

September 10, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-1850

Re: CMS-1693-P

Re: 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; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

On behalf of over 39,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the calendar year (CY) 2019 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule, as numerous 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 important work they do outside the traditional face-to-face visit with the patient. However, CMS balances these burden reductions with unsustainable payment cuts. For example, the proposed reductions to evaluation and management (E/M) levels 4 and 5 new patient visits and the level 5 established patient visit range from 20 to 38 percent. Such reductions could put some physicians and practices in serious financial peril, and thereby also endanger patients' access to available care. Along with these proposed reductions, physicians must face another annual update to Medicare payments that does not cover the increased cost due to inflation of providing care. While statute allows for a 0.25 percent overall increase in payment, due to budget neutrality adjustments CMS is only estimating a 0.13 percent increase in payments in 2019. That update also does 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 ACEP¹ 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)

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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>.

in 1992 and 2016. Even the 2018 Medicare Trustees Report, which was released on June 5, 2018, 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 CMS will keep in mind how adjusting the relative values of certain codes impacts the total Medicare reimbursement that clinicians will receive.

Practice Expense Relative Values

Based on work with a consulting firm, StrategyGen, CMS is proposing updated pricing recommendations for 2,017 supply and equipment items currently used as direct practice expense (PE) inputs. Should CMS choose to review PE inputs, ACEP asks CMS to also consider studying indirect PE associated with the emergency department (ED) including Emergency Medical Treatment and Active Labor Act (EMTALA)-mandated uncompensated care and stand-by time associated with being staffed and ready for any emergency 24 hours a day, seven days a week, and 365 days a year. Emergency physicians are not able to schedule their patients, which would allow them to maximize the use of staff and resources. There are also real costs associated with not only being open, but also having to pay shift differentials to insure adequate coverage over nights, weekends, and holidays.

Determination of Malpractice (MP) Relative Value Units (RVUs)

CMS is required to review, and, if needed, adjust Malpractice (MP) relative value units (RVUs) every five years. CMS is seeking input on the next MP RVU update, which will occur in CY 2020. ACEP would like to reiterate our comments in the [CY 2018 PFS proposed rule](#), where we had supported an open and transparent process for determining MP RVUs. We are concerned that CMS and their contractor will continue to face limitations in collecting premium data in certain states, and in these circumstances calculate blended rates for certain specialties that had previously and appropriately had separate and distinct risk factors for the surgical and non-surgical categories. We therefore strongly urge CMS over the next year to work with specialty societies to obtain more complete and state-specific data.

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

ACEP supports CMS' commitment to expanding the use of telehealth in Medicare, including developing proposed policies that go beyond CMS' traditional authority under Section 1834(m) of the Social Security Act. Specifically, CMS is proposing to pay separately for two newly defined physicians' services furnished using communication technology:

² The 2018 Medicare Trustees Report is available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>

- **Brief Communication Technology-based Service:** This service would cover a “virtual check-in” by a patient via telephone or other telecommunications device to decide whether an office visit or other service is needed.
- **Remote Evaluation of Recorded Video and/or Images Submitted by the Patient:** This service would allow practitioners to be separately paid for reviewing patient-transmitted photo or video information (such as by text message) to assess whether a visit is needed.

We note that one of the purposes of these codes is to avoid an unnecessary office visit. If patients can get a hold of their physicians remotely, speak with them, and/or show them an image, they may not need to come in to physically seek acute care. This same logic also could apply in the case of emergency care. If Medicare beneficiaries were able to get a hold of an emergency physician remotely and discuss whether or not they needed to come into the ED, not only would this improve patient care, but it may reduce overcrowding in the ED. We therefore urge CMS to consider allowing emergency physicians, practicing in the ED, to bill for these new remote physician services. If CMS does apply this policy to the ED setting, ACEP would like to work with CMS to ensure that all EMTALA obligations are fulfilled and that patients use these remote services appropriately and are still able and encouraged to come to the ED with full coverage without any hesitation when there is a chance they might need immediate emergency care. We would also need to work with CMS to determine appropriate reimbursement levels.

Medicare Telehealth Services

CMS is implementing certain telehealth provisions of the Bipartisan Budget Act (BBA) of 2018. ACEP approves of CMS’ implementation of the BBA provision that removes the restrictions on the geographic locations and types of originating sites where acute stroke telehealth services can be furnished. As part of CMS’ proposal, CMS defines a “mobile stroke unit” as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke and also seeks comment on other possible originating sites for telehealth services furnished for the diagnosis, evaluation, or treatment of symptoms of an acute stroke. We encourage CMS to include as an originating site Emergency Medical Service (EMS) transports equipped with telehealth connection to stroke specialists in order to provide faster national access to patients who require an accurate stroke diagnosis.

We do not have any specific comments on the addition of prolonged preventive services to the list of Medicare approved telehealth services. However, we do note that over the years we have requested on several occasions the addition of telemedicine for ED services (CPT codes 99281-99285), and observation services (CPT codes 99217-99220; 99224-99236; and, 99234-99236). Yet CMS has declined each time. There are established examples of high quality, cost-effective telemedicine programs in the ED setting that allow greater access to an emergency physician in inner city or rural EDs that would not normally be able to economically support that level of provider. 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 patients are boarding in the ED. As more and more small and rural hospitals close, EDs close too, leaving a gap in unscheduled acute care in a region. To fill these gaps, emergency physicians housed in what may be a state’s only large or teaching hospital provide telemedicine services to patients and providers in smaller rural or community hospitals that are staffed by RNs and Advance Practice Nurses (APNs). 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 academic medical center before a decision is made to transfer, admit locally, or release the patients. In all, ACEP continues to support Medicare coverage of emergency telehealth services that would benefit patient care both in and out of the ED.

Global Surgical Packages

In an effort to understand the valuation of global surgical packages, CMS has started collecting postoperative visit data. As stated in the rule, CMS requires practitioners in groups with 10 or more practitioners in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island) to use the no-pay CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure) to report postoperative visits. CMS states that only 4 percent of emergency medicine physicians reported this code. CMS is seeking comment on how to “encourage reporting to ensure the validity of the data without imposing undue burden” and on whether the agency needs “to do more to make practitioners aware of their obligation and whether we should consider implementing an enforcement mechanism.”³

ACEP acknowledges that only 4 percent of emergency physicians reported the non-pay CPT code 99024. It is not very common for emergency physicians to bill for an E/M service during a 10-day post-operative period as the operative physician, so we believe that is the reason why the percentage of emergency physicians who reported this code is so low. We urge CMS to continue encouraging the use of this code by all relevant practitioners before considering any changes to the valuation of global surgical packages.

Proposed Valuation of Specific Codes

Application of Long Arm Splint (CPT code 29105)

ACEP appreciates CMS accepting the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) value and rationale associated with the Application of Long Arm Splint (CPT code 29105) at a work RVU of 0.80 and supports this valuation.

Strapping Lower Extremity (CPT codes 29540 and 29550)

For CY 2019, CMS is proposing the RUC-recommended work RVU for two of the CPT codes in the family. ACEP appreciates CMS accepting the RUC value and rationale associated with Strapping Lower Extremity (CPT codes 29540 and 29550) work RVU of 2.11 for CPT code 36568 and the RUC-recommended work RVU of 1.90 for CPT code 36569.

³ CY 2019 Physician Fee Schedule, Medicare Shared Savings Program Requirements, QPP, and Medicaid Promoting Interoperability Program Proposed Rule, 83 Fed. Reg. 35,737 (July 27, 2018).

Gastrostomy Tube Replacement (CPT codes 43X63 and 43X64)

ACEP appreciates CMS accepting the RUC value and rationale associated with Gastrostomy Tube Replacement (CPT codes 43X63 and 43X64) with a work RVU of 0.75 for CPT code 43X63 (Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract.) and a work RVU of 1.41 for CPT code 43X64 (Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract.).

Wound Closure by Adhesive (HCPCS code G0168)

ACEP disagrees with the CMS proposed value of HCPCS code G0168 (Wound closure utilizing tissue adhesive(s) only) at a work value of 0.31 based on a cross walk to code 93293 (Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and without magnet application with analysis, review and report(s) by a physician or other qualified health care professional, up to 90 days; work RVU = 0.31, 5 minutes intra-service time and 13 minutes total time). CMS is proposing a decrease in work RVUs for code G0168 because the current CMS/Other source intra time is 2 minutes pre-time, 10 minutes intra-service time and 4 minutes post-service time and the RUC recommended survey time is 5 minutes evaluation time, 1 minute positioning time, 5 minutes intra-service time and 3 minutes immediate post-service time, which is a difference of 2 minutes total.

