American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

September 23, 2019

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

Re: CMS-1715-P

Re: Medicare Program; CY 2020 Revisions to 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

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Dear Administrator Verma:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the Calendar Year (CY) 2020 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.

The Physician Fee Schedule

In this proposed rule, CMS includes proposals that aim to reduce provider burden and reward clinicians for the valuable time they spend on patient care. However, CMS balances these burden reductions with unsustainable payment cuts. As discussed below, ACEP is especially concerned about the potential reduction to emergency physician payments if all the proposals related to the office and outpatient evaluation and management (E/M) services are finalized in CY 2021. Such reductions could put some physicians and practices in serious financial peril, and thereby also endanger patients' access to available care. 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. These updates also do not take into account the 2 percent sequestration adjustment that continues to apply year after year. 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 2019 Medicare Trustees Report, which was released on April 22, 2019, acknowledges that updates for physician reimbursement are not sufficient. The Trustees believe that, absent a change in the delivery system or future legislative updates to physician rates, access to Medicare-participating physicians will become a significant issue in the long term.[2] Given the fact that annual updates to physician payments are not keeping up with the cost of providing physician services, large-scale reductions to certain codes would make it even more difficult for particular physician specialties to continue providing care. Therefore, as CMS decides whether to modify or finalize certain proposals, including the significant reforms to the E/M codes, we hope that the agency will keep in mind how adjusting the relative values of certain codes impacts the total Medicare reimbursement that clinicians will receive.

Valuation of Emergency Department Evaluation and Management Codes for CY 2020

Every year, CMS re-values codes that have been identified as potentially misvalued. There are a few codes that affect emergency medicine that have proposed revaluations in this year's rule—the largest of which is the set of Emergency Department (ED) E/M codes (CPT codes 99281-99285).

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."[3] 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 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.[4] Therefore, we welcomed the opportunity for the American Medical Association (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 is proposing the RUC-recommended work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285.

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[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 2019 Medicare Trustees Report is available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf.

[3] 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).

[4] 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.

ACEP is extremely pleased that CMS agrees with the RUC recommendations for work RVUs for the ED E/M codes. ACEP members have participated in the RUC process for many years, contributing a tremendous level of effort and commitment providing analysis and documentation supporting the need for equitable E/M codes. We conducted a thorough survey of our members and presented our findings to the RUC at the April 2018 meeting. The RUC, in turn, provided a reasonable and appropriate recommendation for the value of these codes based on our findings. **Therefore, we thank CMS for recognizing the RUC's increase in the valuation of these codes and for recognizing the increase in the intensity of the level 5 service over the past few years. However, as discussed in the "Payment for Office and Outpatient Evaluation and Management (E/M) Visits" section below, we urge CMS to finalize an additional increase in these codes in CY 2020 to maintain the relative value between the new patient office and outpatient codes proposed for CY 2021 and the ED E/M codes.**

Payment for Office and Outpatient Evaluation and Management (E/M) Visits

In last year's rule, CMS finalized significant changes to the office and outpatient E/M payment structure that would become effective in CY 2021. Most notably, CMS consolidated E/M visit levels 2 through 4 into one payment rate. Based on feedback from the CPT and the RUC, CMS is rescinding that major policy and instead keeping these levels separate and proposing new code values for CY 2021. In all, CMS proposes to accept the RUC-recommended work values for all new and established patient office/outpatient E/M codes (including proposing to delete the level 1 office/outpatient visit for new patients). Further, CMS is proposing to refine the two add-on codes for complexity that CMS previously finalized and consolidate those codes into one comprehensive code that both primary care providers and specialists can bill.

ACEP respects the RUC process and supports CMS' decision to accept the RUC's recommendations for these codes. However, we are extremely cognizant of the significant budget neutrality adjustment that would be triggered if CMS finalized all of the proposals as proposed in CY 2021. According to conversations with CMS, the office and outpatient E/M codes represent approximately 20 percent of billed services under the PFS. Further, the AMA estimates that the additional add-on code for complexity has a re-distributional impact of another $1 to $2 billion. Emergency physicians do not tend to bill these codes. Approximately 85 percent of their billable services are from the ED E/M codes discussed in the previous section. Therefore, because emergency physicians do not bill for the office and outpatient E/M services, the budget neutrality impact on our specialty is estimated to be extremely large. Although meant for illustrative purposes, Table 111 of the proposed rule shows a -7 percent reduction to the emergency medicine specialty if the CY 2021 proposals were implemented in CY 2020.[5] While ACEP understands that the -7 percent figure is hypothetical given that there could be other policies in CY 2021 that could shift that percentage up or down, a reduction anywhere close to that magnitude could significantly jeopardize the emergency care safety net, especially in rural areas.

Further, such a large reduction to emergency medicine in CY 2021 does not make sense from a policy perspective. In CY 2020, CMS is proposing to increase the value of the most billed services for emergency physicians (the ED E/M codes) because the agency appropriately believes that these codes are currently

[5] Medicare Program; CY 2020 Revisions to 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Proposed Rule, 84 Fed. Reg. 40886 (August 14, 2019).

undervalued. If CMS finalized the CY 2021 office and outpatient E/M proposals as proposed, all of the increases in emergency physician payments from CY 2020 (if the increases recommended by the RUC are finalized) would be completely eliminated, and instead these physicians would see a significant decrease in Medicare payments. In other words, CMS 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 and decreasing overall payments for emergency physicians. In the end, the ED E/M codes and emergency physician payments would be undervalued once again. This simply does not make sense and would undermine the RUC's recommendation that the ED E/M payments should be more appropriately valued.

Given our concerns with the potential effect of the proposed increases in office and outpatient E/M codes, **we offer the following two solutions: 1) increase the value of the ED E/M codes, levels 1 through 3, to align with the corresponding levels for the office and outpatient E/M codes for new patients; AND 2) delay the implementation of the add-on code for complexity.**

Increase the Value of the ED E/M Codes, Levels 1 through 3, to Align with the Corresponding Levels for the Office and Outpatient E/M Codes for New Patients

ACEP strongly urges CMS to increase the value of the ED E/M codes, levels 1 through 3, to align with the corresponding levels for the office and outpatient E/M codes for new patients. We appreciate that CMS is accepting the RUC's recommended values for these services in CY 2020, but we believe that the CY 2021 office and outpatient E/M proposals have fundamentally altered the state of affairs from when the RUC considered the ED E/M codes in April 2018.

Our proposal is 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. The RUC rationale, which has also been accepted by CMS historically, for the current work values of the ED codes is as follows:

"The RUC agreed that the original assumptions utilized in valuing the Emergency Department visits were flawed. In addition, the RUC's recommendations on the new patient office visits (99201 - 99205) would create a rank order problem if the Emergency Department codes were not addressed. In the first Five-Year Review of the RBRVS, the RUC had recommended that the first 3 levels of Emergency Department services should be valued equivalent to the first three levels of new patient office visits. The RUC had further recommended that Emergency Department levels 4 and 5 should be valued higher than the level 4 and 5 new patient office visits. The RUC reaffirms its previous recommendations with this submitted recommendation."

The ED E/M codes have been undervalued compared to the new patient office codes since the 2010 increase in those codes due to the Medicare elimination of the consultation code from payment. During the recent review, the RUC further reiterated its position on maintaining that relativity and the April 2018 increase was meant to bring the two code families back into alignment. Now that the new patient office codes are proposed to increase again in CY 2021, the inequities will return; perpetuating a problem even before the current fix is implemented.

We specifically request that CMS increase the ED E/M code work values to the same levels as the CY 2021 proposed new patient codes. If code 99201 is removed from the code set, then there is no direct crosswalk to 99281.

ED Code	Work RVU	New Office Code	Work RVU	Difference	Percent Difference
99281	0.48	99201	N/A	N/A	N/A
99282	0.93	99202	.93	0.00	0.0%
99283	1.42	99203	1.60	0.18	-12.6%
99284	2.60	99204	2.60	0.00	0.0%
99285	3.80	99205	3.50	0.30	+7.9%

- We request that 99283 be raised to match the new proposed work RVU of 99203 to be **1.60**.
- We request 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 ask instead for **4.00**, which was the survey median in the 2018 presentation to the RUC based on those that regularly provide the service.
    - That presentation cited numerous peer-reviewed journal articles showing the intensity of 99285 had increased significantly over the past decade because of fewer admissions based on more detailed workups in the ED setting.

Rationale for Request

We are proposing a direct crosswalk between 99202 and 99203 and 99282 and 99283 as in the chart above. Further, to maintain historic relativity and avoid rank order anomalies across both families of codes, for 99284 and 99285, we propose using the relative difference between 99204's and 99205's current work values and the proposed work values, respectively, for CY 2021.

Code	Current RVUw	Proposed RVUw
99204	2.43	2.60
99284	2.56	2.60
99205	3.17	3.50
99285	3.80	3.80

For 99204 to 99284:
(2.43-2.60) / (2.43) = (6.99% X 2.56) = (0.18 +2.56) = **2.74.**

Appling the same methodology to 99205 and 99285:
(3.17/3.50) / (3.17) = (10.41% X 3.80) = (0.396 + 3.80) = **4.20**

Delay the Implementation of the Add-on Code for Complexity

To mitigate the budget neutrality adjustment that would potentially occur in CY 2021, we strongly recommend that CMS delay the implementation of the add-on code for complexity (GPC1X) until CY 2022 or later. As discussed earlier, this code within itself could have a $1 billion to $2 billion re-distributional impact. In fact, in Table 115 of the rule, CMS displays the impacts on specialties if CMS had deleted both the add-on codes for complexity that CMS had previously finalized for 2021 but accepted the other RUC

recommendations for the office and outpatient E/M codes.[6] The table, which displays these impacts as if the policies were implemented in CY 2020, shows a reduction for emergency medicine of -4 percent, much less than the reduction of -7 percent for emergency medicine displayed in Table 111. While we understand that there are multiple caveats around this estimate of -4 percent, we believe that it clearly shows that not finalizing 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 would establish a fairer and more equitable payment structure for other specialties that do not bill office and outpatient E/M codes. Although ACEP does support an increase in payment for primary care and other office-based visits, we think that other physician specialties do not need to experience payment reductions that could be up to 10 percent for CMS to still be able to achieve its overall goal.

Documentation Requirements for Office and Outpatient E/M Visits

CMS is proposing to allow providers to choose to document office and other outpatient E/M level 2 through 5 visits using medical decision-making (MDM) or time, or the current framework based on the 1995 or 1997 Guidelines. ACEP appreciates that these proposals would only apply to the office and outpatient E/M codes and not to the ED E/M codes in CY 2021. In general, we believe that we need to balance any reduction in administrative burden with the need for a clear record of services rendered and the medical necessity for each service, procedure, diagnostic test, and MDM performed for every patient encounter. As we think about potential future changes to documentation requirements that could impact emergency services, we must keep in mind the unique and unpredictable environment of EDs and interactions with our patients. Therefore, if CMS were to propose documentation changes for ED E/M visits, it would be essential to ensure that the changes align with current emergency physician practice patterns and how we treat our patients.

Valuation of the Lumbar Puncture Codes (CPT Codes 62270, 622X0, 62272, and 622X1)

For the lumbar puncture codes (62270, 622X0, 62272, 622X1), CMS proposes values that do not align with the RUC recommended work RVUs for all four codes. Of these codes, emergency physicians typically bill CPT 62270. **We do not support CMS' proposed evaluation of CPT 62270, and strongly urge CMS to accept the RUC recommendation for this code.**

For CPT code 62270, CMS disagrees with the RUC recommended work RVU of 1.44 and proposes a work RVU of 1.22 based on a direct work RVU crosswalk to CPT code 40490 *Biopsy of lip* (work RVU = 1.22, intra-service time of 15 minutes, a total time of 34 minutes). This crosswalk is inappropriate and was chosen based only on a time comparison without consideration to the intensity of the work. Code 40490 is performed over 95 percent of the time in a physician office as an elective procedure while code 62270 is performed on seriously ill patients in the ED or inpatient hospital setting 70 percent of the time and only 5 percent of the time in a physician office. The patient populations are vastly different reflecting the increased intensity in the lumbar puncture procedure. The patient population is now much broader, representing the continuum of patients from newborns to elderly adults. As such, the indications for code 62270 are extensive as well. The procedure is employed in the evaluation of multiple chief complaints, including but not limited to, headache, altered mental status, and fever of unknown origin - with timely, emergent diagnosis required for such concerning pathology as CNS infection and subarachnoid hemorrhage. Emergency medicine represents a unique practice setting,

[6] 84 Fed. Reg. 40906 (August 14, 2019).

which often includes altered or combative patients, patients on anticoagulation or with other hematologic derangements, as well as the potential for interruptions or other patients to require emergent attention. While providing care to patients receiving a lumbar puncture, it is very likely that the emergency physician is taking care of a dozen other patients of variable acuity, but often including the acutely ill or injured.

