally, we do not believe topped-out measures should be capped at seven points, since in many cases topped-out measures remain the most meaningful measures on which certain clinicians can report.

Quality Scoring Flexibility

CMS is increasing flexibility in the Quality category scoring methodology by expanding the list of reasons that a quality measure may be impacted during the performance period, and revising when CMS would allow scoring of the measure with clinicians are unable to report a full 12 months-worth of data. Specifically, CMS proposes to shorten the performance period or suppress a quality measure if it is impacted by "significant changes" that CMS determines may result in patient harm or misleading results. As hospital-based clinicians, there are multiple examples of not being able to receive data, submit timely or incomplete data, or submit incorrect data due to our reliance on receiving this information from hospitals. Further, many of our members belong to groups that contract with hospitals and are not actually employed by the hospital. New contracts with hospital, contract modifications, and contract terminations all can impact the ability for an individual emergency physician and/or the group itself to report data. For example, when a hospital contract with a group ends, the group may only have incomplete data from the hospital and may not be able to fully or accurately report. In addition, when a group wins a new hospital contract, especially late in the year, they may not be able to receive enough data from the new or prior hospital to fully and accurately report data. **We urge CMS to consider these cases as additional factors for shortening the performance period to 9 months.**

Assigning Quality Measure Achievement Points

For the 2021 MIPS performance period, CMS is proposing to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period and that meet the data completeness and case minimum thresholds. However, CMS notes that as CMS moves towards the proposed MVPs, it notes it could possibly remove the 3-point floor in future years. ACEP appreciates CMS' proposal to continue to apply a 3-point floor for measures and encourages CMS to keep that policy in place for the foreseeable future.

Calculating the Final Score

Complex Patient Bonus

CMS proposes to modify the complex patient bonus for the 2022 MIPS payment year (2020 performance period) in response to the COVID-19 PHE by doubling the number of complex bonus points that a clinician receives. Thus, the maximum number of points would increase from 5 to 10. **ACEP strongly supports this proposal and appreciates that CMS acknowledges that treating all patients during the PHE is more difficult and complex.**

We also appreciate CMS' other efforts to shield physicians from payment adjustments if they are unable to meet reporting MIPS reporting requirements due to the COVID-19 PHE. However, we are concerned about the long-term ramifications that the PHE will have on MIPS. Even before the PHE, the maximum positive adjustments that clinicians could receive (if they received a score of 100 percent) were relatively low due to budget neutrality and relatively few clinicians receiving downward payment adjustments. Since CMS is allowing physicians to claim hardship exceptions for the 2020 performance period, we expect the maximum payment adjustment to be low in 2022 as well. If the potential up-side to investing in quality measurement reporting and improvement does not cover the cost of that investment, physicians and other clinicians will transition to cheaper options for meeting MIPS requirements, which may not provide them an avenue to actually improve their performance. CMS must therefore balance policies that will protect physicians from facing downward

payment adjustments due to factors beyond their control with other policies that will incentivize participation and allow those physicians who are able to successfully report to get some return on their investment.

Category Weights

CMS proposes to increase the Cost category to 20 percent in 2021 and to 30 percent by 2022. CMS proposes to make corresponding decreases to the Quality category weight (the Quality category weight would be 40 percent in 2021 and 30 percent in 2022). ACEP recognizes that cost category is required by law to reach this percentage by 2022, but we remain concerned about the lack of available cost measures that are meaningful and attributable to emergency physicians. As discussed in the cost category section above, **we encourage CMS to develop additional episode-based cost measures.**

Performance Threshold

CMS is proposing to increase the performance threshold from 45 points in 2020 to 50 points in 2021. CMS had originally planned on increasing the threshold to 60 points in 2021 but decided to lower that due to disruptions caused by the COVID-19 pandemic. Further, CMS had previously planned on establishing 74.01 points as the performance threshold for the 2022 performance year, but is now seeking comment on whether the agency should adopt a different performance threshold in the final rule if more data becomes available for making such a determination.

ACEP believes that the current proposal represents a reasonable increase in the performance threshold for 2021. However, we caution the agency against increasing the performance thresholds above 60 points however in 2022, given the downstream effects of our continued response to the COVID-19 PHE. It is unclear how COVID-19 will impact MIPS reporting in 2022, so 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. Finally, it is important to consider the implications of the threshold on hospital-based clinicians, who are eligible for the facility-based scoring option. Under this option, clinicians or groups receive a score for the Quality and Cost categories of MIPS based on the performance of their hospital in the Hospital Value-based Purchasing (HVBP) program. Due to the COVID-19 PHE, CMS made the first six months of reporting in the HVBP optional for 2020. It is unclear what effect this policy will have on HVBP and associated MIPS scores in 2020, and whether there will be any rippling effects on scores in 2021 or in future years.

Additional Performance Threshold for Exceptional Performance

ACEP supports CMS' proposal to maintain the additional performance threshold at 85 points for the 2021 MIPS performance period. ACEP believes the additional performance threshold should be kept at 85 points for the next couple of years as well. Eighty-five points is a high threshold to meet, and in order to reach that point level, clinicians would have to successfully report and perform in multiple MIPS categories. By raising the exceptional performance threshold above 85 points going forward, specialties without a significant breadth of reportable measures will be adversely affected while those specialties that do have large numbers of measures with full scoring potential in all deciles will benefit. This seems unfair and discourages high performance for those clinicians and groups within specialties that cannot hope to achieve a score above 85 points.