We believe our survey results, from 125 physician who frequently provide this service, reflect the intensity and skill of closing a facial laceration on the face, typically near the eye, using a surgical tissue adhesive to be greater than that of code 93293. CMS should not compare the valid survey time to the initial CMS/Other time because the initial CMS/Other source data is flawed and maintains zero validity for comparison. The initial CMS/Other time does not capture accurate physician time or direct practice expense inputs from the current dominant specialties performing this service. In 2000, CMS cross-walked code G0168 to code 99212 Office or other outpatient visit for the evaluation and management of an established patient for physician work and time, therefore surveyed time was never obtained from physicians who perform this service and should not be used as a comparison. A second reference service is MPC code 51702 (Insertion of temporary indwelling bladder catheter; simple (eg. Foley) (work RVU = 0.50 and 5 minutes intra-service time). ACEP urges CMS not to compare this surveyed code to flawed times established by a proxy. We do not think the work has changed for performing this serve, rather we believe it was misvalued based on a faulty cross walk previously. As such, we urge CMS to reconsider and adopt the RUC recommendation of a 0.45 work value.

Evaluation & Management (E/M) Visits

CMS is proposing several changes to Evaluation and Management (E/M) visit documentation and payment. The proposed changes would only apply to office/outpatient visit codes (CPT codes 99201 through 99215), In the rule, CMS specifically discusses why the agency chose not to initially include the ED E/M visit code set (CPT codes 99281-99285). While these ED codes are exempt from the proposed policies discussed in the rule, CMS seeks comment on whether the agency “should make any changes to

it in future years, whether by way of documentation, coding, and/or payment and, if so, what the changes should be.”⁴ ACEP would like to respond to this comment solicitation by first discussing our views on the proposed policy for office/outpatient visit codes and then specifically highlighting how emergency medicine is unique.

Background on the Proposal

CMS proposes a new, single blended payment rate for new and established patients for office/outpatient E/M level 2 through 5 visits, and a series of add-on codes (called “G” codes) to reflect resources involved in furnishing primary care and non-procedural specialty generally recognized services.

Alongside this proposal, CMS is proposing to apply a minimum documentation standard that allows practitioners to choose, as an alternative to the current E/M guidelines, either medical decision making (MDM) or time as a basis to determine the appropriate level of E/M visit.

- By giving providers a choice between: 1) the current guidelines; 2) MDM; or 3) time, different practitioners in different specialties will be able to choose to document the factor(s) that matter most given the nature of their clinical practice.
- Practitioners could choose to document additional information for clinical, legal, operational or other purposes.

The new payment levels for both new and established patients would fall between the current values for levels 3 and 4. CMS is proposing a number of add-on codes including creating a G-code that would account for more resource intensive office visits that currently would typically be either levels 4 or 5. However, at the same time, CMS is expanding its policy to reduce payment for services delivered by the same physician on the same day. Specifically, CMS would reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) delivered on the same day as a separately identifiable E/M visit, identified on the claim by an appended modifier -25.

ACEP Comments on the Proposal

Burden Reduction

Since some of our members see patients in settings outside of the ED such as urgent care facilities and hospital clinics, these changes will still impact emergency medicine as a specialty. In fact, the AMA estimates that the proposal will have a -2 percent impact on our specialty. In order to arrive at that estimate, the AMA analyzed CPT Codes 99201-99215, GCG0X, GPC1X, GPD0X, and GPD1X using CY 2017 Medicare utilization data and the CY 2019 Medicare Conversion Factor. Some specialties are obviously impacted far greater than ours. CMS justifies the reduction in payment to certain specialties by touting the significant reduction in burden by only requiring clinicians to document at a level 2 for reimbursement purposes. In the regulatory impact analysis, CMS estimates that the proposals would save

⁴ 83 Fed. Reg. 35,848.

clinicians approximately 1.6 minutes of time per office/outpatient E/M visit billed to Medicare, or 51 hours per year. However, CMS numerous times throughout the proposed regulation discusses how clinicians could and perhaps even should continue to document to match the acuity level of patients for other purposes. Specifically, CMS states that “Practitioners could choose to document more information for clinical, legal, operational or other purposes, and we anticipate that for those reasons, they would continue generally to seek to document medical record information that is consistent with the level of care furnished,”⁵ and that “our expectation is that practitioners would continue to perform and document E/M visits as medically necessary for the patient to ensure quality and continuity of care.”⁶

CMS even acknowledges in the impact analysis that clinicians “will still need to document substantial information in their progress notes for clinical, legal, operational, quality reporting and other purposes, as well as potentially for other payers. Furthermore, there may be a ramp-up period for physicians and non-physician practitioners to implement the proposed documentation changes in their clinical workflow and EHR such that the effects of mitigating documentation burden may not be immediately realized. Accordingly, we believe the total amount of time practitioners spend on E/M visit documentation may remain high, despite the time savings that we estimate in this section could result from our E/M documentation proposals.”⁷

ACEP agrees with CMS’ own admission and believes that overall burden will not be significantly diminished for clinicians if this proposal were finalized.

Add-on Code for Complexity

ACEP supports the concept of CMS’ proposal to allow clinicians to include an add-on code (GCG0X) to capture the added complexity of certain office visits. However, CMS sets the value of this code at \$14, which, added to the proposed payment rates for either new or established patients, does not even amount to the current payment level for a level 4 visit. If CMS were to enact this policy, ACEP strongly recommends increasing the value of the code to at least match the value of a level 4 visit. As discussed in more detail below, E/M services provided in the ED are usually at a higher acuity level. Therefore, if CMS were to expand this policy in the future to the ED code set (CPT codes 99281-99285), CMS would need to allow emergency physicians treating patients with complex conditions to include this add-on code on each claim.

It is also extremely unclear in the rule which clinicians can report these new G-codes. In the rule, CMS describes the code as “Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care.”⁸ When estimating the impact of this policy, CMS, for the purposes of their modeling, also assumes that these specific specialties would use the add-on G code for every office/outpatient E/M visit. ACEP understands from conversations with CMS that other specialties besides those listed would be able to use

⁵ 83 Fed. Reg. 35,836.

⁶ 83 Fed. Reg. 35,838.

⁷ 83 Fed. Reg. 36,068.

⁸ 83 Fed. Reg. 35,842

this G-code. In fact, Section 1848(c)(6) of the Social Security Act states that CMS cannot vary reimbursement amounts for particular specialties. If this code is finalized in the final rule, CMS should clarify who is eligible to use it and under what specific circumstances. Since there are many situations where a patient and the associated visit could be “complex,” CMS should take a broader, more comprehensive approach to defining complexity.

Add on Code for Prolonged Services

CMS is proposing to create a new HCPCS code GPRO1 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service). Both this code and the add-on code for complexity could be reported for office/outpatient E/M visits.

ACEP notes that for some specialties, time is not an accurate measure of the intensity of the service. Therefore, while this add-on code could be beneficial for some, it does not help make the total reimbursement level for some services more appropriate and in-line with the level of the service provided. If CMS were to make changes in the future to the ED code set (CPT codes 99281-99285), ACEP would want to work with the agency to ensure that appropriate adjustments were included to capture the high intensity-level of services provided in the ED.

MPPR Policy/Modifier-25

ACEP strongly opposes CMS’ proposal to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician within the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier -25. The AMA RUC and the CPT Panel already account for administrative efficiencies when recommending and setting code values. Therefore, a possible 50 percent reduction to either a procedure or visit would create an artificially low value that simply would have no empirical basis.

While CMS attempts to tie this multiple procedure payment reduction (MPPR) policy to the other changes the agency is proposing to office/outpatient E/M codes, it is not entirely clear whether this specific proposal would apply only to the office/outpatient E/M codes or to all E/M codes, including the ED E/M code set. We request that CMS clarify how broadly the MPPR policy would apply if the proposal were finalized.

Marshfield Clinic

CMS states that the agency has heard from stakeholders that the “practitioners rely on unofficial Marshfield Clinic or other criteria to help them document E/M visit levels. These commenters conveyed that the Marshfield “point system” is commonly used to supplement the E/M documentation guidelines, because of a lack of concrete criteria for certain elements of medical decision making in the 1995 and

1997 guidelines or in CPT guidance.”⁹ CMS is therefore seeking comment on whether Medicare should adopt any aspects of other E/M documentation systems, such as the Marshfield tool.

Although it is true that the Marshfield Clinic scoresheet is widely used by payers and providers to suggest the appropriate level of E/M service to report, ACEP has a few concerns about its use as an audit tool. The Marshfield Clinic scoresheet was designed for use in office-based practice and therefore does not always reflect the nature of emergency department practice. The score sheet accurately reflects CMS documentation guidelines for history and physical exam but makes some assumptions in scoring the medical decision-making component of an E/M service, because of lack of direction in the CMS documentation guidelines that lends itself to a point system. For example, Marshfield uses terms such as “additional work up planned”, which does not apply to the ED setting, and do not appear in either CPT or the 1995 documentation guidelines as a proxy for the amount and complexity of data reviewed MDM element. Even so, some payers, including various Medicare regional contractors, are inconsistent in their interpretation and application of the Marshfield Clinic scoresheet, which makes training and compliance at the national level difficult. ACEP asks for a balance between relevant application of any coding guidelines used and consistent application among Medicare contractors.