Clinically, the two procedures are not similar at all. Code 40490 is a superficial biopsy of a visible lesion whereas code 62270 requires the physician to guide a needle from the skin, through the soft tissues, between the posterior elements of the lumbar spine, and into the thecal sac within the spinal canal in a patient that is presenting with neurologic symptoms necessitating an emergent procedure. Complications of code 62270 include epidural hematoma leading to neurologic compromise and brain herniation. In comparison to a lip biopsy, there is the real risk of irreversible central and peripheral nervous system damage with the spinal needle. There also exists the inherently imperfect pain control/local anesthesia leading, on average, to a moving target and making the procedure more difficult and intense. The work of code 62270 may be performed in a similar time as code 40490 but it is a more intense process, which was discussed in detail at the RUC.

CMS has proposed a work RVU reduction of 1.22 for CPT code 62270 by justifying that the intra-service and total time has decreased and so should the work value for this service. The RUC strongly disagrees with the Agency's statement that the lower intra-service time in CPT code 62270 should result in a lower work value. The RUC agreed that although the current times of CPT code 62270 have changed, the overall intensity and complexity has increased due to expected change in a dominant specialty to emergency medicine. The RUC also agreed that the recommended work RVU of 1.44 for CPT code 62270 maintains relativity within the lumbar puncture family.

The RUC recommendation was based well below the 25th percentile work RVU from robust survey results and favorable comparison to the direct work RVU crosswalk and MPC code 12004 *Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm* (work RVU = 1.44, intra-service time of 17 minutes, and total time of 29 minutes). The survey results demonstrate that the work RVU for code 62270 was undervalued at the current work value of 1.37. **ACEP urges CMS to accept a work RVU of 1.44 for CPT code 62270.**

<u>Opioid Use Disorder Coverage</u>

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) added a new Medicare benefit beginning in 2020 for opioid use disorder (OUD) treatment services delivered by an opioid treatment program (OTP). In this rule, CMS establishes requirements to govern Medicare coverage of and payment for OUD treatment services furnished in OTPs. CMS also proposes Medicare enrollment requirements and a program integrity approach for OTPs.

ACEP understands that EDs are not included in the proposed definition of OTPs. CMS is proposing that OTPs must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and meet certain accreditation standards. However, as described in more detail in the next section on bundled payments for substance use disorders (SUD), ACEP feels strongly about reducing barriers to treatment for patients with SUD, including OUD. One significant barrier to providing medication-assisted treatment (MAT) outside of OTPs is the "X waiver" requirement mandated by the Drug Addiction Treatment Act (DATA) of 2000. Under the DATA 2000 law, physicians wishing to prescribe buprenorphine outside of OTPs must take an 8-hour course, receive a waiver from the Drug Enforcement Agency (DEA), and comply with numerous logging and audit requirements. The presence of this requirement has led to a misperception about MAT and

increased stigma about OUD and the treatment of this disease. In surveys that ACEP has conducted on the X-waiver, we have found that many physicians are not receiving an X-waiver for prescribing buprenorphine, and even if they are, they are still not prescribing the medication. Many physicians are not familiar with the drug and its side effects/dosing; others cannot prescribe buprenorphine even if they have a waiver because it is not covered on their hospital's ED formulary; and finally, due to misperception, some do not believe in treating opioid withdrawal with opioids.

To improve access to OUD treatment, we may need to engage in a broader educational campaign, and ACEP stands ready to work with CMS and other agencies including SAMHSA to help educate providers about the benefits of MAT and help reduce the stigma and misperception around both this disease and treatment protocol. While removing the X waiver would require legislation from Congress, on the regulatory side, we also strongly support modification to the current "three-day rule" (Title 21, Code of Federal Regulations, Part 1306.07(b)). This rule represents a significant barrier to treatment since it requires providers to administer buprenorphine each day over a three-day period, forcing patients to need to come back to the ED or other settings each day to receive treatment – a substantial and often unsurmountable challenge for patients struggling with withdrawal.

Bundled Payments for Substance Use Disorder

In last year's rule, CMS sought comment on the use of MAT in the ED setting (including initiation of MAT and referral or follow-up care) and whether it should consider separate payment for such services in future rulemaking given that, while OUD can first become noticeable in ED, there is no specific coding that describes diagnosis of OUD in the ED, or the initiation of, or referral for, MAT in the ED setting. In this year's rule, CMS is proposing to establish bundled payments for "overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities."[7] Specifically, CMS proposes to create two new G-codes for monthly bundles for the overall management, care coordination, individual and group psychotherapy and counseling for office-based OUD treatment as well as an add-on code. ACEP recognizes that these G-codes are for office-based treatment of SUD. **We strongly recommend that CMS expand the use of the G-codes to make them applicable in the ED setting.**

CMS is, though, specifically seeking comment on the use of MAT in the ED setting (including initiation of MAT and referral or follow-up care) and whether it should consider separate payment for such services in future rulemaking. **ACEP is extremely supportive of a future policy that would pay separately for MAT initiated in the ED and strongly encourages CMS to include such a proposal in next year's rule.** Emergency physicians working in the ED are on the front lines treating patients who overdose, but unfortunately there are a large number of patients treated in the ED who survive to be discharged, but do not receive sufficient attention or treatment afterwards. A recent study found that 1 in 20 individuals treated in EDs for nonfatal opioid overdose died within a year.[8] We believe this study demonstrates the importance of initiating MAT (e.g., buprenorphine) in the ED and intervening on these high-risk patients when we have the opportunity to do so while they are in the ED.

We have seen great results with initiating treatment in the ED and starting patients on the path to recovery. By implementing this treatment regimen, we can address an OUD patient's immediate symptoms and cravings,

[7] 84 Fed. Reg. 40542 (August 14, 2019).

[8] Weiner, SG, et al. "One-Year Mortality of Patients After Emergency Department Treatment for Nonfatal Opioid Overdose." Ann Emerg Med. 2019 Jun 19. pii: S0196-0644(19)30343-9.

which allows time to coordinate care and provide a "warm handoff" to substance use disorder specialists and other community resources who can appropriately carry out the long-term treatment. There are numerous study results showing promise for ED-initiated buprenorphine and its effectiveness in treating opioid use disorder. Initiating MAT in the ED has shown to be more successful than simple referral – after one month, 78 percent of patients started on MAT in the ED remained in treatment programs, compared to 37 percent who only received a simple referral.[9] Furthermore, studies of patients in California and elsewhere with opioid addiction 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.[10] Another study tracked patients on buprenorphine for MAT for up to 43 months. The cohort still taking buprenorphine at 12 months had a 17.5 percent less than the expected rate of ED visits.[11] Finally, a study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal found no instances of precipitated opioid withdrawal (a potential medical complication of buprenorphine), and 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 for usual care.[12] 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.

In terms of payment, currently there is no way to capture the work it takes to initiate MAT programs in the ED outside the E/M levels of service (CPT codes 99281-99285). It takes a significant amount of time (sometimes two to three hours) to titrate the appropriate dosage. Therefore, ACEP strongly encourages CMS to ensure that the payment adequately funds ED-initiated MAT along with the other necessary wrap-around features of MAT such as treatment management and counseling. ACEP would be happy to work with CMS on finding the appropriate crosswalk to set a proper reimbursement rate for these services.

Medicare Telehealth Services

CMS proposes to add the G-codes for SUD monthly bundled payments to the list of Medicare Telehealth services for CY 2020. As mentioned above, we strongly encourage CMS to allow emergency physicians providing SUD treatment to be able to bill for these services, both in-person and via telehealth.

In all, **ACEP strongly supports the delivery of telehealth services by board-certified emergency physicians**. There are established examples of high quality, cost-effective telehealth programs in the ED setting that allow greater access to an emergency physician in inner-city or rural EDs that would not usually be able to economically support that level of provider on a 24/7 basis, if at all. Additionally, telehealth access from the ED setting to other medical specialists such as neurologists or psychiatrists can help provide faster access to specialty care and reduce delays in critically needed treatment, and the time these patients remain in the ED waiting for a psychiatric bed to become available (i.e., ED "boarding"). Finally, utilizing telehealth can help smaller hospitals treat more of their patients with emergency medical conditions instead of transferring them.

[9] D'Onofrio G, O'Connor PG, Pantalon MV, et al. "Emergency Department-initiated Buprenorphine/Naloxone Treatment for Opioid Dependence: a Randomized Clinical Trial." JAMA. 2015;313(16):1636-1644.

[10] 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.

[11] Schwarz R, Zelenev A, Bruce RD, et al. Retention on Buprenorphine Treatment Reduces Emergency Department Utilization, But Not Hospitalization, Among Treatment-seeking Patients with Opioid Dependence. J Subst Abuse Treat. 2012 Dec;43(4):451-7

[12] 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.

As more and more small and rural hospitals close, their EDs close too, leaving a gap in emergency care in a region.[13] To fill these gaps, emergency physicians housed in what may be a state's only large or teaching hospital to provide telehealth services to patients and providers in smaller rural or community hospitals that are staffed by registered nurses and advance practice nurses. These valuable services provide clinical expertise in real-time to stabilize patients who may need to be transferred long distances or may be observed at timely intervals over several hours by the emergency physician team at the teaching hospital before a decision is made to transfer, admit locally, or release the patients.

Section 1834(m) of the Social Security Act (SSA) establishes the specific telehealth services that may be reimbursed by Medicare**. Emergency medicine services currently are not included in this list of eligible services.** CMS has the discretion through rulemaking to add new codes to the list of approved telehealth services. However, CMS has instituted stringent criteria for adding new codes. To add new codes to the list, the codes must fall under two categories. The first category includes services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. The second category includes services that are not similar to those on the current list of telehealth services. CMS' review of these requests includes an "assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient." [14]

This second category has proven to be an extremely high bar to meet since there must be proven evidence that the service provided through the use of a telecommunications system has clinical benefit. We perceive telehealth as a tool that physicians and other health care providers can rely upon to deliver the same high-quality care they would otherwise provide in-person. Thus, it does not seem appropriate to evaluate whether a service should be added to the list of approved telehealth services only if it adds clinical value when it is delivered through the use of a telecommunications system. The service itself adds clinical value, and the telecommunication system only represents how the service is furnished.

ACEP continues to support Medicare coverage of emergency telehealth services that would benefit patient care, and strongly encourages CMS to revise their criteria for adding new codes to the list of approved telehealth services to make it easier to add appropriate codes to this list.

Physician Supervision for Physician Assistant (PA) Services

CMS is proposing to modify current regulations around the physician supervision of PA services. CMS clarifies that the physician supervision requirement under Medicare is met as long as PAs deliver their services in accordance with state law and state scope of practice rules, with medical direction and appropriate supervision as provided by that state law. In the absence of state law, physician supervision would be evidenced by including documentation in the medical record describing the PA's approach to working with physicians in delivering their services.

[13] Tribble, Sarah Jane. "After A Rural Hospital Closes, Delays In Emergency Care Cost Patients Dearly." Kaiser Health News. August 19, 2019. https://khn.org/news/emergency-room-care-rural-hospital-closes-uncertain-future/.

[14] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program— Accountable Care Organizations— Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act Final Rule, 83 Fed. Reg. 59870 (November 23, 2018).