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 for four years 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)(l) 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.**

Please find our specific comments on QCDR proposals below:

Data Validation Audit and Targeted Audit Requirements

CMS proposes to codify requirements that, beginning with the 2023 MIPS payment year as condition of approval, each QCDR must conduct annual data validation audits and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits. CMS also proposes specific obligations for those audits. CMS requests comments on the specific requirements, including whether stakeholders are concerned with implementing these policies for the 2023 MIPS payment year, and if so, what barriers they believe they would face in implementing these requirements.

ACEP understands that most of the requirements outlined here are already in place. However, many of the requirements do not have clearly delineated guidelines. CMS should provide very specific information for what they expect for these audits. Further, we would like to propose the following clarification. The process of calculating and auditing is distinctly different for electronically calculated measures and manually abstracted measures. The use of the term "chart review" is unclear. Electronic measures specify the exact mechanisms

whereby the quality measure is calculated. If the clinician incorrectly documents a case by entering conflicting information in the clinical note from the discrete, electronic data fields which make up the measure specification, or the EHR stores the data in an incomprehensible manner, information in these areas of the chart should not be considered in the chart review. Chart review should be defined as a review of the chart data which applies to the measure specification and is available in the manner necessary for the measure calculation process (electronic or human abstraction). This would align the QPP audit process with electronic clinical quality measure (eCQM) reporting. These electronic measures do not consider clinician notes, audio, images, videos, and other non-computable aspects of the chart in their calculation. They would suffer the same failures during audit if the chart review included areas of the chart not included in the eCQM specification.

QCDR Measure Testing

CMS proposes that QCDR measures must be "face valid" to be approved for the 2024 MIPS payment year. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

CMS proposes that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. In addition, CMS proposes that these measures, which were approved for the preceding MIPS performance year with face validity (i.e., CY 2024 MIPS payment year), would be required to be fully tested prior to being self-nominated for any subsequent performance periods (i.e., CY 2025 MIPS payment year and beyond) in order to be considered for inclusion in the MIPS program.

CMS clarifies in this proposed rule that for purposes of QCDR measures, it would expect QCDR measures to complete "beta" testing to be considered fully tested. CMS acknowledges that there is a cost involved with full testing of quality measures, but believes it is important that all measures used within the MIPS program are fully tested and reliable. CMS believes this incremental approach in testing would allow QCDRs time to plan appropriately to complete measure testing in a timely, efficient, and effective manner. However, CMS encourages QCDRs to submit fully tested QCDR measures to the extent possible, as it has a strong preference for QCDR measures that are fully tested versus those that have only completed face validity testing.

ACEP understands the rationale behind these proposals but do believe they would add significant costs to the QCDR measure development process. At a certain point, the costs of measure development will outweigh the benefit of operating QCDRs. All in all, **CMS is inherently making it impossible for small organizations to run QCDRs and develop new measures.**

Duplicative QCDR Measures

CMS proposes to clarify that, beginning with the 2022 MIPS payment year, CMS may provisionally approve QCDR measures that are found to be duplicative of others. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure. CMS also proposes that, beginning with the 2023 MIPS payment year, QCDR measures may be approved for two years, at CMS discretion, by attaining approval status by meeting QCDR measure considerations and requirements. ACEP supports these proposals and we look forward to continuing to work with CMS and other entities to harmonize emergency medicine quality measures and eliminate any duplicative measures. As part of this effort, ACEP is committed to establishing the Emergency Care Quality Measures Consortium (ECQMC). ECQMC is an industry-leading coalition that

includes ACEP members, physician groups, health insurance payers' medical associations, academic and research leaders, and other quality collaboratives. The goal of the consortium is to recommend and align core sets of quality measures in emergency and acute, unscheduled care—thereby ensuring that quality measures across emergency medicine are all meaningful and harmonized.

Physician Compare

ACEP continues to be concerned that all quality measures reported by clinicians are included in the Physician 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, *Physician Compare* 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 Physician 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. ACEP developed a physician-focused payment model (PFPM) called the Acute Unscheduled Care Model (AUCM). The AUCM, if implemented, would fill a very important gap in terms of models currently available to emergency physicians. Structured as a bundled payment model, it 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. It 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.

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, and **the PTAC recommended the AUCM to the HHS Secretary for full implementation**. 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. The PTAC submitted its report to the Secretary in October 2018. In September 2019, HHS Secretary Alex Azar stated that he believes the core concepts of the

AUCM should be incorporated into the APMs that CMMI is developing. However, CMMI has not yet taken action on this model. 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 an Qualifying APM participant (QP) is expiring in 2024 and the QP threshold is extremely high (the QP payment amount threshold is increasing to 75 percent and the QP patient count threshold is increasing to 50 percent). 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, and, even if they did, their total payments or patients tied to the Advanced APM probably would not surpass the threshold. We therefore encourage CMS to use its regulatory flexibility to decrease the patient count threshold and we continue to push 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 Affairs at jdavis@acep.org.

Sincerely,

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