Emergency Department E/M Code Set (CPT codes 99281-99285)

ACEP agrees with CMS’ decision to initially exempt the ED visit code set (CPT codes 99281-99285) from the proposed documentation and coding changes in the proposed rule. The ED visit code set is currently at review at the AMA RUC and we believe that it is important for the RUC to continue its important work and provide recommended values to CMS first. Proposing changes to these codes now would be premature and would undercut the AMA RUC process. Our previous comments on documentation and payment issues related to the ED E/M visit code set mirrored the comments that CMS references in the proposal rule. We agree that intensity, and not time, is the main determinant of code level in EDs. Emergency physicians also typically see patients that are extremely complex. Over the past few years, we have seen 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.¹⁰

As we think about potential future changes to documentation requirements, we must keep in mind the unique and unpredictable environment of EDs and interactions with our patients. 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. Appropriate record keeping is even more essential in the world we live in today, where there has been an effort across multiple payers to retroactively deny coverage and payment of services that are

⁹ 83 Fed. Reg. 35,837-35,838.

¹⁰ 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.

later deemed “non-emergent” based on only on final diagnosis, or inappropriately downgrading payment to lower acuity levels. The AMA RUC evaluation of the ED E/M visit code set provides an excellent opportunity for the CMS and the emergency medicine community to re-evaluate payment and documentation requirements for these visits. We look forward to commenting on the RUC evaluations and CMS’ proposals related to it in next year’s rule.

Proposed Implementation Date

CMS proposes an implementation date for the documentation and payment changes that would apply to office/outpatient E/M codes of January 1, 2019. Since the final rule is required to be released by November 1, 2018, there would theoretically be only two months for clinicians, billing companies, electronic health record (EHR) vendors, and other stakeholders to 1) be educated about these substantial changes and 2) update their systems, policies, and billing and coding internal procedures. This is an impossible task in such a short time-frame (which includes several major holidays); therefore, CMS should definitely delay the start date to at least January 1, 2020 or even later. These proposed changes are also so significant that CMS may even want to consider another full round of rulemaking to provide CMS time to digest all the feedback the agency will likely receive on the proposals in this year’s proposed rule, develop more refined proposals that take into account this feedback, and provide another chance for the clinician community and others to weigh in. CMS should also continue to work with the medical community through these complicated issues. ACEP supports the AMA’s creation of a workgroup of physicians and other health professionals with deep expertise in defining and valuing codes, and who also use the office visit codes to describe and bill for services provided to Medicare patients.

Teaching Physician Documentation Requirements for Evaluation and Management Services

Based on feedback from stakeholders, CMS is proposing to remove the current requirement that teaching physicians document the extent of their participation in the review and direction of the services furnished to each beneficiary. CMS is instead proposing that the medical record must document that the teaching physician was present at the time the service is furnished. CMS states that the extent of the teaching physician’s participation may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

While we appreciate this attempt to reduce burden for teaching physicians, ACEP is concerned that the proposed rule did not mention requirements around medical students. In fact, the rule does not address recent CMS guidance issued in May of this year¹¹ that allows teaching physicians to use medical student documentation, including history, physical exam and/or medical student decision making as long as the teaching physicians perform or re-perform the physical exam and medical decision making of the E/M service and verify the student’s documentation. CMS needs to make medical student documentation consistent across all carriers with a proper attestation statement from the attending. ACEP would also like to reiterate that the issue at hand is a documentation exemption rather than a performance exemption for the supervising physician. Including medical student documentation in the revised policy would extend the intended relief from the regulatory burden of duplicate documentation on the same patient.

¹¹ This guidance is available at:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4068CP.PDF>

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

Certain drugs under Medicare Part B are currently paid at Wholesale Acquisition Cost (WAC) + 6 percent (+4.3 percent after accounting for sequestration). Based on a report by the Medicare Payment Advisory Commission (MedPAC), CMS is proposing to reduce the payment of these drugs from WAC + 6 percent to WAC +3 percent (+1.4 percent after sequestration). This large reduction could impact Medicare beneficiaries' ability to access new and innovative therapies that could potentially keep them healthy and out of the hospital or ED. ACEP therefore does not support this proposal and urges CMS to maintain the existing payment rate of WAC + 6 percent for these drugs.

Bundled Episode Payment for Substance Use Disorder (SUD) Treatment

In the proposed rule, CMS states that “routine counseling, either associated with medication assisted treatment (MAT) or on its own, can increase the effectiveness of treatment for substance use disorders (SUDs)”¹² and that creating a bundled payment model of care for components of MAT such as management and counseling services could help expand access to treatment for SUDs. CMS is therefore seeking comment on developing a bundled episode-based payment for SUD treatment, including: coding and payment options, components of a MAT program, regulatory changes to help prevent opioid use disorder and improve access to treatment, identification of non-opioid alternatives for pain management, and barriers to coverage of these alternatives.

ACEP is extremely supportive of MAT and the use of non-opioid alternatives for pain management. As emergency physicians, we are on the front lines of the opioid epidemic – in the past year alone, there was a 30 percent increase in opioid overdoses presenting in the ED for treatment.¹³ In addition to addressing this crisis on the treatment side, emergency physicians are also taking steps to address this crisis on the prevention side by implementing innovative alternative treatments to opioids (ALTO) programs.

ALTO uses evidence-based protocols like nitrous oxide, nerve blocks, trigger point injections, and other non-opioid pain management tools to treat a patient's pain in the ED. Successful ALTO programs in New Jersey and Colorado have dramatically and quickly reduced opioid prescriptions in the ED. In New Jersey, the ALTO program at St. Joseph's Hospital saw opioid prescriptions drop by 82 percent over two years. These results were recently replicated at 10 hospitals in Colorado, where hospital systems noted a 36 percent drop in opioid prescriptions in just the first six months of the program.

With respect to MAT on the treatment side, we have seen great results with initiating treatment (e.g., buprenorphine) in the ED and starting patients on the path to recovery. By implementing this treatment regimen, we can address an SUD patient's immediate symptoms and cravings, 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 long-term treatment. There are study results showing promise for ED-initiated buprenorphine and its effectiveness in treating opioid use disorder.

¹² 83 Fed. Reg. 35,730.

¹³ The Centers for Disease Control, “Opioid Overdoses Treated in Emergency Departments.” <https://www.cdc.gov/vitalsigns/opioid-overdoses/index.html>.

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.¹⁴ 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.¹⁵ 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.¹⁶ 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, if CMS does develop a bundled payment, 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. However, given the importance of using MAT as a tool to address the opioid crisis, we also urge CMS to go beyond the scope of their proposal, which would create a bundled payment within the confines of the budget-neutral physician fee schedule, and instead make a significant investment in MAT, either through a payment model or grant funded by the Center for Medicare & Medicaid Innovation (CMMI).

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

The 2014 law, “Protecting Access to Medicare Act” (PAMA) directed CMS to set up a process for using Appropriate Use Criteria (AUC) by April 1, 2016; implement AUC consultation and reporting process by January 1, 2017; and identify outliers for services furnished after January 1, 2017. This federal effort was designed to further reduce “inappropriate” advanced imaging use and will affect nearly all practicing physicians. Requirements of PAMA include:

- Advanced Diagnostic imaging: CT, MRI, PET, etc. (X-ray, ultrasound, and fluoroscopy are excluded)
- Applicable settings: a physician’s office, a hospital outpatient department (including ED) and an ambulatory surgical center (ASC). Inpatient hospital services are excluded.

The implementation of the program has been significantly delayed. In last year’s PFS rule, CMS established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic

¹⁴ 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.

¹⁵ 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.

¹⁶ 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.

imaging services. CMS also established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who are ready may begin to participate in the program.

This year's rule keeps the current implementation timeline intact, but proposes a number of changes including:

- Revising the definition of applicable setting to add an independent diagnostic testing facility (IDTF).
- Allowing the consultation with AUC through a qualified clinical decision support mechanism (CDSM) to be performed by clinical staff working under the direction of the ordering professional.
- Allowing ordering professionals to self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order and such attestation be supported with documentation of significant hardship.

CMS also requests comments on any additional circumstances beyond the current list of hardship exemptions (insufficient internet access; EHR or CDSM vendor issues; or Extreme and uncontrollable circumstances) that would cause the act of consulting AUC to be particularly difficult or challenging for the ordering professional, and for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program.

Allow the Consultation of AUC Through a Qualified CDSM to be Performed by Clinical Staff

ACEP supports the proposal to allow the consultation with AUC through a qualified CDSM to be performed by clinical staff working under the direction of the ordering professional, subject to applicable State licensure and scope of practice law. As discussed in detail below, we have significant concerns with emergency physicians consulting with AUC when dealing with potentially emergent situations in EDs. However, in general, and potentially non-emergent situations, allowing clinical staff to consult with the AUC would be beneficial to both the patient and the physician.

Hardship Exemption Comment Solicitation

ACEP remains extremely disappointed and concerned that CMS is not categorically exempting ED encounters from the AUC Program. PAMA exempts emergency services defined as an “applicable imaging service ordered for an individual with an emergency medical condition” (as defined by EMTALA). ACEP appreciated the recognition in the law that the federal EMTALA law imposes a duty to provide a medical screening exam to any individual who comes to the ED. But Congress, through an inadvertent drafting error, referenced the section of EMTALA Sec.1867(e)(1) that defines an emergency medical condition, rather than referencing Sec. 1867(a) 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.