ACEP understands that the purpose of this proposed policy is to align existing requirements with state scope of practice laws. In general, ACEP believes that 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.

Given our position on this issue, we urge CMS to remove the proposed regulatory language: "In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services." Most, but not all states require physician supervision. Some states require physician collaboration, which still requires that physicians maintain the ultimate responsibility for coordinating and managing the patient's care. Yet, this proposed language could be interpreted to preempt these state laws, which could have the unintended consequence of eliminating any physician oversight of physician assistants, opening the door for independent practice of PAs.

Review and Verification of Medical Record Documentation

ACEP supports CMS' commitment to eliminating barriers that impede our ability to provide the best possible care to our patients. We want to especially thank CMS for their recent policy changes that have reduced documentation burden for teaching physicians. First, CMS issued a clarification that allows a teaching physician to rely on medical student documentation. Specifically, the teaching physician can verify medical student documentation for an E/M service by providing a signature and date, rather than having to re-document the service[15]. Further, in the CY 2019 Medicare PFS and QPP final rule, CMS finalized a policy that would allow physicians, residents, or nurses to document the presence of a teaching physician during E/M services performed by residents.[16] We appreciate the multiple clarifications CMS provided to this policy through their updates to the CMS Manual System in Transmittal 4283.[17]

ACEP received some questions from members about what were acceptable versus unacceptable forms of documentation. Given the current active audit environment (including the Targeted Probe and Educate—TPE—process involving emergency medicine), these clarifications provided in Transmittal 4283 helped make our members more comfortable with operationalizing this policy. Overall, these changes around teaching physician documentation requirements provide a significant amount of relief to emergency physicians working in academic medical centers, allowing them to spend more time on patient care.

In this year's rule, CMS is proposing to provide even more flexibility to physicians surrounding documentation. Specifically, CMS is proposing to allow the physician, the physician assistant, or the advanced practice registered nurse who delivers and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students, or other members of the medical team.[18] **We believe that this broad flexibility will significantly reduce burden for teaching**

[15] MLN Matters, "Medical Review of Evaluation and Management (E/M) Documentation," available at https://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10627.pdf.
[16] 83 Fed. Reg. 59653-59654 (November 23, 2018).
[17] Transmittal 4283 is available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4283CP.pdf
[18] 84 Fed. Reg. 40548 (August 14, 2019).

physicians and urge CMS to finalize this proposal. However, we do seek confirmation from CMS that only physicians are responsible for signing and verifying the documentation of the residents and medical students.

Care Management Services

CMS is proposing to increase payment for Transitional Care Management (TCM) and implement a set of Medicare-developed HCPCS G-codes for certain Chronic Care Management (CCM) services. Additionally, CMS is proposing to create new coding for Principal Care Management (PCM) services, which would pay clinicians for providing care management for patients with a single serious and high-risk condition.

We support these proposals, as we believe that the care management included in many of the E/M services do not adequately describe the typical non-face-to-face care management involved for treating patients with one or multiple chronic conditions. Emergency physicians and hospital clinical staff can and do provide a growing amount of care coordination to link beneficiaries with care in the community and with post-acute providers, to help patients avoid return trips to the ED and or hospital for re-admission. As part of CMS' initiative to expand care management, we believe it is appropriate to consider the development of a care coordination service that would be specific to the services required for providing non-face-to-face follow-up with both the patient and community health care providers for a complex Medicare patient discharged from the ED.

Changes to the Ambulance Physician Certification Statement Requirement

CMS is proposing to clarify that there is no prescribed form for physician certification statements for ambulance transports. If the elements required by regulation are clearly conveyed, ambulance suppliers and providers would be allowed to choose the format by which the information is displayed, and they may find that other forms that may be required by other legal requirements to perform the transport may also satisfy the function of the PCS.

CMS is also proposing to grant ambulance suppliers and providers greater flexibility around who may sign a non-physician certification statement in certain circumstances. The proposal would also add licensed practical nurses (LPNs), social workers, and case managers as staff members who may sign the non-physician certification statement if the provider/supplier is unable to obtain the attending physician's signature within 48 hours of the transport. ACEP supports these two proposals as it would significantly reduce clinician burden.

Establish a Medicare Ground Ambulance Services Data Collection System

CMS is required by law to develop a data collection system to collect cost, revenue, utilization, and other information determined appropriate with respect to ground ambulance providers suppliers. CMS is proposing the data collection format and elements, a sampling methodology that CMS would use to identify ground ambulance organizations for reporting each year through 2024 and not less than every three years after 2024, and reporting timeframes. CMS is also proposing to reduce by 10 percent the payments that would otherwise be made to a ground ambulance organization that is identified for reporting but fails to sufficiently submit data, as well as a process under which a ground ambulance organization can request a hardship exemption that, if granted by CMS, would allow it to avoid the payment reduction. ACEP has no objections with how CMS is proposing to implement this statutory requirement.

Application of the Physician Self-Referral Law

CMS is soliciting additional comments on potential changes to its advisory opinion process to address stakeholder comments received from last year's Request for Information (RFI) on how to address unnecessary burden created by the Stark physician self-referral rules. Overall, ACEP supports the intent of the proposed reforms and values CMS' thoughtful effort to streamline this arduous process. We also think it is appropriate to re-echo our comments from the RFI about reducing barriers to care coordination caused by the physician self-referral rules.

We believe that it is often unclear whether many of the new value-based arrangements are legally permissible. With all the consolidation in health care, especially with health systems purchasing provider practices, it is difficult for the average physician to know for sure whether some of the care coordination they are providing is permissible. In order for emergency physicians to actively participate in value-based models and coordinate care for patients that come to the ED, we need to be assured that we are in compliance with all federal laws and regulations, especially those regarding referral patterns of care. For all current and future APMs, CMS should allow a wide range of referrals from physicians based in external locations, such as skilled nursing facilities (SNFs) to the ED. Likewise, CMS should allow all referrals of care to take place from the ED to observation and inpatient hospitalists as wells as referrals from the ED or inpatient setting to post-acute physicians and facilities like SNFs and home health agencies.

We also think that there is a lot of potential for new APMs that allow emergency physicians to coordinate a patient's care with other providers in other healthcare settings. The goal of these APMs would be to potentially keep a patient out of the ED in the first place or to ensure that the patient receives the appropriate follow-up treatment after an ED visit and avoids having to go back to the ED. Restricting the ability for emergency physicians and other providers to refer patients to the most appropriate healthcare providers or facilities would significantly limit the potential for these APMs to be successful. ACEP is eager to work with CMS going forward on specific ways to modify the Physician Self-Referral law that would facilitate the development and implementation of APMs focused on emergency care.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

CMS does not specifically address the Appropriate Use Criteria (AUC) Program in the rule. However, we would like to thank CMS for their clarification to the definition of "emergency medical condition" under the Appropriate Use Criteria (AUC) Program. Created by the Protecting Access to Medicare Act of 2014 (PAMA), the AUC program will eventually require physicians ordering advanced imaging for Medicare beneficiaries to first consult appropriate use criteria through approved clinical decision support mechanisms in order for the furnishing provider of that advanced imaging to be able to receive payment. PAMA exempts emergency services defined as an "applicable imaging service ordered for an individual with an emergency medical condition" (as defined by the Emergency Medical Treatment & Labor Act, or EMTALA). ACEP appreciated the recognition in PAMA that the federal EMTALA law imposes a duty to provide a medical screening exam to any individual who comes to the emergency department (ED). But Congress, through an inadvertent drafting error, referenced the section of EMTALA Sections 1867(e)(1) of the Social Security Act (SSA) that defines an emergency medical condition, rather than referencing Sec. 1867(a) of the SSA which codifies the requirement to provide a medical screening exam. Aside from cases of obvious trauma or severe visible medical symptoms, in most cases, a medical screening exam is required before definitively establishing that an emergency medical condition exists.

We had asked for years that CMS rectify this drafting error through regulation, and categorically exempt ED encounters from the AUC Program. If CMS did not adopt a categorical exemption, then we asked CMS to at least clarify that the AUC exception also applies in cases where an emergency medical condition is suspected, but not yet confirmed. We believed that this needed change would address the fundamental concern that certain advanced imaging tests may need to be quickly ordered to establish whether an emergency medical condition even exists or not. Requiring an ordering professional in the ED to make a distinction between patients that require AUC and those that have an AUC exemption is an additional burden that would directly impact the provision of timely needed care.

In the CY 2019 PFS and QPP final rule, CMS did provide that clarification, stating that this exemption includes cases where an emergency medical condition is suspected, but not yet confirmed. Examples include severe allergic reactions and pain.[19] Additionally, CMS has followed up with guidance on July 26, 2019 that instructs clinicians to use modifier "MA" on the same line as the CPT code for the advanced diagnostic imaging service in cases where the service is "being rendered to a patient with a suspected or confirmed emergency medical condition."[20]

While we appreciate the actions CMS has taken thus far related to the AUC Program, we believe that more can be done to help emergency physicians focus their efforts on providing high-quality patient care. Despite the clarification described above (and the fact that the program does not start until 2020), hospitals are already starting to force emergency physicians to consult appropriate use criteria before ordering advanced imaging services. From these experiences, we have heard antidotally that the clinical decision support tools are not user-friendly, are burdensome, and do not apply to the cases emergency physicians typically see in the ED. We are attempting to educate our members and hospitals about the exemption for emergency medical conditions. However, we need more time to properly ensure that all emergency providers understand the exemption. **Therefore, ACEP requests that CMS postpone the AUC Program requirements until at least 2021. Since CMS did not propose this delay in the rule, CMS should issue an interim final rule announcing the delay.**

Postponing the AUC program would allow us more time to educate our members and hospitals about when the exemption for emergency medical conditions is applicable and how to appropriately apply the MA modifier to the claim for the advanced diagnostic imaging service. A delay would also provide more time for emergency physicians to continue improving their performance in the Merit-based Incentive Program (MIPS). In many ways, MIPS, through the Cost Category, achieves the same ultimate goal as the AUC program does—to manage the utilization of services. Thus, in effect, MIPS has replaced the need to have an AUC program in place. From the emergency medicine perspective, it makes much more sense for emergency physicians to spend their time focusing on improving quality and reducing costs through MIPS rather than having to constantly evaluate whether each Medicare beneficiary who needs advance imaging would qualify for this exception (and if the beneficiary does not qualify, having to use a clinical decision support tool and adhere to appropriate use criteria that are not applicable to the ED setting).

[19] 83 Fed. Reg. 59699 (November 23, 2018).

[20] MLN Matters, "Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging – Educational and Operations Testing Period - Claims Processing Requirements," available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11268.pdf.

Medicare Shared Savings Program

CMS is soliciting comment on how to potentially align the Medicare Shared Savings Program quality performance scoring methodology more closely with the MIPS quality performance scoring methodology. Additionally, CMS is proposing modifications to the program's current set of quality measures. ACEP is generally concerned that making such a drastic change to the MSSP quality performance standard at the same time ACOs must decide if they will take downside risk presents too much instability and complexity into the program. If CMS finalizes the proposal, we believe that more ACOs will choose to leave the program.

We also note that overall, we have heard that only a limited number of emergency physicians actually participate directly in the Medicare Shared Savings Program. While emergency physicians could possibly be part of a larger physician group or hospital participating in the Medicare Shared Savings Program or another ACO model, emergency physicians do not play an active role in these initiatives. ACEP believes that one of the contributing factors leading to the paucity of emergency physicians actively participating in the Medicare Shared Savings Program is that there are not many measures in the program that are relevant to providers practicing in the ED setting. Therefore, we would like to recommend some measures that are meaningful to emergency medicine. Found below is a list of emergency medicine-related Quality Payment Program (QPP) measures that could be applicable to the Shared Savings Program. These measures, 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. They correlate to some of the current overuse Shared Savings Program measures including ACO-44 (Use of Imaging Studies for Low Back Pain) and ACO-28 (Hypertension (HTN): Controlling High Blood Pressure).

Adding these QPP measures to the Medicare Shared Savings Program would make participation in the Program more consequential to many of their members, 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
QPP76	Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections	Patient Safety
QPP254	Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain	Effective Clinical Care
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

ID	DESCRIPTION	NATIONAL QUALITY STRATEGY (NQS) DOMAIN
QPP332	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patient with Acute Bacterial Sinusitis (Appropriate Use)	Efficiency and Cost Reduction
QPP333	Adult Sinusitis: Computerized Tomography 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
QPP419	Overuse Of Imaging for the Evaluation of Primary Headache	Efficiency & Cost Reduction

The Quality Payment Program (QPP)

ACEP appreciates the opportunity to comment on the proposed policies for the fourth year of the QPP. Before delving into the specific proposals, we would like to note that most of our members participate in the first "track" of the QPP, the Merit-based Incentive Payment System (MIPS). While many emergency physicians are ready to take on downside risk and participate in Advanced Alternative Payment Models (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. The PTAC, established by MACRA, is a federal advisory committee with the primary responsibility for evaluating physician-focused payment models and providing recommendations to the Secretary. **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. As of the date of this letter, we are still waiting on the HHS Secretary to respond to the PTAC's recommendation—nearly a year after the PTAC submitted its report. Therefore, we urge CMS and the HHS Secretary to seriously consider the PTAC's recommendation, and we look forward to continuing to work with CMS and HHS to improve emergency patient care through the implementation of the model.

The Merit-based Incentive Payment System (MIPS)

MIPS Value Pathways Request for Information

ACEP has long supported the concept of allowing clinicians to report on one set of measures and receive credit in multiple categories of MIPS, as it will help reduce the burden of reporting for physicians and also link elements of the program together into one cohesive function. Further, as noted above, many of our members are eager to transition to Advanced APMs. Therefore, we are encouraged by the proposed introduction of the MIPS Value Pathways (MVP) framework in the rule. However, we are generally concerned about the implementation timeline CMS is proposing. While CMS is proposing the MVP concept in this year's rule, the agency is seeking comment on a plethora of the structural details in a request for information (RFI). Therefore, while CMS can finalize the MVP concept in this year's rulemaking cycle, the agency will have to wait until the CY 2021 rulemaking cycle to propose and finalize the details. Since CMS is proposing to start transitioning clinicians to MVPs in CY 2021, this gives little to no time for clinicians to fully understand the MVP framework and make the practice changes necessary to successfully participate. **Therefore, we strongly recommend that CMS slow down their implementation timetable, allowing an additional year or two for CMS to**

continue to flesh out the details, receive additional public input, and propose and develop the first cohort of MVPs.

We have numerous other questions and comments about MVPs and are appreciative of the opportunity to provide our feedback to some of the issues CMS raises in the MVP RFI.

Overall MVP Approach

Guiding Principles

CMS lays out the following four guiding principles for MVPs:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to the selection of measures and activities, simplify scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
3. MVPs should include measures that encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

In general, ACEP supports these principles. We understand that MVPs are meant to help streamline MIPS reporting and reduce the number of options available in MIPS, and we have heard from our members that meeting MIPS requirements is currently burdensome and costly. **However, we do NOT believe that MVPs should simply replace the current MIPS program that is in place. We strongly believe that participation in MVPs should be voluntary, not mandatory.** As emergency physicians, we do not want to lose the flexibilities that are available to us and other hospital-based clinicians, primarily the facility-based scoring option. We would like to preserve the existing policy for the facility-based scoring option in which applicable individuals and groups automatically receives a facility-based quality and cost score and CMS takes the higher of that score and a traditional MIPS score for purposes of determining an individual or group's MIPS performance.

Structure and Development of MVPs

CMS seeks comment on a number of issues around how MVPs should be organized and how CMS should best engage stakeholders in the development of MVPs. First, we believe that CMS should provide a menu of MVP choices to physicians, including those that are episode-based and specialty-based. As discussed below, we do not believe CMS should assign MVPs to clinicians, but instead, leave it as an option for clinicians to participate in an MVP or report traditionally in MIPS (and for certain facility-based providers, also have the choice of simply relying on the facility-based score). Second, we believe that specialty societies such as ACEP can play a vital role in developing new APMs that are applicable to their members. With respect to emergency medicine, for example, we believe that CMS can use the clinical episodes included in ACEP's APM, the AUCM to help build MVPs for emergency providers. The AUCM initially focuses on four conditions: abdominal pain, altered mental status, chest pain, and syncope. These conditions are high volume, high cost, symptom-driven diagnoses that were identified as showing marked variation in risk-adjusted ED readmission rates.

While input from specialty societies is critical, we also recognize the amount of time and resources that would be required in developing MVPs. If CMS were to rely too heavily on specialty societies to develop MVP

concepts for their societies and the quality and cost measures associated with the MVP, some specialty societies would not have the financial resources necessary to conduct this work. Further, we are concerned about the work and cost it would be to develop new quality measures. For example, if CMS were to adopt the episodes included in the AUCM as MVPs, the agency would likely need to help support the development of new quality measures that would be included in the MVPs. Therefore, CMS must find the right balance between conducting their own analyses and relying on specialty societies. CMS should consider conducting multiple webinars, phone calls, and other meetings with specialty societies throughout the year to develop a new MVP. However, CMS should not force specialty societies to take on the cost of developing new measures and activities. If CMS is committed to developing robust MVPs, we believe that it is CMS' responsibility to bear that cost.

Another factor that may limit the development of MVPs for certain specialties is the lack of cost measures that are currently available. It is unclear from the rule whether cost measures need to be developed first prior to an MVP being developed and approved. CMS should clarify whether cost measures are indeed a required factor to move forward with designing an MVP, and if so, CMS should develop a process, similar to the current process for designing, testing, and proposing new episode-based cost measures, to develop new MVP cost-measures.

With respect to the regulatory process for creating new MVPs, CMS seeks comment on whether the agency should initiate a "Call for MVPs" process that aligns with policies developed for the Call for Measures and Measure Selection Process or the process that is used to seek recommendations for new specialty measure sets. ACEP would support either process as long as CMS does not make any new process too burdensome on specialty societies. Specialty societies already conduct a lot of work each year to develop new measures or review and provide updates to existing measures. Adding another process on top of these existing processes would be difficult for some specialty societies to handle, putting them at a significant disadvantage for proposing and developing new MVPs. It is also unclear whether the development and approval of a new MVP would need to go through the formal rulemaking process or whether MVPs can be developed and approved through a sub-regulatory process. If MVPs need to go through formal rulemaking, that would significantly slow down the transition to MVPs.

Again, we encourage CMS to work with specialty societies throughout the year and be prepared to provide a menu of MVP options before the start of the next performance year to give clinicians time to choose an MVP that best fits their practice. CMS should provide MVP options to each clinician through multiple avenues, including the QPP Participation Status Tool, QPP submission portal, and the performance feedback report provided to clinicians regarding their previous years' data.

Promoting Interoperability

CMS seeks comment on how to build upon the Promoting Interoperability category of MIPS, which is an integral part of MVPs. As discussed in the "Promoting Interoperability Category" section of our comments below, we have some suggestions about how CMS can restructure this category so that it is more meaningful to clinicians and better advances the goal of interoperability. CMS should also 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**.

Transition to APMs

CMS asks how MVPs can effectively reduce barriers to clinician movement into APMs, such as practice inexperience with cost measurement and lack of readiness to take on financial risk. While the transition to Advanced APMs is a laudable goal, it is extremely unclear how participating in MVPs would help make this goal into a reality. The Center for Medicare & Medicaid Innovation (CMMI) operates most of the existing Advanced APMs. Their criteria for developing new models are extremely stringent, and their internal process for developing a new model can take years. Thus, even if an MVP proves to be successful in helping to drive down costs and improve quality, it would be a multi-year process before the MVP itself could transition to an Advanced APM. The Qualifying APM Participant (QP) five percent payment bonus is only available through 2024, leaving no time for this multi-year process to unfold.

If the goal of MVPs is simply to prepare clinicians to participate in another Advanced APM, unrelated to the MVPs themselves, the existing problem of the lack of available Advanced APMs for emergency physicians and other specialists remains unsolved. In other words, even if MVPs helped clinicians improve their quality of care and reduce costs better than the existing MIPS program does, many clinicians still will not have a clear pathway to participating in Advanced APMs. Again, to help push emergency physicians into Advanced APMs, we strongly urge CMS and the HHS Secretary to seriously consider implementing ACEP's APM, the AUCM.

Selection of Measures and Activities for MVPs

Assignment of MVPs

CMS seeks feedback on the selection of measures and activities within MVPs and whether MVPs should be assigned. As mentioned above, **ACEP does not support CMS assigning MVPs to clinicians.** Especially in the first few years as CMS transitions to MVPs, clinicians need to continue to have the option of reporting traditionally through MIPS and to an MVP. Further, as hospital-based providers, it does not make sense to be assigned to an MVP if a clinician simply decides to rely on the Hospital Value-based Purchasing (VBP) program cost and the quality score he or she receives under the facility-based scoring option.

In a listening session on September 9, 2019, CMS explained that "assignment" in this context means that CMS would simply inform clinicians what MVPs they could participate in based on the clinician's specialty and a few other identifying characteristics, leaving them the choice of whether to participate in an MVP or traditional MIPS. ACEP supports this concept and **requests that CMS clarify the assignment policy in the final rule**.

Improvement Activities

CMS seeks comments on a number of questions around improvement activities. **ACEP strongly supports the concept of allowing attestation to participation in a specialty accreditation program to satisfy the improvement activities performance category requirements for an MVP.** There are many examples of accreditation programs aimed at ensuring that facilities and health care clinicians provide the most appropriate care to their patients, using the most up-to-date clinical guidelines. For example, ACEP has developed the Geriatric Emergency Department Accreditation Program (GEDA), aimed at ensuring that older patients receive well-coordinated, quality care at the appropriate level at every ED encounter. Under GEDA, EDs can obtain three levels of accreditation based on their adherence to a standardized set of guidelines. These guidelines create a template for staffing, equipment, education, policies and procedures, follow-up care, and performance

improvement measures. MVPs focused on emergency care could definitely include GEDA accreditation as a means to satisfy the improvement activities category requirement.

Transitioning to MVPs

CMS seeks comment on approaches to accelerate the development and implementation of MVPs, as well as any comments on the optimal timeline for transition. As discussed above, we believe that CMS should delay their overall timeline for implementation. We also believe it would be preferable if CMS did not have to go through the federal rulemaking process to develop and establish MVPs. However, we also believe that there must be an appropriate amount of time, once a new MVP has been established, to educate eligible clinicians about the MVP, and provide an additional amount of support (through technical assistance, webinars, and other means) to ensure that clinicians understand how they may be able to successfully report the MVP measures.

ACEP recognizes that CMS may only have a few MVPs developed initially. For those MVPs that are ready to go at that time and for those that are added each subsequent year, we strongly encourage CMS to slowly phase in the reporting requirements. Just as 2017 was a transition year for MIPS, CMS could implement a similar type of "pick-up your pace" approach for the first year of a newly established MVP. Thus, if a clinician decided to participate in a new MVP, CMS could loosen scoring requirements for the first year to give that clinician the time he or she needs to adjust his or her practice patterns and previously-established MIPS reporting processes and not penalize him or her for being the "guinea pig" for the new MVP. One idea put forth by the American Medical Association (AMA) that ACEP supports is to establish a minimum point floor for those who report MVPs that is equal to the performance threshold. Specific features of the MVP approach should also be refined and improved over time as physicians gain experience with the MVP option.

Adjusting MVPs for Different Practice Characteristics

Small and Rural Practices

ACEP believes that small and rural practices would likely be less nimble in their ability to shift their clinical practice patterns and reporting processes to transition to MVPs and successfully meet the reporting requirements. Therefore, we would be in support of a policy that would allow small and rural practices to report fewer measures and activities within an MVP. CMS should consider providing a small and rural bonus to certain small and rural groups that choose the MVP option.