This is a decision based on the emergency physician's clinical assessment of the patient's presenting symptoms/condition. There are many occasions when the patient appears quite ill or injured and advanced imaging is ordered before the emergency physician can even complete the medical screening exam. In fact, CMS noted in the CY 2017 physician fee schedule proposed rule that:

“While the acuity of some patients in the emergency department might be the same as in a physician's office, in general, more acutely ill patients are more likely to be seen in the emergency department, and that difference is part of the reason there are separate codes describing evaluation and management visits in the Emergency Department setting. Given that the practice of emergency medicine often requires frequent and fast-paced patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants, it differs from the pace, intensity, and acuity associated with visits that occur in the office or outpatient setting.”

¹⁷

This is in contrast to CMS's explanation of the AUC section in the same rule that stated (emphasis ours) “furthermore, we recognize that **most encounters in an emergency department are not for an emergency medical condition** as defined in section 1867(e)(1) of the Act.”¹⁸ It is also runs directly counter to the annual ED survey data collected by the Center for Disease Control (CDC). According to the CDC's most recent National Hospital Ambulatory Medical Care Survey (NHAMCS), only 5.5 percent of ED visits are avoidable (considered non-urgent).¹⁹

We have pointed these concerns out to CMS staff on several occasions over the past few years to no avail. The House Energy and Commerce Health Subcommittee Chair, Rep. Pitts agreed that this was indeed a drafting error and wrote to CMS's then-Acting Principal Deputy Administration Dr. Patrick Conway on April 15, 2016. Among other requests included in the letter, on page four Chairman Pitts stated:

*“When Congress enacted PAMA...we wanted to ensure these provisions did not have an unintended consequence of delaying care for patients who sought medical attention in an ED until after it was determined that they did not have an emergency medical condition (defined in Sec. 1867(e)(1)). **This exception not only covers individuals with an identified emergency medical condition, but also the applicable imaging service ordered to determine whether or not the individual has an emergency medical condition.**”* (Emphasis ours).

CMS responded to Chairman Pitts later in 2016 noting that “we will consider this issue as we work on implementing the AUC program.” Instead, several months later the Agency in the CY 2017 Physician Fee Schedule Final Rule said (emphasis ours), “We do not have a reason at this time to believe that a categorical exception granted to emergency departments would foster inappropriate use of advanced imaging services. However, we believe such a categorical exception would not be consistent with the statutory requirement under section 1834(q)(4)(C)(i) of the Act, which is framed in terms of individual

¹⁷ CY 2017 Physician Fee Schedule Proposed Rule, 81 Fed. Reg. 46,182 (July 15, 2016).

¹⁸ 81 Fed. Reg. 46,393

¹⁹ The 2015 National Hospital Ambulatory Medical Care Survey (NHAMCS) Report is found at https://www.cdc.gov/nchs/data/nhamcs/web_tables/2015_ed_web_tables.pdf.

services.” This directly contradicts what Chairman Pitts, who was involved in PAMA’s drafting himself, has stated on Congressional intent.

We therefore again ask CMS to revise the language of 42 CFR. 414.94 to clarify that the AUC exception also applies for the purposes of conducting the required medical screening exam in cases where an emergency medical condition is suspected, not “determined” (a term not found in EMTALA). This needed change will address Congress’ request as well as the logic 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 will directly impact provision of timely needed care.

As stated above, CMS is seeking comment in the rule on additional hardship exemptions. If CMS does not codify this exception as we have requested, we ask CMS to at least consider creating an additional exemption in cases where clinicians, in their best judgment, believe that their patients may be experiencing an emergency at the time of ordering. Just as CMS lays out in the proposed rule, physicians or clinical staff (if the proposal regarding clinical staff is finalized) would have the opportunity for each patient encounter to request an exemption when they believe their patient is experiencing an emergency. That way, for the safety of these patients, clinicians can move quickly and determine the diagnosis and treatment options. By not addressing this issue and at the very least granting this exemption, CMS may be putting patients’ lives at risk.

Medicare Shared Savings Program Quality Measures

CMS is proposing to eliminate 10 measures and to add one measure to the Medicare Shared Savings Program (MSSP) quality measure set. CMS also proposes to score two CAHPS Summary Survey Measures that are already collected for information purposes. This would result in 24 measures for which ACOs would be held accountable in 2019.

One measure that CMS is proposing to retire is the claims-based measure, *ACO-44: Use of Imaging Studies for Low Back Pain*, since this measure is restricted to individuals 18-50 years of age, which results in low denominator rates and is not a valuable reflection of the beneficiaries cared for by MSSP accountable care organizations (ACOs). ACEP supports this proposal, as we had expressed concerns in the past that ACO-44 relied solely on claims data. We believed that the measure was inherently problematic for the purposes of evaluating quality since it failed to account for important details about the patient that might be in the clinical chart, but not captured in claims.

The Quality Payment Program

ACEP appreciates the opportunity to comment on the proposed policies for the third year of the Quality Payment Program (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. We therefore

strongly encourage CMS to consider developing models geared towards emergency physicians. ACEP has developed its own proposed physician-focused payment model that was recently recommended to the Secretary for full implementation by the Physician-Focused Payment Model Technical Advisory Committee (PTAC), called the Acute Unscheduled Care Model (AUCM).²⁰ The model aims to improve quality and reduce costs in Medicare by allowing emergency physicians to accept some financial risk for the decisions they make around discharges for certain episodes of acute unscheduled care. We are willing and eager to work with you to further develop and implement this transformational model.

The Merit-based Incentive Payment System (MIPS)

MIPS determination period

CMS is proposing, beginning with the 2021 MIPS payment year, to establish a “MIPS determination period,” which would be a “24-month assessment period including a two-segment analysis of claims data consisting of: (1) an initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.”²¹ Under CMS’ proposal, clinicians who did not meet the low-volume threshold or were identified as non-patient facing, a small practice, hospital-based, or ASC-based during the first segment would continue to be identified as such regardless of the second segment.

ACEP supports this proposal, as it provides multiple opportunities for clinicians to learn about their MIPS eligibility status before the start of the performance period. One of our major concerns with the first couple years of MIPS has been that our members have not learned about their eligibility status and reporting options/requirements until part of the way through the actual performance year. Of particular concern has been the lack of transparency around whether groups are deemed “hospital-based” and therefore exempt from the Advancing Care Information (now called Promoting Interoperability) category of MIPS. In the first year of MIPS, many groups thought they met the criteria to be classified as “hospital-based” and exempt from this category of MIPS only to find out after the performance period had ended that they in fact did not meet the criteria and needed to report measures in order to get full MIPS credit. This left many groups scrambling to get the required data necessary to report. ACEP hopes that this policy of creating a 24-month assessment period will help avoid any last-minute questions about an individual clinician or group’s eligibility status. With respect to the definition of “hospital-based” specifically, ACEP also has significant concerns about how CMS continues to make this determination at the group level. We discuss this issue in the “Group Reporting” section of our comments below.

²⁰ The Acute Unscheduled Care Model (AUCM) proposal can be found at: <https://aspe.hhs.gov/system/files/pdf/255906/ACEPResubmissionofAUCMtoPTAC.PDF>

²¹ 83 Fed. Reg. 35,886.

Low-volume Threshold

ACEP generally supports CMS's proposals around the low-volume threshold. CMS is proposing that beginning in the 2019, clinicians and groups must meet at least one of the following criterion to be exempted from MIPS:

- Have less than \$90,000 in Medicare Part B allowed charges for covered professional services,
- Provide care to fewer than 200 beneficiaries, or
- Provide less than 200 covered professional services under the PFS

Clinicians or groups will be able to opt-in to MIPS starting in 2019 if they meet or exceed one or two, but not all, of the low-volume threshold criteria.

ACEP recognizes that some clinicians may not have the resources necessary to participate in MIPS, but also believes that every clinician should have an opportunity to engage in quality reporting and qualify for positive payment adjustments. Finding the appropriate balance between required participation, a total exemption, and optional participation will become more difficult as the size of the adjustments increase. Under CMS' proposal and estimated impact analysis, only 43 percent of clinicians will participate in MIPS. After assuming that around one-third of clinicians who are not required to report will opt-in, CMS estimates that 482,574 (31 percent of clinicians) will not choose to opt-in and report either as a group or individually and another 88,070 (6 percent) will meet all three criteria of the low-volume threshold. The remaining 20 percent of clinicians will be exempt from MIPS for other reasons. Since only 43 percent of MIPS eligible clinicians are expected to participate, and 91 percent of these clinicians are expected to both report data and avoid a downward payment adjustment, the size of the pool available for positive adjustments will likely be small.²² In fact, in the example CMS provides in Figure A of the rule, CMS estimates that the 7 percent positive adjustment that is available in 2021 (based on 2019 reporting) will be scaled all the way down to 1.6 percent. Clinicians who are eligible for an exceptional performance adjustment could receive up to another 4.1 percent.²³ Thus, exceptional performers are still likely to receive an upward adjustment of less than the 7 percent that Congress set in statute.