Multispecialty Practices' Participation in MVPs

ACEP supports the concept of using the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of services delivered by a multi-specialty group practice. Some of our members practice in multi-specialty groups, and if they were to choose to participate in an MVP, then they should have the option and ability to be in one that is meaningful to them. However, from an administrative and programmatic perspective, we understand that it would not be feasible for each individual clinician within a multi-specialty group practice to participate in different MVPs, especially if each individual in the group had reassigned their billing rights to an individual group practice Tax Identification Number (TIN). Therefore, we believe that CMS could give a multi-specialty group practice the option of reporting on two or three MVPs that are based on the composition of their practice. The practice could self-identify the specialty composition of their practice and indicate which MVPs their clinicians would like to participate in.

CMS could also consider creating MVPs that cross specialties and allow clinicians within a multi-specialty group to work together to report measures and attest to activities that pertain to a specific episode or condition. CMS could therefore provide multi-specialty groups with the option of reporting on one cross-cutting MVP or multiple MVPs that individual clinicians within the group could report on.

Qualified Clinical Data Registries (QCDRs)

ACEP strongly urges CMS 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 strongly encourage CMS to allow QCDRs to 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 think 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. In all, incorporating QCDR measures would help CMS achieve all of the four proposed principles for MVPs highlighted above.

We also support the concept of QCDRs becoming a "one-stop-shop" for reporting in MIPS and think that principle aligns with the MVP approach. However, as discussed in the QCDR section below, we are generally concerned that CMS is increasing burden on QCDRs, making the quality measure development and self-nomination processes more time-consuming and expensive. If CMS is to encourage clinicians to use QCDRs under MVPs, CMS must do more to streamline QCDR requirements and provide QCDRs more flexibility and support to develop measures that are meaningful to clinicians.

Scoring MVP Performance

CMS seeks comments on what scoring policies can be simplified or eliminated with the introduction of MVPs. ACEP supports keeping the 10-point scoring system for the Cost and Quality categories the same as it is under the traditional MIPS program. Maintaining the current scoring system would help reduce complexity as clinicians begin to transition to MVPs. **We also urge CMS to maintain the 3-point floor for each submitted measure that can be reliably scored, as well as the scoring bonuses that are currently available under the program.** Making these modifications initially would be premature, since clinicians have had no experience reporting MVP measures. In all, ACEP recommends keeping scoring policies the same, if feasible, until both clinicians and CMS gain more experience with MVPs.

CMS also seeks comments on how to score multi-specialty groups reporting multiple MVPs. We would support the approach of scoring specialists separately depending on which MVP they selected, understanding that this would in result in different scores within a single group. This would more fairly and accurately reward or penalize clinicians based on their performance on the MVPs that they specifically participate in.

MVP Population Health Quality Measure Set

ACEP does not support the use of administrative claims-based measures in all MVPs. Overall, we believe that measures that should be included in MVPs are those that have been developed by specialty societies to ensure they are meaningful to a physician's particular practice and patients and measure things a physician can actually control. As hospital-based clinicians, we share the concerns that CMS cites in the rule 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 administrative 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.

While CMS is aware of these concerns and is examining ways to mitigate them, 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.

Clinician Data Feedback

ACEP encourages CMS to provide robust, timely, and actionable feedback on MVP measures and activities. As an incentive to participate in an MVP, CMS may want to provide bonus points to clinicians who use feedback reports to improve their performance in an MVP. That would encourage ongoing participation in MVPs as well as incentivize them to learn how to use data and analytics to enhance the care they provide to patients.

Patient-Reported Measures

ACEP appreciates the importance of accurately measuring patient experience and satisfaction. However, as discussed in the "Consumer Assessment of Health Providers (CAHPS) for MIPS Survey," section below, we have concerns with the ability for patient experience and satisfaction measures to actually measure performance that is attributable to an individual clinician. If CMS were to incorporate these measures into MVPs, we strongly suggest that they not be used for scoring purposes. Instead, they should only be used in feedback reports to help individual clinicians and groups identify areas for improvement and work towards solving issues identified by patients. Applying the measures towards individual clinicians and groups' performance scores could penalize them for issues beyond their direct control.

Publicly Reporting MVP Performance Information

ACEP has no objections with the concept of a "value indicator" to publicly report clinicians' performance on MVPs. However, we think this discussion of public reporting MVP performance is premature. **ACEP strongly urges CMS to wait to publicly post any MVP results until clinicians have one to two years of experience reporting MVPs.** Participating in an MVP could require individual clinicians and groups to make significant changes in how they practice, so CMS should provide them a couple of years to feel comfortable participating in MVPs before publicly reporting their results. During that time, based on initial results, CMS should think about the best way of measuring overall performance in MVPs and displaying that information on Physician Compare.

Category Weights

CMS proposes to increase the Cost category incrementally over time, reaching 30 percent by 2022. CMS proposes to make corresponding decreases to the Quality category weight each year. ACEP recognizes that cost category is required by law to reach this percentage by 2022, but, as discussed below, we remain concerned about the lack of available cost measures that are meaningful and attributable to emergency physicians.

Therefore, we recommend that CMS maintain the Cost category percentage at 15 percent for one more year to provide CMS more time to develop more episode-based cost measures. ACEP suggests the following approach to increasing the cost category to 30 percent by 2022.

- Performance Category Weights ACEP Proposes for 2020:
  - **Quality: 45% (same as 2019)**
  - **Cost: 15% (same as 2019)**
  - Promoting Interoperability (EHR): 25% (same as 2019)
  - Improvement Activities: 15% (same as 2019)
- Performance Category Weights ACEP Proposes for 2021:
  - **Quality: 40% (down from 45% in 2020)**
  - **Cost: 20% (up from 15% in 2020)**
  - Promoting Interoperability (EHR): 25% (same as 2020)
  - Improvement Activities: 15% (same as 2020)
- Performance Category Weights ACEP Proposes for 2022:
  - **Quality: 30% (down from 40% in 2021)**
  - **Cost: 30% (up from 20% in 2021)**
  - Promoting Interoperability (EHR): 25% (same as 2021)
  - Improvement Activities: 15% (same as 2021)

Quality Performance Category

Data Completeness Threshold

ACEP does not support the proposed increase in the data completeness threshold to 70 percent. We believe that the current threshold of 60 percent is appropriate. However, we do note that as hospital-based clinicians, some of our members struggle to get enough data from their hospitals to meet even this threshold. A large number of emergency physicians and groups that use ACEP's QCDR, the Clinical Emergency Data Registry (CEDR), to report quality measures do not receive any data from their hospitals. Data from hospitals could include critical information such as medications, labs, and other test results for patients. Without the data elements, the measures cannot be fully calculated and scored. Therefore, since CEDR is unable to calculate the measures, these emergency physicians and groups are unable to meet the full MIPS requirements for quality, making it more likely that they will receive a downward payment adjustment under MIPS. Hospitals claim that they cannot share the data for privacy and security purposes, but CMS has indicated that there are no regulations that impede hospitals from doing so. **Since this is a serious issue for hospital-based clinicians, we urge CMS to take immediate action to help improve the flow of information by requiring hospitals to share clinical data with registries.**

ACEP also notes that there is no CMS guidance that tells clinicians or groups how to select the 60 percent (or 70 percent as proposed) of the patients they want to report on. This lack of guidance leads to an inconsistent way of submitting data. ACEP recommends that CMS require, for any data submission, which includes less than 100 percent of the eligible population, that the data must be statistically representative of the total population performance. For example, if 60 percent of the eligible population is reported, then the performance on a given measure for that 60 percent must be reasonably similar to the performance of the entire eligible population.

Consumer Assessment of Health Providers (CAHPS) for MIPS Survey

CMS is not proposing any changes to the established submission criteria for the CAHPS for MIPS Survey. 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 currently under development by CMS. 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 providers feedback and resultant skills training to improve physician-patient communication.

CMS also seeks comment for future rulemaking on adding narratives to the CAHPS for MIPS survey and on whether the survey should collect data at the individual eligible clinician level. While ACEP supports the concept of collecting feedback from patients and using that to improve patient care, we are concerned about the potential for CMS to use unstructured patient narratives to adjust physician payments. In some cases, patient feedback relates to issues that are beyond the control of physicians, and while it is important to understand and address any concerns raised by a patient, the feedback itself should not be used for payment purposes. CMS also asks whether a tool should be developed to collect patient experience information about individual clinicians, or should this information be kept at the group level only. Notwithstanding our concerns mentioned above, ACEP supports measuring patient experience data at the group level and not the individual level.

Topped Out Measures

In last year's rule, CMS had finalized a proposal to remove extremely topped out measures (for example, a measure with an average mean performance within the 98th to 100th percentile range) in one year instead of following the full four-year topped out measure removal process that CMS previously established. We continue to believe that removing measures in the next rulemaking cycle measures results in severely limited reporting options available to many specialties. By phasing these measures slowly out of MIPS, CMS would provide time for more measures to be developed that certain specialties can report. We do not think that CMS should adopt this aggressive policy of removing certain topped out measures after only one year. We also note that CMS has not yet done a thorough analysis of how clinicians performed in MIPS and on particular quality measures in the first year of the program. Making changes such as this prematurely before analyzing the results could have unintended consequences.

ACEP also believes that the current structure of the MIPS program provides a clear incentive for participants to only report the six measures where they perform the highest relative to their peers. As a result of this practice, the benchmarks for these measures are artificially inflated, thereby leading to the measures being inappropriately topped out. Furthermore, the high performance on measures has the potential of skewing the long-term results of the program. While it may appear that overall quality is improving, this could in fact simply be a result of participants reporting measures on which they perform well above than their peers.

CMS seeks comment on whether the agency should increase the data completeness threshold for quality measures that are identified as extremely topped out but are retained in the program due to the limited

availability of quality measures for a specific specialty. **ACEP strongly urges CMS not to raise the data completeness threshold under any circumstances. Physicians who do not have an adequate number of measures to report on should not be punished for something that is out of their control.**

Removal of Quality Measures

CMS proposes to remove 55 quality measures in CY 2020, which results in a 21 percent decrease in the total number of available MIPS quality measures. Over the last two years, CMS has removed approximately 32 percent of MIPS traditional quality measures. CMS also proposes to add an additional removal factor: remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive CY performance periods. ACEP recommends maintaining the existing MIPS quality measures to ensure consistency with program requirements, reduce the creation of additional burden, and allow for more measures to form the basis of MVPs. We also recommend that CMS not finalize the new measure removal factor.

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. Eliminating a measure only after two years in the program will also deter measure stewards from investing in and developing new measures, maintaining existing measures, and putting forward MVP proposals. The proposed rule presents the real potential of removing measures that developers have spent more than two years to develop and test to only have it in the program for a small number of years (even just two years).

While ACEP supports keeping all the measures in the program, we are especially concerned with CMS' proposal to remove measure #91, "Acute Otitis Externa (AOE): Topical Therapy," from the emergency medicine specialty set. We understand that CMS' rationale for removing the measure is that it is clinical equivalent to the previously finalized measure "Q93: Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use." However, we believe that for emergency physicians, measure #91 remains the more meaningful measure. Further, it is an extremely popular measure in our measure set and eliminating it would significantly reduce burden for many of our clinicians by forcing them to report on another, less meaningful measure. **We strongly urge CMS to keep measure #91, "Acute Otitis Externa (AOE): Topical Therapy," in the emergency medicine measure set in CY 2020.**

Cost Performance Category

MSPB and Total Per Capita Cost Measure

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 recognize that CMS is proposing significant changes to the attribution and risk-adjustment methodologies for both measures. However, we continue to believe that the measures are severely flawed, and the proposed methodological changes do not address our previously-expressed concerns. The proposed changes would potentially help other physicians, as they are aimed at improving attribution for primary care physicians and would potentially eliminate the problem of attributing costs that occurred before the physician ever saw the patient.

In all, 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 risk adjustment proposed changes, the measures will still be 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

ACEP applauds CMS for developing ten new episode-based measures, in addition to the eight CMS finalized last year. 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, despite the majority of these admissions come through the ED. ACEP has previously been told in discussions with CMS staff that the role of the emergency physician wouldn't meet any currently used attribution thresholds. More recently, ACEP has been involved in CMS' ongoing work to develop new episode-based cost measures that are meaningful to emergency physicians, including on a cost measure related to sepsis. We thank CMS for including ACEP in this important work.