Overall, while ACEP supports these proposals and is appreciative of the flexibility CMS has introduced with the adjusted low-volume threshold, we also ask that the agency be mindful of how low positive adjustments could affect participation going forward. Some clinicians may eventually decide that the return on investment is not great enough to invest in the infrastructure and technology necessary to be successful in all four MIPS categories. While some of these groups may continue reporting for the sake of performance improvement, others, especially those who have the choice to opt-in, may not choose to participate.

²² 83 Fed. Reg. 36,060.

²³ 83 Fed. Reg. 35,977.

Group Reporting

As mentioned above, ACEP is significantly concerned about the definition of “hospital-based” clinicians for groups. Clinicians that 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 would lose the exemption status if one of them does not meet the definition of “hospital-based.” This “all or nothing rule” is unfair and penalizes hospital-based clinicians who work in multi-specialty groups. With respect to emergency medicine groups, there are also situations where a member of the group works in multiple settings. For example, an emergency physician might work two days a week at an urgent care center in order to provide additional staffing due to a colleague’s maternity leave or due to a flu epidemic. The whole group should not be penalized by this type of policy. The definition also does not align with how CMS treats groups for the purposes of the “facility-based scoring option.” In order to qualify for that option as a group, only 75 percent of individuals in the group need to have met the criteria to be eligible for the option as individuals.

Although CMS may argue that one possible solution is for clinicians who are deemed hospital-based to report as individuals, **ACEP believes that for many of our members who have reported as part of a group in the past, especially those practicing in rural areas, reporting as individuals would be a significant administrative burden.** Overall, while CMS did not make a specific proposal related to the definition of hospital-based clinicians for groups, ACEP will continue advocating strongly for a policy change.

MIPS Performance Period

CMS is proposing to continue the same performance period lengths for 2019 that the agency finalized for 2018. Specifically, the performance periods for the Quality and Cost categories will continue to be 12-months and the performance periods for the Promoting Interoperability and Advancing Care Information categories will continue to be 90 days. With respect to the performance period length for the quality and cost categories, CMS states that “we continue to believe that a full calendar year performance period for the quality and cost performance categories will be less confusing for MIPS eligible clinicians. Further, a longer performance period for the quality and cost performance categories will likely include more patient encounters, which will increase the denominator of the quality and cost measures. Statistically, larger sample sizes provide more accurate and actionable information. Additionally, a full calendar year performance period is consistent with how many of the measures used in our program were designed to be performed and reported.”²⁴ CMS also seeks comments about the length of future reporting periods.

ACEP understands CMS’ rationale for continuing the same performance period lengths that were established for 2018. However, in order for clinicians to successfully perform over a 12-month period for the cost and quality categories, they must know before the start of the performance period their full eligibility status for MIPS. CMS cannot continue to expect to hold clinicians accountable for a whole 12-month performance period when the agency does not even notify clinicians about their eligibility status until a few months into the year. Therefore, ACEP recommends that CMS commit in the final rule to notifying clinicians about their eligibility status before the start of the performance period.

²⁴ 83 Fed. Reg. 35,893.

Quality Performance Category

Data Completeness

In our comments on the CY 2018 QPP proposed rule, ACEP did not oppose CMS' proposal to set the data completeness threshold at 60 percent for the 2021 payment year, but we encouraged the agency not to increase it above 60 percent for at least one more year. While we continue to believe a 60 percent threshold is acceptable, we do note that as hospital-based providers, some of our members struggle to get enough data from their hospitals to meet this threshold. A large number of emergency physicians and groups that use ACEP's qualified clinical data registry (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 would like to know what more CMS can do to help improve the flow of information.

ACEP also notes that there is no CMS guidance that tells clinicians or groups how to select the 60 percent 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

For clinicians and groups selecting this option, the CAHPS for MIPS Survey would count for one of the six required Quality category measures. 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 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.

Topped Out Measures

CMS is proposing 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. Removing measures in the next rulemaking cycle measures could result 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.

Proposed Emergency Measure Specialty Set

ACEP understands that the specialty measure sets are merely suggestions intended to help clinicians navigate a large inventory of quality measures. We appreciate CMS including them in the QPP, and support maintaining the concept of suggested specialty and sub-specialty measure sets to help guide clinicians in the future, while at the same time allowing them to exercise autonomy in MIPS reporting.

- #66: Appropriate Testing for Children with Pharyngitis. This measure, which CMS has characterized as part of the Efficiency and Cost Reduction domain, promotes neither efficiency or cost reduction in the emergency setting. In fact, it does just the opposite. When a strep test is ordered in the emergency setting, it must be run through a lab system, rather than at the point of care, as a result of Clinical Laboratory Improvement Amendments (CLIA) requirements. As a result, a reflex culture is also ordered and results sent back to the ED, which is then responsible for calling back patients who are often not part of the larger system. Because this measure promotes inefficient practices and actually drives costs up, we do not recommend including it in this measure set.
- #107: Adult Major Depressive Disorder: Suicide Risk Assessment: ACEP is concerned that the specified denominator for this measure, “All patients aged 18 years and older with a diagnosis of major depressive disorder (MDD)” relies on a diagnosis that is generally not used in emergency departments, and notes that in the future the measure should be broadened to include other initial diagnoses, such as Depression, Not Otherwise Specified, that are much more commonly used in the ED.

Cost Performance Category

Cost Category Weight

ACEP does not support CMS' proposal to increase the Cost category weight to 15 percent and urges CMS to maintain the current weight of 10 percent. As discussed below, CMS has developed 8 new episode-based measures, and ACEP is extremely supportive of CMS' work in developing episode-based measures. However, since CMS is just starting to introduce more measures, we believe it would be prudent to wait to increase the Cost category weight until clinicians have more experience being held accountable for the cost of specific episodes of care.

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. These continue to be severely flawed measures that have produced very little actionable data to date. Providing data on these measures, even if only confidentially, will only result in confusion and frustration among clinicians and divert attention away from more important value-driven efforts. These measures were developed for hospital-level accountability and are inappropriate for 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. Our opposition to the MSPB measure is heightened by CMS's decision in the 2017 final rule to further weaken it by removing the specialty adjustment and drastically lowering the required number of cases that must be attributed under the measure for it to be scored. This will simply result in a larger number of clinicians inappropriately being held accountable for this flawed measure. The measures are also insufficiently adjusted for risk, which punishes physicians repeatedly for caring for the most vulnerable patients with high cost, multiple chronic conditions. Furthermore, the beneficiary attribution methodology for the MSPB does not align with how emergency physicians practice. 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 eight new episode-based measures. 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 emergency department. 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. We urge CMS to ensure emergency physicians are included in the agency's ongoing work to develop new episode-based cost measures.

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 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 Category

Public Emergency Criterion

ACEP supports the proposal to adopt an additional criterion entitled “Include a public health emergency as determined by the Secretary” to the list of criteria for nominating new improvement activities beginning with the CY 2019 performance period. We agree with CMS that adding new improvement activities that relate to a clinician’s response to public health emergencies would help promote and enforce the adoption of best practices. As emergency physicians, we act as front-line responders to emergencies and therefore see firsthand the absolute necessity of a well-coordinated response to combating public health emergencies. Given our unique perspective, we would be happy to work with CMS to develop new improvement activities that could fit under this criterion, if it is finalized.

Improvement Activities Inventory

CMS is proposing to add 6 new improvement activities, modify 5 existing activities, and remove 1 existing activity from the current inventory of improvement activities. ACEP supports many of the proposed improvement activities as they could be incorporated into 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. There are four main focus areas within E-QUAL: sepsis, imaging, chest pain, and opioid management. The following proposed measures could fit within the focus areas:

- The proposed “Relationship-Centered Communication” activity could be incorporated into E-QUAL’s learning collaboratives involving sepsis care and evaluation of chest pain.
- The proposed “Patient Medication Risk Education and Practice Assessment” and “Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support” activities could both be incorporated into E-QUAL’s Opioid Management learning collaborative.
- The revised “Use of Patient Safety Tools” activity could be incorporated into E-QUAL’s Opioid Management learning collaborative.

ACEP would also like to note that CMS references participation in TCPI throughout the Improvement Activities section of the proposed rule. Not only does participating in TCPI count as a medium-weighted activity, but, as mentioned above, E-QUAL’s learning collaboratives give emergency physicians and other providers a platform to attest to other improvement activities. CMS does not state in the proposed rule

what adjustments to the Improvement Activities category will be made once TCPI concludes at the end of September 2019. Many clinicians who are currently participating in TCPI and who use the initiative as a means to attesting to improvement activities may not know what options they have going forward. ACEP recommends that CMS address this issue in the final rule.

Promoting Interoperability Performance Category

Exclusions

ACEP appreciates that CMS is proposing to maintain its policy that hospital-based clinicians receive an automatic exclusion from the Promoting Interoperability category. However, we strongly encourage CMS to reduce the threshold of hospital-based services from 75 percent of covered professional services to the majority (i.e., 51 percent) of one's covered professional services in an inpatient hospital (Place of Service, or POS, 21), on-campus outpatient hospital (POS 22), off-campus outpatient hospital (POS 19) or emergency room setting (POS 23). As stated earlier in our letter, physicians work in multiple settings may need to do shifts in an urgent care center to best meet the needs of their community. In such a case the physician should still be considered "hospital-based," but with a 75 percent threshold might miss that qualification. Reducing the threshold to the majority of the clinician's time, i.e. at minimum 51 percent rather than 75 percent, would ensure they are still appropriately recognized as hospital-based.

Certification Requirements

ACEP understand CMS' rationale to require the use of the 2015 Edition of CEHRT. However, we encourage CMS to 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 actually practice.

New Performance-based Approach

CMS is proposing a new scoring methodology and moving away from the base, performance, and bonus score methodology that is currently used. CMS is retaining some measures and adding new measures, but is bundling them all into a smaller set of four objectives. The revised set of objectives would include e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. Clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level.

As stated earlier, some of our members are deemed "hospital-based" and exempt from this performance category. While ACEP appreciates CMS' effort to reduce complexity and burden, on behalf of our members who do not meet the exclusion threshold or who voluntarily participate in this performance category, we are concerned that CMS has gone back to an "all or nothing" approach, which existed in the original meaningful use program. Under CMS' proposal, clinicians would be required to report on all required measures within each of the four objectives. Failure to report on one measure without claiming an exclusion would make the clinician receive a score of zero. CMS does consider an alternative approach that would allow 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.

ACEP supports this alternative. To realize the full potential of EHRs, requirements of this category need to be flexible in order to allow clinicians to incorporate 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.

Furthermore, as we have stated in the past, it is equally critical that clinicians not be limited by existing technology barriers and penalized for factors outside of their control. CMS must resolve basic 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 actually 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.

Addition of Two Opioid-Related Measures

CMS proposes to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement, both of which support HHS initiatives related to the prevention and treatment of opioid and substance use disorders. The reporting of these two measures would be optional in 2019, given they may not be fully developed by their health IT vendor or not fully implemented in time for data capture and reporting. Beginning with the EHR reporting period in 2020, CMS proposes to require these two measures with an offered exclusion for each, given variation in State requirements associated with prescribing of controlled substances. The exclusion would provide that any eligible MIPS clinician who could not report on these measures in accordance with applicable state law would be excluded from reporting the measures.

While ACEP believes that PDMPs play an important role in identifying high-risk patients, we recommend that CMS move slowly on this measure to allow sufficient time for PDMPs to become more 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 in 2019. With respect to 2020, we believe that, under only certain conditions, would it be appropriate for CMS to require a clinician to query a

PDPM for at least one Schedule II opioid that is electronically prescribed. These conditions include having the Office of the National Coordinator (ONC) consider adopting new EHR certification criteria that requires EHRs to integrate PDPMs into their existing capabilities. Furthermore, CMS should require all PDPMs to be interoperable and to include certain standards, such as privacy and security protocols that protect patient-sensitive information.

Multi-category Measures

Given the changes CMS is proposing for the Promoting Interoperability of MIPS, CMS is proposing to discontinue the bonus for completing certain improvement activities using CEHRT for performance year 2019 and future years. CMS acknowledges that the removal of this bonus could be seen as increasing burden and is therefore seeking comment on ways to align and streamline the different performance categories under the MIPS. Specifically, one possibility CMS has looked into has been linking three of the performance categories -- Quality, Improvement Activities, and Promoting Interoperability -- and establish several sets of new multi-category measures that would allow MIPS eligible clinicians to report once for credit in all three performance categories.

ACEP supports this 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. Specifically, if the three performance categories of Quality, Improvement Activities, and Promoting Interoperability were linked together, the program could incentivize clinicians to use technological interventions to develop improvement initiatives and activities that improve patient care. We also believe that clinicians who use certified EHRs to participate in a clinician-led QCDR should be qualified as fully achieving all points for the Promoting Interoperability category. This would align with CMS's Patients Over Paperwork Initiative, as providing full Promoting Interoperability credit to these clinicians would significantly reduce unnecessary burden for providers.

MIPS Final Score Methodology

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

For the 2019 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. CMS also proposes to maintain the policies regarding measures that do not meet the case-minimum requirement or do not meet the data completeness criteria for the CY 2019 MIPS performance period, but proposes to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period.

ACEP appreciates CMS' proposal to continue to apply a 3-point floor for measures. We, however, do not support CMS' proposal to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period. 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. Finalizing this policy change in the CY 2020 MIPS performance period would again be penalizing clinicians for something that is beyond their control.

CMS is also seeking comment on their current case minimum policy. ACEP is supportive of CMS' current policy but we agree with CMS that small practices and individual MIPS eligible clinicians may have difficulty meeting this standard. We also note that because the case minimum is the same for both individual and group reporting, it is inherently easier for clinicians to meet the case minimums for each measure if they report as part of a group rather than individually.

Suppressing Measures

Given concerns about using measures that rely on outdated guidelines, and to further align with policies adopted within other value-based programs, CMS is proposing to suppress a measure without rulemaking if a measure is significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns during the performance period. ACEP is concerned that clinicians may be penalized for putting in the effort to collect data on a measure for part of the year only to find out later that a measure has been supportive. Although CMS does propose a scoring approach for suppressed measures that accounts for the eligible clinician's inability to receive a score for the suppressed measure, we believe that CMS should still allow clinicians to report, and receive a score for, each suppressed measure for the time-period in which the measure was not suppressed. For example, if a measure is suppressed in July of a performance period, clinicians could still have the option to report on half a year of data and receive a partial score. This would reward clinicians for having collected data on the measure for part of the year.

ACEP also assumes that CMS would not suppress measures very often. If CMS began to suppress a lot of measures each year, clinicians could potentially game the MIPS program by selecting these measures to report, receiving zero achievement points for the measures, and then having their total available measure achievement points reduced by 10 points for each of the measures. Therefore, this policy could theoretically allow clinicians to not have to report on all six required measures, but not be penalized for doing so.

Changes to Scoring for the Quality Performance Category

CMS describes potential approaches to redesigning the quality performance category to reduce burden and increase the value of the measures the agency is collecting. Under one possible approach, CMS would give each measure a particular value—defined as gold, silver, or bronze. In this approach, CMS would set a pre-determined denominator for points at 50, and then establish a point system for each tier of measures up to 15 to 20 points in the top tier (gold); up to 10 points in the next tier (silver); and up to 5 points in the lowest tier (bronze). Similar to the structure of the improvement activities performance category, a clinician that chooses a top-tier measure would not have to submit as many measures to MIPS. CMS also

considers an option which would maintain the requirement to the current approach for the quality performance category requiring 6 measures including one outcome measure, with every measure worth up to 10 measure achievement points in the denominator, but would change the minimum number of measure achievement points available to vary by the measure tier.

ACEP understands CMS' rationale for perhaps eventually creating values for certain measures and agrees that not all measures are created equal. However, ACEP would like to remind CMS that certain specialties do not have the opportunity to select from a large assortment of measures. Therefore, under both of CMS' proposed approaches, clinicians unable to report gold measures would be penalized. As CMS considers redesigning the quality performance category, CMS must assess the impact of any proposed policies on all specialties to make sure that every clinician would have an opportunity to receive a high score in the category. Furthermore, assigning values gives the illusion of clinical importance, and clinicians may determine that a clinical process for one measure for the same disease process is more important than another simply because of the measure value, which could be based on the quality and difficulty of the measure itself, and have no bearing on clinical importance. If values are assigned to measures, CMS should be clear about why the values are assigned and what they signify. Finally, ACEP asks that CMS refrain from making any significant changes to scoring the quality performance category until the agency does a thorough analysis of how clinicians have performed thus far in MIPS.

Facility-based Scoring Option

In the CY 2018 QPP final rule, CMS established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year. In this year's rule, CMS reiterates some policies finalized in last year's rule and makes some modifications.

Eligibility for the Facility-based Scoring Option

CMS is proposing that, under the facility-based scoring option, individuals or groups that have 75 percent or more of their covered Part B professional services in an inpatient hospital (POS 21), on-campus outpatient hospital (POS 22), or emergency room (POS 23) setting would automatically receive the performance score for their hospital through the Hospital Value-based Purchasing (HVBP) Program. CMS estimates that most emergency physicians would qualify for this option. CMS is also proposing that that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room. Furthermore, if CMS is unable to identify a facility with a VBP score to attribute a clinician's performance, that clinician is not eligible for facility-based measurement.