Reliability

We are disappointed that CMS did not propose an adjustment to the reliability threshold of 0.4 that the agency set for measures in the Cost performance category. The agency has itself admitted in the past that reliability levels between 0.4 and 0.7 indicate only "moderate" reliability. No policy that holds clinicians publicly accountable should rely on such a low level of reliability given its impact on attribution.

Improvement Activities Performance Category

Improvement Activities Inventory

CMS is proposing to add two new improvement activities, modify seven existing activities, and remove 15 existing activity from the current inventory of improvement activities. ACEP notes that many of the current improvement activities are used in our Emergency Quality (E-QUAL) Network. E-QUAL is a learning collaborative aimed at improving emergency care and lowering costs. It is a CMS-supported Support and Alignment Network (SAN) in the Transforming Clinical Practice Initiative (TCPI). Participation in E-QUAL can earn clinicians Improvement Activity credit. We do not believe that any of the proposed changes to the Improvement Activities inventory would detrimentally affect clinicians that participate in E-QUAL or their ability to improve care for the patients they serve.

Improvement Activities Data Submission

ACEP strongly opposes CMS' proposal to increase the minimum number of clinicians in a group who are required to perform an improvement activity to 50 percent beginning with the 2020 performance year and future years. Under that proposal, at least 50 percent of a group's NPIs must perform the same activity for the same continuous 90 days in the performance period. Currently, only one member of the group

needs to attest to an improvement activity for the group to receive credit. Raising the bar to 50 percent of clinicians in a group would significantly increase burden and make it impossible in some cases for groups to attest to the required number of activities in order to receive partial or full credit for the category. In many cases, there are few clinician leaders in a group who are actively engaged in a particular improvement activity. Other members of the group may not have the time or resources necessary to participate in that activity. By significantly increasing the threshold to 50 percent, CMS would be disincentivizing those clinician leaders from participating in the activity, since they would know that there would be no way their group would receive credit. **We therefore strongly urge CMS to maintain the existing policy of only requiring one clinician in a group to participate in an improvement activity.** If CMS feels strongly that the agency must increase the threshold in CY 2020 and future years, ACEP requests that CMS more gradually increases the requirement to 5 or 10 percent.

Promoting Interoperability

Definition of Hospital-based Clinician

In previous comments to CMS, ACEP has expressed significant concerns with how CMS defines "hospital-based" to approve hardship exemptions for Promoting Interoperability category of MIPS. Currently, clinicians who are deemed "hospital-based" as individuals are exempt from the Promoting Interoperability category of MIPS. However, if individual clinicians decide to report as a group, they lose the exemption status if one of them does not meet the definition of "hospital-based." We have repeatedly argued that this "all or nothing rule" is unfair and penalizes hospital-based clinicians who work in multi-specialty groups. **We are therefore extremely appreciative that CMS is proposing to modify this policy in the rule by exempting groups from the Promoting Interoperability category if 75 percent of the individuals in the group meet the definition of hospital-based. We strongly urge CMS to finalize this proposal.**

Overall Concerns with the Category

In last year's rule, CMS finalized a new scoring for the Promoting Interoperability category of MIPS. While ACEP appreciates CMS' effort to reduce complexity and burden, we are concerned that CMS has gone back to an "all or nothing" approach, which existed in the original Meaningful Use program. Under CMS' final policy, clinicians are required to report on all measures within each of the four objectives unless they claim an exclusion for a particular measure. Failure to report on one measure would make the clinician receive a score of zero for the entire category. CMS did not propose any changes to the Promoting Interoperability scoring methodology in this rule.

However, CMS did consider an alternative approach in the CY 2019 PFS and QPP proposed rule that would have allowed scoring to occur at the objective instead of individual measure level. Under this alternative, if an objective includes two measures and clinicians did not report accurately on one measure (and failed to claim an exclusion) but did report accurately on the other, they would still be able to receive a Promoting Interoperability score. In ACEP's comments on the proposed rule, ACEP had supported this alternative. We believe that in order to realize the full potential of EHRs, requirements of the Promoting Interoperability category need to flexible in order to allow clinicians to incorporate available technology into their unique clinical workflows, to mitigate data access and functionality issues that might be unique to their practice and outside of the individual clinician's direct control, and to use EHRs in a manner that more directly responds to their patients' needs. Requiring that clinicians report every single measure or have to actively claim an exclusion creates an unfair burden and is antithetical to CMS' overall goal to streamline reporting requirements. Another possible change

to the scoring methodology for the Promoting Interoperability category of MIPS that would reduce complexity would be to assign point values for each measure proportionate to their overall value relative to the MIPS composite score. The total number of points in the Promoting Interoperability category would, therefore, be 25 (since the Promoting Interoperability category represents 25 percent of the total MIPS score), and clinicians would receive points for the measures that they choose to report. This approach would also eliminate the "all or nothing" scoring methodology that is currently in place and reward clinicians for reporting on those measures that are meaningful to them. Finally, ACEP supports a proposal put forth by the American Medical Association that would set a threshold of points that would dictate whether a clinician has "successfully" reported. Under this proposal, CMS would give full credit for the Promoting Interoperability category to any clinician with a score of over 50 points.

ACEP also believes that it is critical that clinicians not be limited by existing technology barriers and penalized for factors outside of their control. CMS must resolve fundamental cornerstones necessary for data exchange (e.g., patient matching, provider directories, standards, and privacy and security) and focus on increasing the functional interoperability between vendors and among vendors and registries to ensure this aspect of MIPS is achievable, meaningful, and not another unnecessary regulatory burden on clinicians. The Promoting Interoperability metrics themselves should focus only on what the individual clinician has direct influence over and not on the actions of other individuals—whether patients or other clinicians—or technology. CMS could also revisit the current certification structure more generally since it significantly stifles innovation for EHR developers and disincentivizes the development of user interfaces that more closely match how physicians practice.

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. However, based on feedback from health IT vendors and hospitals, CMS is now proposing to make the Query of PDMP measure optional in CY 2020 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 2020. Going forward, we believe that, under only certain conditions, it would 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.

Requests for Information (RFIs)

RFI on a Metric to Improve Efficiency of Providers within EHRs

CMS is seeking comment on a potential metric to evaluate health care provider efficiency using EHRs under the Promoting Interoperability Program. In general, ACEP believes that it is the responsibility of EHR vendors to make their products more efficient and easier for providers to use. With respect to emergency medicine, emergency physicians do not have control over the specific EHR vendor or product their hospital is using and how the hospital chooses to implement the overall system. Therefore, EHR vendors should do more to integrate EHRs into emergency physicians' clinical workflow and to improve the usability of data that is retrieved from the EHR. CMS should also take specific actions to increase the efficiency of health care provider interactions with EHRs. The agency could provide incentives to hospitals through the Promoting Interoperability Program or alter its current scoring methodology to build in an efficiency measure that rewards hospitals for investing in new technologies, such as instituting a single sign-on for all of their IT systems.

EHRs contain vast amounts of data, and we need better tools to be able to utilize that data efficiently and effectively to serve our patients better. The ability to find information quickly is most critical when emergency physicians and other emergency medical service (EMS) providers respond to both man-made and natural disasters. During disasters, we must have access to real-time data regarding all of the available health care resources in the affected region. However, unfortunately, emergency physicians do not always know where or how to find this essential information. ACEP surveyed its members in May 2018 and found that over a quarter of emergency physicians did not have complete access to real-time data when responding to a natural or man-made disaster or mass casualty incident.[21] This is not acceptable, and we strongly encourage the Administration to help improve providers' access to clinical data and information on available health care resources during these devastating events.

The lack of consistency regarding how data are displayed in EHRs also makes it hard for us as emergency physicians to search for what we need and find it in a timely manner. For example, some information can be stored in the EHR as a scanned image rather than as structured data, making it almost impossible at times to find the data we are looking for. Finally, we need to improve the way patient information is collected and entered into EHRs to better integrate it into the clinical workflow. A lot of the data we are forced to collect and screenings we are required to perform are not necessary and do not add clinical value. Also, as referenced above, we believe that a lot of the documentation and provider entry that we currently do is duplicative. We support the use of non-physician aids to put in orders and data and also encourage the use of scribes and dictation to reduce physician burden further. Going forward, we would like to see more advancements in technical innovations that would further automate the collection process of structured data (such as voice recognition technology and connected devices) and make it even easier for providers to enter usable information into EHRs.

RFI on the Provider to Patient Exchange Objective

Building off proposals in both the CMS Interoperability and Patient Access Proposed Rule[22] and the ONC

[21] ACEP New Release, "Most Emergency Physicians Report Hospitals Lack Critical Medicines; Not "Fully Prepared" for Disasters, Mass Casualty Incidents," May 22, 2018, http://newsroom.acep.org/2018-05-22-Most-Emergency-Physicians-Report-Hospitals-Lack-Critical-Medicines-Not-Fully-Prepared-for-Disasters-Mass-Casualty-Incidents.

[22] Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care

Interoperability and Information Proposed Rule[23], CMS is seeking comment on whether MIPS eligible clinicians should make patient health information available immediately through the open, standards-based application programming interface (API), no later than one business day after it is available to the clinicians in their CEHRT. ACEP believes that imposing tight deadlines on clinicians could lead to mistakes and inaccurate information being put on the API. These issues would be exacerbated in the emergency care setting. A large proportion of emergency care involves the acute diagnosis, treatment, and stabilization of diffuse and undifferentiated clinical conditions. For example, two of the most common patient presentations are "chest pain" and "abdominal pain." These initial symptoms have a large range of ultimate diagnoses and require a large variety of patient-specific lab tests, radiology exams, and other interventions. Due to the unpredictability of emergency care, sorting out claims for individual cases is a complex and timely process. **We therefore strongly recommend that CMS does not require clinicians to make patient health information available through the API no later than one business day after it is available to the clinicians in their CEHRT**. While we understand the need to get information to consumers as quickly as possible so that they can make more informed decisions about their health care, what is even more important is that the information they are receiving is accurate.

Similar to the CMS and ONC Interoperability proposed rules, CMS also seeks comments on ways for ONC and CMS to continue to facilitate a workable and scalable patient matching strategy so that the lack of a specific unique patient identifier (UPI) does not impede the free flow of information. As emergency physicians, we recognize the critical importance of being able to quickly identify our patients and track them across different health care settings. When it comes to treating patients with acute medical needs, minutes and even seconds matter. Therefore, the inability to know who our patients are, and what other services they may have previously received, really impacts our ability to provide the best possible care. To underscore the problem, in 2016, Harris Health System in Houston reported it had 2,488 records with the name "Maria Garcia;" of those, 231 shared the same birthdate, suggesting some of them refer to the same individual.[24] Notably, if all health care organizations collected certain pieces of demographic data uniformly, patient-match rates would increase significantly.

Therefore, in general, ACEP supports efforts to create a patient identifier or tracking system. We are cognizant however, about privacy and security concerns around creating a patient identifier. An identifier could become as sensitive as a person's social security number, so creating safeguards to protect it is essential. Further, if the patient identifier is based on a patient's date of birth, former address, or any other background piece of information about the patient, even that has its potential issues. Some patients, especially those who have suffered a trauma, may not know or be able to easily recall this information, which could lead to confusion and potential medical errors.

In addition, we ask CMS to consider the concept of an "error reporting registry" to track patient mismatches and common mistakes that may or may not be Health Insurance Portability and Accountability Act (HIPAA) violations. This registry could help inform further process improvements and necessary updates to both the API and provider processes pertaining to patient record matching. A simple, straightforward way for providers

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Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers Proposed Rule, 84 Fed. Reg. (March 4, 2019).

[23] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, 84 Fed. Reg. (March 4, 2019).

[24] Giuseppe Lippi et al., "Patient and Sample Identification: Out of the Maze?" Journal of Medical Biochemistry 36 (2017): 1-6, http://dx.doi. org/10.1515/jomb-2017-0003; Harris Health System, "Harris County Hospital District Puts Patient Safety in the Palm of Your Hand" (April 5, 2011), https://www.harrishealth.org/en/news/pages/patient-safety-biometric-palm-scanner.aspx.

and patients to report instances of information blocking under any variety of circumstances, including faxing, would be of great benefit, particularly to smaller providers.