In last year's rule, CMS had not proposed to include POS 22 in the list of eligible settings. While CMS is adding that setting on the list, the agency also believes that a clinician who is to be measured according to the performance of a hospital should at least have a minimal presence in the inpatient or emergency room setting. ACEP had previously supported the inclusion of POS 22 and therefore supports CMS' proposal. We believed that including POS 22 would ensure that this reporting option is more widely available to clinicians who still struggle to identify six relevant MIPS measures and wish to instead be evaluated based on the facility in which they practice. We also thought that it would help to better align

CMS's "facility-based" definition with its definition for "hospital-based," which would minimize confusion for clinicians already struggling to keep up with the complex rules of MIPS.

With respect to the definition of "facility-based," similar to the comments we offer regarding "hospital-based" clinicians (see section on Promoting Interoperability Performance Category), we also recommend that CMS reduce the threshold used to define "facility-based" clinicians from 75 percent of covered professional services to the majority (i.e., 51 percent) to account for the fact that clinicians often work in multiple settings.

Individual and Group Attribution

Under CMS' proposal, individual clinicians who qualify for the facility-based scoring option would automatically receive a MIPS quality and cost payment score derived from the HVBP score for the facility at which the individual clinician provided services to the most Medicare beneficiaries. If there are an equal number of Medicare beneficiaries treated at more than one facility, the value-based purchasing score for the highest scoring facility is used. Groups can qualify for the facility-based scoring option if 75 percent or more of clinicians in the group meet the requirements described above for individuals. A facility-based group automatically receives a MIPS quality and cost payment score that is derived from the HVBP score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined if they reported as individuals.

ACEP understands that under the facility-reporting option, groups (no matter what size) would receive one HVBP score from one hospital, which is determined based on where the plurality of their individual clinicians saw the most Medicare beneficiaries. ACEP is concerned that it would be almost impossible for large groups to try to predict what hospital they would be attributed to. If one Tax Identification Number (TIN) includes individual clinicians practicing in multiple settings, that TIN would have to first figure out which of their clinicians were eligible for the facility-based reporting option and then determine where these clinicians saw the majority of their patients. Once the TIN was able to ascertain this information, it would have to notify individual clinicians about their reporting options. As described below, while we appreciate CMS' attempt to reduce burden by creating this option, clinicians must have a good understanding of how they would fare under this option in order to make important decisions about how to participate in MIPS. One possible solution would be to give large TINs the option of voluntarily opting-in and notifying CMS which individual National Provider Identifiers (NPIs) that fall under the TIN should have their quality and cost performance category scores determined based on a facility's performance. By incorporating this opt-in policy, CMS would create a pathway for TINs to coordinate with individual physicians on meaningful quality measures or seek the input of physicians of how they would like to participate in MIPS. This would also make it easier for groups to be notified about their performance prior to the start of the MIPS performance period, which would in turn help them decide whether or not to report through traditional MIPS.

Timeline for Determining Eligibility

In order to determine whether an individual is eligible for the facility-based reporting option, CMS proposes to use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year

preceding the applicable performance period with a 30-day claims run out. Therefore, theoretically, clinicians could know their eligibility status before the start of the performance period. However, it is unclear from the proposed rule when exactly clinicians and groups will be notified that they qualify for the facility-based option and what hospital they will be aligned to. **ACEP asks that CMS clarify in the final rule 1) when both individual clinicians and groups will be notified that they qualify for the facility-based option; and 2) when both individual and groups will be notified about what hospital they are aligned to.**

ACEP has heard from CMS that the agency hopes to notify individual clinicians that they would qualify for the facility-based scoring option around the same time that they tell clinicians whether they are eligible for MIPS. Again, this notification should take place before the start of the performance period. However, we note that CMS has not yet met this deadline for the first two years of the Program.

CMS is also proposing individuals and groups can still report quality measures through another submission mechanism (such as a QCDR) and receive a “traditional” MIPS score for quality. If they do so, CMS would automatically take the highest of the HVBP score and the traditional MIPS score. While ACEP supports CMS’ proposal to allow clinicians to continue reporting traditionally and automatically applying the higher score, we nevertheless want to make sure that clinicians understand all of their options before the start of the performance period.

Since CMS is proposing that the quality performance period will be 12-months, clinicians need to know up front, before the start of the performance period, whether they meet the eligibility criteria for the facility-based reporting option. If they do, they will need to have time to make decisions about whether to report individually or as a group and whether to still report quality measures traditionally or simply rely on their hospital’s HVBP score. We believe that if CMS does not notify clinicians ahead of time about their eligibility status, this new option, which is meant to reduce burden, will instead add a layer of complexity to the program that will make it difficult for clinicians to be successful.

Measures in Facility-Based Scoring

CMS is proposing to adopt all the measures for the Hospital VBP Program into MIPS for purposes of facility-based scoring. CMS also proposes to adopt for facility-based measurement the measure set that CMS finalizes for the fiscal year Hospital VBP program for which payment begins during the applicable MIPS performance period. For example, for the 2019 MIPS performance period, which runs on the 2019 calendar year, CMS proposes to adopt the FY 2020 Hospital VBP Program measure set, for which payment begins on October 1, 2019. CMS will also apply the same timeline to the total performance score methodology. Given this timeline, it is unclear when individuals and groups will actually find out what their hospitals’ VBP scores are. **ACEP asks that CMS clarify in the final rule when both individual clinicians and groups will be told what their hospital’s VBP score is for a given year. ACEP recommends that CMS inform individual clinicians and groups about their hospitals VBP score as soon as practically feasible, preferably before clinicians are required to report data for the performance period.**

Furthermore, CMS is proposing that the quality and cost performance category scores would be established by determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year. ACEP agrees with this methodology and believes that is an appropriate way of translating the hospital's VBP score to a MIPS score. However, ACEP encourages CMS to be extremely transparent with individual clinicians and groups when describing how their hospital's VBP score translates to their MIPS score.

Expansion of Facility-Based Measurement to Use in Other Settings

CMS notes that the agency may consider opportunities to expand the concept of facility-based measurement into other facilities and programs and future years. CMS is particularly interested in the opportunity to expand facility-based measurement into post-acute care (PAC) and the end-stage renal disease (ESRD) settings and seeks comment on how CMS may do so. ACEP supports the idea of expanding the policy beyond the inpatient setting. While MACRA specifically prohibits the use of measures for hospital outpatient departments under this policy, there is an explicit exception in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. Therefore, when implementing this policy in future years, we strongly urge CMS to recognize the variety of other emergency-focused, facility-level measures now in use, such as those developed by ACEP's CEDR and those used under the Hospital Outpatient Quality Reporting Program. ACEP would appreciate the opportunity to work with CMS in the coming year to identify alternative facility-based measures that would better capture the quality of emergency care.

Calculating the Final Score

CMS is proposing to continue applying the complex patient bonus for the 2021 MIPS payment year. 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 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 proposes a performance threshold of 30 points for the 2021 MIPS payment year. CMS believes that this threshold would provide a gradual and incremental transition to the performance threshold that the agency would establish for the 2024 MIPS payment year, which is estimated to be between 63.50 and 68.98 points (the projected mean final score). CMS also seeks comment on whether establishing a path

forward to a performance threshold for the 2024 MIPS payment year that provides certainty to clinicians and ensures a gradual increase from the performance threshold for the 2021 MIPS payment year to the estimated performance threshold for the 2024 MIPS payment year would be beneficial. For example, CMS could consider setting a performance threshold of 30 points for the 2021 MIPS payment year, 50 points for the 2022 MIPS payment year, and 70 points for the 2023 MIPS payment year.

ACEP believes that a 50 percent increase in the performance threshold, from 15 points to 30 points, is a large jump for CMS to make in one year. We encourage CMS to establish a more reasonable performance threshold of 25 points. We also caution the agency against increasing the performance threshold to 70 points by the 2023 MIPS payment year. Seventy points is the current performance threshold for exceptional performance and even exceeds the performance threshold that CMS is projecting for 2024 (between 63.50 and 68.98 points). ACEP would support a more gradual transition, such as 25 points for the 2021 MIPS payment year, approximately 35 to 40 points for the 2022 MIPS payment year, and 50 points for the 2023 MIPS payment year.

Additional Performance Threshold for Exceptional Performance

CMS proposes to set the additional performance threshold at 80 points for the 2019 MIPS performance period (2021 MIPS payment year), which is higher than the 25th percentile of the range of the possible final scores above the performance threshold. ACEP believes the additional performance threshold should be kept at 70 points. Seventy points is still 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 performer threshold to 80 points, 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 of 80 points.

MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

In conjunction with releasing this proposed rule, CMS is announcing the MAQI Demonstration, authorized under section 402 of the Social Security Amendments of 1968 (as amended). The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and payment adjustment will increase or maintain participation in payment arrangements similar to Advanced APMs with MAOs and change the manner in which clinicians deliver care. As stated above, ACEP is seeking opportunities for emergency physicians to participate in APMs. We look forward to hearing more details about this demonstration as CMS continues to roll it out.