Beyond patient identification, the number of administrative roadblocks that currently exist to get information about our patients is equally as concerning. We often see patients who have received care from another ED, hospital, or provider, sometimes the same day. When a patient comes to the ED, emergency physicians can rarely see any of the information from the previous healthcare encounter. When we reach out to the other ED, hospital, or provider to ask what happened to avoid duplication of workup and make sure nothing is being missed, we are referred to a medical records office instead of the treating provider and are told that we need to have the patient sign a consent form for release of information and that they cannot be given information over the phone. When health care providers have the opportunity to talk directly to each other, they almost always share all the relevant information that is necessary to treat individual patients. Breaking down the barriers that inhibit or delay these types of conversations from taking place could improve clinical workflow and our ability to provide effective patient care while still preserving patient privacy and data security.

RFI on Engaging in Activities that Promote the Safety of the EHR

CMS is seeking comment on how to further mitigate the specific safety risks that may arise from technology implementation. Specifically, CMS seeks feedback on ways that the Promoting Interoperability Program may reward hospitals for engaging in activities that can help to reduce errors and other patient safety issues associated with EHR implementation. **First and foremost, ACEP strongly believes that physicians should never be penalized for reporting medical errors caused by poor EHR usability. Efforts in some states such as Rhode Island to punish doctors for reporting mistakes that are meant to draw attention to risks in their EHR systems are unjustifiable.**[25]

Studies have shown that poor EHR usability has led to certain types of medical errors, as physicians, nurses, and other clinicians use these systems to care for patients, and there is increasing evidence showing the association between usability issues and safety. For example, a study in Health Affairs examining 9,000 health information technology and medication safety events in three pediatric hospitals showed that inadequate usability contributed to approximately a third of the errors, many of which resulted in patient harm.[26]

In August 2018, the Pew Charitable Trusts, MedStar Health's National Center for Human Factors in Healthcare, and the American Medical Association conducted a literature review and convened a multidisciplinary expert panel composed of physicians, nurses, pharmacists, EHR vendors, patients, and health information technology experts. This information led to the development of:

- Recommendations on how to advance usability and safety throughout the EHR software life cycle, which can be used as the foundation for a voluntary certification process for developers and EHR implementers; and
- Criteria are detailing what constitutes a rigorous safety test case and the creation of sample test case scenarios based on reported EHR safety challenges.[27]

[25] Allen, A. "Rhode Island docs alarmed by subpoenas they link to EHRs," Politico (30 Jan. 2019) https://www.politico.com/story/2019/01/30/medical-misconduct-subpoenas-ehr-1107689.

[26] Ratwani, R. et al. "Identifying Electronic Health Record Usability And Safety Challenges In Pediatric Settings," Health Affairs, Vol. 37, NO.11 (Nov. 2018).

[27] The Pew Charitable Trusts, American Medical Association, & Medstar Health, "Ways to Improve Electronic Health Record Safety: Rigorous testing and establishment of voluntary criteria can protect patients," (Aug. 2018), https://www.pewtrusts.org/-/media/assets/2018/08/healthit_safe_use_of_ehrs_report.pdf.

We urge CMS to review the findings of this report and work with ONC to incorporate its recommendations, as appropriate.

Calculating MIPS APM Performance Category Scores

ACEP appreciates the intent of the proposal to allow clinicians in APMs to have the option of reporting on MIPS quality measures beginning in CY 2020. We recognize that currently in some cases, clinicians in APMs do not receive quality scores because CMS is unable to score performance data on APM quality measures for purposes of MIPS in time. However, we are concerned that CMS is proposing an unfair scoring methodology. Under the proposed methodology, if a MIPS eligible clinician has no quality performance category score (i.e. an individual clinician does not report) that MIPS eligible clinician would contribute a score of zero to the aggregate APM Entity group score. We think that this could penalize individual clinicians in a group that attempt to report MIPS quality measures when doing so is not required. Instead, we believe that CMS should only count those individuals in a group that report MIPS measures to the overall group score.

We also support the proposal for APM Entity groups participating in MIPS APMs to receive a minimum score of one-half of the highest potential score for the quality performance category. However, we want to confirm that this proposal does not mean that reporting MIPS quality measures is mandatory for APM entities rather than voluntary. In other words, we want CMS to state clearly in the final rule that APM entities that choose not report MIPS measures and do not receive an APM quality score due to timing issues outside of their control still have the Quality component of their overall MIPS score re-weighted to other performance categories, as is done currently.

MIPS Final Score Methodology: Performance Scores

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements

For the 2020 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. We, however, do not support CMS potentially assigning zero points for measures that do not meet data completeness going forward. We believe that CMS should continue to provide a minimum level of credit to clinicians who attempt to report measures and, through no fault of their own, fail to meet the data completeness threshold. As hospital-based clinicians, many of our members struggle to get all the necessary data from hospitals and/or their billing companies to report on 60 percent of all their applicable patients. While it may be easier to get data on some patients, such as those in Medicare, it may be more difficult to get data on others. For example, emergency physicians are often contractors for the hospitals in which they work, and sometimes these hospitals refuse to release data to the QCDRs that the emergency physicians are using. Changing this policy going forward would penalize clinicians for something that is beyond their control.

Calculating the Final Score

CMS is proposing to continue applying the complex patient bonus for the 2020 performance period. CMS does not believe it has sufficient information available at this time to develop a long-term solution to account for patient risk factors in MIPS. **ACEP strongly supports CMS continuing to account for social risk factors in MIPS.** Emergency Medicine is among the very highest in specialties in the average ratio of dual-eligible beneficiaries, and therefore emergency physicians face additional challenges relative to others participating in MIPS, even when providing the highest quality care. Stratifying scores of participating clinicians based on their ratio of dual-eligible patients could provide a more fair and direct comparison to their peers. ACEP would also support using geographic area of residence as an additional method of accounting for social risk. ED patients in rural parts of the country, as well as those in urban, medically underserved areas, often have much higher social risk than those in geographic areas that are better served, with less access to the many resources and community services needed to ensure better health outcomes.

Performance Threshold

CMS is proposing to increase the performance threshold from 30 points in 2019 to 45 points in 2020 and 60 points in 2021. CMS believes that this threshold would provide a gradual and incremental transition to the performance threshold that the agency would establish for the 2022 performance year, which is estimated to be 74.01 points. CMS also seeks comment on whether establishing the agency should adopt a different performance threshold in the final rule if the actual mean or median final scores for the 2018 performance year are higher or lower than its estimated performance threshold for the 2022 performance year of 74.01 points.

ACEP believes that the current proposal represents a reasonable increase in the performance threshold over the next two years. We caution the agency against increasing the performance thresholds above 45 points in 2020 and 60 percent in 2021 even if the actual mean or median scores for 2018 come in higher than expected. Increasing the thresholds above these scores would disadvantage small and rural practices who may not have the resources necessary to score as high as large and urban practices.

Additional Performance Threshold for Exceptional Performance

CMS proposes to set the additional performance threshold at 80 points for the 2020 MIPS performance period and 85 points for the 2021 MIPS performance year. ACEP believes the additional performance threshold should be kept at 80 points for both 2020 and 2021. Eighty 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 80 points in 2021, 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 80 points.

Reweighting Performance Categories due to Data that are Inaccurate, Unusable, or Otherwise Compromised

ACEP supports CMS' proposal to allow reweighing for any performance category if, based on information CMS learns prior to the beginning of a MIPS payment year, the agency determines that data for that performance category are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the MIPS eligible clinician or its third-party-agents. CMS is also seeking comment on this proposal and alternatives to ensure that clinicians are not penalized for having data in a performance category that are

inaccurate, unusable, or are otherwise compromised, through no fault of their own. 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 "inaccurate, unusable, or otherwise compromised data" when the agency finalizes this policy.**

Qualified Clinical Data Registries

In the proposed rule, CMS includes numerous proposals that impact QCDRs. 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 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.

With respect to the proposals in the proposed rule, we are concerned that some of them may, in fact, make it more difficult and burdensome for QCDRs to participate in MIPS successfully. In fact, CMS estimates in the Collection of Information Requirements section of the rule that the total number of hours and the cost for QCDRs to go through the Self-Nomination and measure submission process will increase by 21 to 35 percent

if the policies in the rule are finalized.[28] In all, we fear that CMS is attempting to shift costs and burden of administering the MIPS program onto specialty societies that create measures and operate QCDRs.

The Requirement for QCDRs to Submit Data in Each Category

CMS is proposing that starting in 2021, QCDRs would be required to submit data in the Quality, Improvement Activities, and Promoting Interoperability Categories. However, CMS notes that QCDRs that serve a specific specialty or group that is traditionally exempt from one of the categories does not have to include that capability. As noted in our MVP comments above, ACEP supports the concept of QCDRs becoming a "one-stop-shop" for MIPS reporting. In fact, CEDR already allows clinicians to report measures in the Quality Category and attest to activities in the Improvement Activities category. Further, while most emergency physician groups will be deemed hospital-based and exempt from the Promoting Interoperability Category of MIPS if CMS finalizes the change in the definition of "hospital-based" discussed above, CEDR will also have the capability to meet the Promoting Interoperability requirements for those groups that are still not exempt.

Requirement for QCDRs to Engage in Activities that Foster Improvement in Quality of Care

CMS is proposing that beginning in 2021, QCDRs must engage in additional activities that will "foster the improvement in the quality of care" beyond those included in the Improvement Activities Category. CMS believes that "educational services in quality improvement for eligible clinicians and groups would encourage meaningful and actionable feedback for clinicians to make improvements in patient care." While CMS does include some examples in the proposed rule, we still believe that this is a relatively vague proposal and that CMS should provide additional guidance if the proposal is finalized. We also note that QCDRs are already expected to conduct numerous activities and issue reports aimed at improving quality. This new requirement therefore may be unnecessary, and simply add on to the burden of operating a QCDR.

Performance Feedback Requirements

QCDRs are currently required to submit reports to clinicians at least four times per year. Starting in 2021, CMS is proposing to require QCDRs to include information on how participants compare to other clinicians within the QCDR cohort who have submitted data on a given measure. CMS had also heard from QCDR stakeholders that in some cases clinicians wait until the end of the performance period to submit data to the QCDR, who are then unable to provide meaningful feedback to their clinicians four times a year. Therefore, CMS is also seeking comment for future notice-and-comment rulemaking on whether to require clinicians who utilize a QCDR to submit data throughout the performance period and prior to the close of the performance period CMS is also seeking comment for future notice and- comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the QCDR is providing feedback and the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

ACEP supports CMS' proposal to include in the four reports assessments of how clinician's performance compares to other clinicians on a particular measure. CEDR already includes such a comparison in its feedback reports. **However, we do not support a new requirement to force clinicians to report four times a year.** CEDR has numerous clinicians who wait until the end of the year to report. In some cases, hospitals cannot

[28] 84 Fed. Reg. 40854 (August 14, 2019).

share data with clinicians until late in the year. The proposal would also add to clinician burden, making QCDRs a less attractive reporting option.

QCDR Measure Requirements

CMS is proposing numerous new requirements for both 2020 and 2021.

Beginning in performance period 2020, CMS is proposing that:

- In instances in which multiple, similar QCDR measures exist that warrant approval, CMS may provisionally approve the individual QCDR measures for one year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. Duplicative QCDR measures would not be approved if QCDRs do not elect to harmonize identified measures as requested by CMS within the allotted timeframe.
    - **ACEP does not support this proposal.** We believe that CMS should grant two years of provisional approval to allow sufficient time to harmonize a measure. Further, since it takes two years to conduct proper data validation for measures, we believe that this requirement should align with that timeframe as well.

      In addition, CMS fails to provide any details regarding the criteria used to identify duplicative measures. We strongly urge CMS to publish clear guidance on when measures should be harmonized in order to ensure that contractor decisions are as uniform as possible. It is imperative that CMS and their contractors consult with clinicians and measurement staff in the specialty societies regarding clinical aspects of measurement. If CMS identifies a measure that needs to be harmonized, CMS should provide the clinical rationale for harmonization.

      CMS should also implement a formal process for appealing decisions regarding measure harmonization. An appeal process would give QCDRs an opportunity to provide CMS with additional information, including if there is a clinical rationale for why measures should not be harmonized or if a measure is a derivative work of another existing measure. If the measure owner can provide a documented clinical rationale for keeping the measures separate, then CMS should not require measure harmonization.

      Although we understand that CMS' goal for this policy is to avoid redundant measures, we believe that CMS should tread cautiously in determining which measures are subject to harmonization. We encourage CMS to consider the level of rigor in evidence or testing process between QCDRs prior to requesting harmonization. In identifying related and competing measures, CMS should base its determination on a comparison of the technical specifications, rather than measure titles. Furthermore, we believe that there are particular instances where harmonization is inappropriate. We also believe that an existing measure with baseline performance should not be rejected in favor of a new measure without prior data collection or baseline performance.

      We are also concerned that the problems of inaccurate use of measures by QCDRs that do not have appropriate experience or expertise in the field of medicine covered by the measure would be exacerbated by CMS's proposed harmonization policy. There is no accountability for how such QCDRs would report on the same measures and no standardization for how they would use data. Even if a QCDR meets CMS's revised definition of an eligible QCDR by having clinical expertise and

experience in measure development, that does not guarantee the QCDR will have relevant expertise or experience in the specialty or treatment area covered by a particular measure. Registries with less expertise on how to accurately implement measures may employ different methods for obtaining, risk adjusting, and aggregating data, which creates variation in how providers are measured and how their care is classified. Given the inconsistencies in implementation and methods, harmonizing measures across registries does not ensure accurate benchmarking. Therefore, ACEP recommends that CMS implement appropriate safeguards to ensure that measure harmonization occurs only when doing so is clinically appropriate.

Beginning in performance period 2021, CMS is proposing that**:**

- QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) cost measure; (b) Improvement Activity; or (c) CMS developed MVPs.
    - ACEP cannot support this proposal until we receive additional information. ACEP understands the intent of this proposal but has concerns about timing and requests additional clarity around the requirement. First, it is unclear whether QCDRs must link each of their measures to cost measures, Improvement Activities, and CMS developed MVPs, or just to one of these. CMS must clarify this in the final rule. Also, as CMS begins to develop new episode-based cost measures and new MVPs, it may be impossible for QCDR measure owners to appropriately identify applicable cost measures and CMS developed MVPs at the time of self-nomination. This is especially true now when there is a paucity of episode-based cost measures (none currently applicable to emergency medicine), and CMS only expects to have a few MVPs developed in time for the 2021 performance period. Further, CMS has not provided guidance to QCDRs regarding how they should "identify a linkage" between all three items.

      We do, however, appreciate CMS's recognition that not all measures may have a direct link cost measure, improvement activity, or an MVP and agree with CMS that an exception should exist in cases where a QCDR measure lacks a clear link to one of these areas.

- QCDR Measures would be required to be fully developed with completed testing results at the clinician level and must be ready for implementation at the time of self-nomination.
    - ACEP opposes this potentially burdensome proposal, as it would stifle measure development. Currently, many QCDRs review performance data after implementing a measure in the registry. This allows these QCDRs time to determine how feasible it is for providers to report the measure. Full measure testing prior to self-nomination would require QCDRs to reach out to practices and other participating providers to ask for volunteers to test the validity of measures. It would require QCDRs to invest significantly more resources in terms of time and money with uncertain benefits with respect to measure validity.

      In addition, submitting a measure for endorsement by National Quality Forum (NQF) or some similar entity would require even more time and resources and would likely require some costs to be passed on to practices. Given the heightened level of measure review, QCDRs may encounter barriers to recruiting practices to volunteer for measure testing. The additional time and costs associated with NQF-type endorsement may deter the development of QCDR measures. Most QCDRs are administered by nonprofit medical societies that do not have the resources available to fully test all of their QCDR measures according to the testing standards proposed.

      Mandating measure testing may actually cause some QCDRs to cease measure development

altogether, which would be counter to the statutory mandate to encourage the use of QCDRs. Some QCDR measure developers may be forced to increase measure licensing fees to cover the increased cost of measure testing or to increase fees for clinicians participating in the registries. We ultimately believe that this proposal is contrary to MACRA's requirement to encourage the use of QCDRs for reporting measures, especially given that MIPS measure developers are not subject to this proposed testing requirement.

For these reasons, we urge CMS to reconsider and withdraw this proposal.

- QCDRs would be required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.
  - ACEP does not support this proposal. Although we recognize the value in collecting data as early as possible, this proposal would establish an unrealistic and unduly burdensome deadline for the collection of data on new measures. It would also significantly increase the cost of developing new measures.

- CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.
  - ACEP understands the intent of this proposal but is extremely concerned that CMS does not define what "available" means in the proposed rule. CMS has informed us in conversations that "available" means that a QCDR measure owner would offer to enter into a licensing agreement with another QCDR if the other QCDR was interested in reporting on a particular measure. If this is the case, we would not object to that proposal, as long as CMS did not dictate the terms of the licensing agreement and did not penalize a QCDR measure owner if the other QCDR did not agree to the terms set by the QCDR measure owner for licensing its measure.

    Without an explicit definition of "available" in the rule, ACEP cannot support this proposal. Additional guidance MUST be provided. It is entirely unclear as written what circumstances or standards CMS will apply to declare that a measure is not available and unilaterally decide to reject the measure. It is also unclear what appeal process will be available to QCDRs when CMS makes this determination.

    We are also concerned about preserving the integrity of our measures. We would like to reiterate our comments from last year when CMS proposed the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. If CMS defines "available" in such a way that it would put undue pressure on QCDR measure owners to license their measures to QCDRs that do not have the experience or expertise to properly implement a measure would lead to confusing and potentially inconsistent results. Ultimately, effectively requiring inappropriate licensing of QCDR measures to other QCDRs will discourage the development of QCDR measures because the measure developers will have no effective control over who uses their measures and will not be able to recoup their investments through reasonable royalty fees.

- CMS is proposing a QCDR measure that does not meet case minimum and reporting volumes required

for benchmarking after being in the program for two consecutive CY performance may not continue to be approved in the future.
    - ACEP does not support this proposal, just as we do not support the same proposal that would be applied to all MIPS measures. Eliminating a measure only after two years in the program would deter measure stewards from investing in and developing new measures, maintaining existing measures, and putting forward MVP proposals. The proposed rule presents the real potential of removing measures that developers have spent more than two years to develop and test to only have it in the program for a small number of years (even just two years). Further, the selection of a two-year time frame appears arbitrary. We encourage CMS to perform analysis and work with measure stewards to learn the time it takes for measures to achieve acceptable numbers of adoption.

- At CMS' discretion, QCDR measures may be approved for two years, contingent on additional factors.
    - **ACEP appreciates and supports CMS' proposal to adopt a multi-year approval cycle for QCDRs**. This proposal appropriately rewards QCDRs that have remained in good standing in the program and alleviates the burden associated with the annual self-nomination process. It would allow group practices and QCDRs the necessary time to put in the substantial work required to develop and implement measures, especially with the increasing complexity of outcomes-related measures and the movement toward automated data integration for reporting.

      However, we do believe that the two-year QCDR measure approval should not be subject to CMS discretion, and that CMS should approve all QCDR measures for two years as long as they satisfy QCDR measure requirements.

QCDR Measure Rejections

CMS is proposing the following guidelines to help QCDRs understand when a QCDR measure would likely be rejected during the annual self-nomination process:

- QCDR measures that are duplicative of an existing measure or one that has been removed from MIPS or legacy programs.
    - ACEP understands the rationale behind this proposal but requests additional clarification on what criteria CMS will use to determine whether a measure is actually duplicative with another measure.

- Existing QCDR measures that are "topped out" (though these may be resubmitted in future years).
    - ACEP continues to strongly object to the topped-out policy for QCDRs. In last year's rule, CMS proposed and finalized a proposal to exclude QCDR measures from the four-year topped-out timeline in place for MIPS measures. Once a QCDR measure reaches topped out status under the QCDR measure approval process, it is not approved as a QCDR measure for the applicable performance period. By not providing QCDRs a grace period to phase out measures, CMS is limiting the number of specialty-specific measures available in the MIPS program. Allowing QCDR measures to be phased out over more than a one-year period will give measure owners time to appropriately phase out the measure, and determine what subsequent action to take, such as retiring the measure, modifying the measure to make it more robust, or creating a complementary measure.

- QCDR measures that are process-based (consideration is given to the impact on the number of measures available for a specific specialty) or have no actionable quality action.
    - ACEP understands the intent of this proposal and has no objections.

- Considerations and evaluation of the measure's performance data, to determine whether performance

variance exists.
    - ACEP understands the intent of this proposal and has no objections.

- QCDR measures that don't address a priority area highlighted in the Measure Development Plan.
    - ACEP understands the intent of this proposal and has no objections.

- QCDR measures that have the potential for unintended consequences QCDR measures that split a single clinical practice/action into several measures or that focus on rare events.
    - ACEP understands the intent of this proposal and has no objections.

- QCDR measures that are "check-box" with no actionable quality action.
    - ACEP understands the intent of this proposal and has no objections.

- Existing QCDR measures that have been in MIPS for two years and have failed to reach benchmarking thresholds due to low adoption (unless a plan to improve adoption is submitted and approved).
    - ACEP understands the intent of this proposal and has no objections.

- Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality action, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.
    - ACEP requests additional clarification on how CMS plans to define "robust." CMS should include a definition in the final rule.

- QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician. (that is, the quality aspect being measured cannot be attributed to the clinician or is not under the direct control of the reporting clinician).
    - ACEP does not support this proposal. As hospital-based clinicians, it is often the case that a quality action is not in our direct control. We are part of a care team that treats a patient during an emergency encounter. However, that does mean that we should not take responsibility for ensuring high quality of care. This criterion also seems to be contrary to CMS' overarching goal of promoting and rewarding coordinated care.

- QCDR measures that focus on rare events or "never events" in the measurement period.
    - ACEP understands the intent of this proposal and has no objections.

Physician Compare

CMS is proposing to make aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores, available on Physician Compare beginning with 2018 data. The agency is also proposing to post on Physician Compare an indicator on that displays if a clinician is scored using facility-based measurement. While ACEP does not have any issues with these proposals, we continue to be concerned that all the 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. 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 Alternative Payment Model (APM) Proposals

ACEP appreciates that CMS is continuing to make adjustments to their Advanced APM definitions as clinicians gain more experience participating in Advanced APMs. However, we are in general concerned that the proposed changes would add unnecessary levels of complexity to an already complicated program. For example, CMS is considering a change in the way the agency applies Partial Qualify APM Participant (QP) status because the agency believes some Partial QPs would like to be able to earn positive MIPS incentive payments. Under the current system, decisions about Partial QPs being excluded from MIPS are likely made at an APM Entity level and the physician may not have an opportunity to influence the Entity's decision. The change CMS is proposing would only apply the Partial QP status to the TIN/NPI combination through which Partial QP status is attained so that physicians can report through the MIPS program through other TINs in which they are involved. While this sounds like a beneficial proposal, our concern is that it would create more confusion about whether a clinician would qualify for Partial QP status. CMS also proposes to change the requirements for marginal risk for Other Payer APMs. Again, while the intent of the proposal is to make a technical fix that would help clinicians, ACEP urges CMS to simplify the requirements for Other Payer APMs to help physicians achieve QP status, not make them even more complicated than they already are. CMS should be adopting successful private sector APMs to the Medicare program, not excluding them from the QPP with ever-changing regulations.

We also want to reiterate again that although many emergency physicians are ready to take on downside risk and participate in Advanced APMs, there simply are not any opportunities to do so. We therefore strongly encourage CMS to develop more Advanced APMs that our members can directly participate in, starting with ACEP's APM, the Acute Unscheduled Care Model.

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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