Qualified Clinical Data Registries

QCDR Benchmarks

CMS has heard concerns from clinicians using QCDRs that they are hesitant to report QCDR measures because they are not certain that a benchmark could be calculated and established for the MIPS performance period, and they would therefore be limited to a 3-point score for that QCDR measure. In addition, registries have asked about the possibility of creating QCDR benchmarks. To encourage reporting of QCDR measures, CMS is seeking comment on an approach to develop QCDR measure benchmarks based off historical measure data. This may require QCDRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. CMS states that the QCDR measure data would probably need to be submitted at the time of self-nomination of the QCDR measure, during the self-nomination period. CMS also states some concerns with this proposal and seeks comments on these concerns. Specifically, one such issue with respect to utilizing historical data provided by QCDRs to develop benchmarks “is whether QCDRs have the capability to filter through their historical measure data to extract only data from MIPS eligible clinicians and groups prior to submitting the historical data to CMS for QCDR measure benchmarking consideration. Furthermore, once the historical data is submitted by the QCDR, CMS would analyze the data to ensure that it met benchmarking standards prior to it being accepted to form a benchmark. However, to perform this analysis CMS may need additional data elements such as the sources of the data, data completeness, and the collection period.”²⁵

ACEP generally supports the concept of allowing QCDRs to submit data to CMS that would allow them to create benchmarks for QCDR measures. ACEP’s QCDR, CEDR, has access to historical data and would be willing to share it with CMS for the purposes of developing benchmarks for measures. In fact, CEDR analyzes historical data as part of the measure development process to identify measure gaps.

However, we understand the limitations with the data and the fact that CEDR or other registries may not be able to provide CMS everything they may need. In fact, CMS is not entirely clear in the rule what “form or manner” of the data would meet the agency’s needs. Some data might be harder to obtain, especially from participants that push data to QCDRs. Furthermore, QCDRs may run into operational issues, especially in terms of only submitting data that includes MIPS eligible clinicians. Thus, we ask that CMS clarify their specific needs in the final rule and work with QCDRs on how to obtain the necessary data.

We also note that developing benchmarks could be a lengthy process, taking more than one year to complete. Another alternative CMS could consider is instituting a more dynamic process for benchmarking QCDR measures. Under such an approach, CMS would accept quarterly data for new measures so that the agency can create preliminary benchmarks that they would share with QCDRs before the final benchmarks are established.

Define the Timeline for Topped Out QCDR Measures

In the CY 2018 QPP Final Rule, CMS finalized a 4-year timeline to identify topped out measures, after which CMS may seek to remove such measures through rulemaking. Since QCDR measures (as opposed

²⁵ 83 Fed. Reg. 35,955.

to MIPS measures) are not approved or removed from MIPS through rulemaking, CMS proposes to exclude QCDR measures from the topped out 4-year timeline that was finalized. Under the proposal, once a QCDR measure reaches topped out status under the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

ACEP does not support this proposal. By not providing QCDRs a grace period to phase out measures, CMS could limit the number of specialty-specific measures available in the MIPS program. By allowing QCDR measures the same 4-year timeline when topped out, CMS 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 complimentary measure.

Updated Definition of QCDR

CMS proposes to modify the definition of a QCDR to require that an approved entity have clinical expertise in medicine and quality measure development, starting in the 2022 MIPS payment year. Entities may also meet this definition through a signed, written agreement with an external organization with expertise in medicine and quality measure development. CMS does not believe that these types of entities, in the absence of clinical expertise in quality measurement, meet the intent of QCDRs.

There are currently no assurances to practices participating in MIPS, or to the Medicare program, that EHR companies and other commercial organizations are able to interpret, extract and calculate the quality measures accurately. Commercial QCDRs without quality measurement expertise threaten the integrity of quality measure performance data and may inappropriately impact the CMS benchmarks used to calculate MIPS Quality scores. Therefore, ACEP supports CMS' proposal to require that an approved entity have clinical and measure expertise; however, CMS should be careful in how they allow technical entities to partner with an external organization to gain this expertise. If this creates a loophole that allows technical entities to easily bypass this requirement, this policy will be ineffective.

Clinical registries should be designed and managed by entities that understand the intricacies of clinical operations. The requirement of clinical expertise is especially important for quality measurement development, as sound and valid measurement requires clinical expertise and scientific rigor. Measures developed and approved for the MIPS program without this expertise and rigor are not comparable to measures that undergo such process, and it ultimately gives QCDRs without such clinical expertise a greater advantage.

Revised Self-Nomination Period for QCDRs

CMS proposes to revise the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Under this proposal, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs would need to self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year.

ACEP strongly opposes this proposal and requests that CMS does not revise the start of the self-nomination period from September 1 to July 1 of the calendar year. Like many other entities, ACEP follows a lifecycle approach for quality measure development and maintenance, and the revised self-nomination period that is proposed in this rule would interrupt the lifecycle timeline. With the previous year's reporting period ending on March 31, it would be difficult for our team to access the necessary data out of our QCDR and conduct required analysis for measure maintenance in time for the July 1 self-nomination period start. In addition, because CMS requires more data to be submitted with self-nomination applications, the revised reporting period will be more difficult.

Information Required at the Time of Self-Nomination

ACEP supports CMS' proposal to require QCDRs to include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to CMS.

Updated Consideration Criteria for Approval of QCDR Measures

CMS proposes to consolidate their previously finalized standards and criteria used for selecting and approving QCDR measures. Specifically, CMS proposes to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year. CMS believes that as it has gained additional experience with QCDRs in MIPS, it would be appropriate to further align these criteria for QCDR measures with those of MIPS quality measures in future program years.

ACEP does not support this proposal and requests that CMS reconsider these criteria as a requirement, and instead make the criteria high-priority. By requiring these criteria, CMS would limit the number of measures available for QCDR participants. While it is important for measures to be outcomes-based and meaningful, there are existing process measures that are evidence-based and are far from being topped out. These measures are still valuable to improving patient care and should still be considered for inclusion in the QCDR program.

QCDRs Seeking Permission from Another QCDR to Use an Existing Approved Measure

In the CY 2018 QPP final rule, CMS finalized that, beginning with the 2018 performance period, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. CMS now believes that, similar to the MIPS quality measures, once a QCDR measure is approved for reporting in MIPS, it should be generally available for other QCDRs to report on for purposes of MIPS without a fee for use. As a result, CMS proposes that, beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, 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 a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

ACEP strongly opposes this proposal. This proposal would prevent the entity that owns the measure (measure owner) from recouping any of the financial investment put into developing and maintaining the measure, as the measure owner would no longer be allowed to charge a licensing fee. If third parties can routinely use these measures and, in the case of commercial QCDRs, profit off of the societies' time and expense, medical societies may no longer be able to dedicate resources to developing QCDR measures. Without the contribution of medical societies, the measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance. We also have concerns about loss of control, as if other entities can use measures without licensing agreements, the measure owner is not able to control how they are being implemented. Maintenance will be more difficult as well, as the measure owner will not be able to review data collected from the measures. This rule blurs the line between QCDR measures and QPP measures. If a measure owner was ready to take a measure to the national stage, they would submit it to CMS under the Measures Under Consideration (MUC) process, which is the pathway for becoming a QPP measure. Simply applying to use their own measure in a QCDR does not mean a measure owner is prepared to release their measure to the masses, and this rule would force them to do so. Finally, we note that all measures that are internally developed by ACEP are considered intellectual property and have a copyright. By allowing these measures to be accessed by other QCDRs without a licensing agreement, CMS is effectively violating the copyright of each measure.

Physician Compare

Quality

In last year's rule, CMS finalized a policy to make all measures under the MIPS quality performance category available for public reporting on Physician Compare. CMS stated that the agency would not publicly report first year quality measures, meaning any measure in its first year of use in the quality performance category. CMS is now proposing to not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category. ACEP supports this proposed change and agrees with CMS that it would encourage clinicians and groups to report new measures, get feedback on those measures, and learn from the early years of reporting measures before measure are made public.

However, ACEP continues 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.

Achievable Benchmark of Care (ABC™)

CMS is proposing to modify their existing policy to use the ABC™ methodology to determine benchmarks for the Quality, Cost, Improvement Activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). Specifically, benchmarks would be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period would be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks would be published prior to the start of the performance period, as technically feasible. CMS states that this approach would provide eligible clinicians and groups with valuable information about the benchmark to meet to receive a 5-star rating on Physician Compare before data collection starts for the performance period. CMS is also proposing to extend the use of the ABC™ methodology and equal ranges method to determine a benchmark and 5-star rating for QCDR measures.

ACEP appreciates CMS’ attempt to help clinicians understand the benchmarks that will be used for the 5-star ratings before the start of the performance period. ACEP members have struggled to understand how their performance in MIPS and other previous programs has been translated into a rating on Physician Compare. ACEP urges CMS to continue to be transparent and do a better job of educating physicians about the Physician Compare rating system.

Advanced Alternative Payment Model (APM) Proposals

Use of Certified EHR Technology (CEHRT)

CMS previously finalized that in order to meet the “Use of CEHRT” Advanced APM criterion, an Advanced APM must require that at least 50 percent of eligible clinicians in each APM Entity use CEHRT to document and communicate clinical care with patients and other health care professionals. CMS is now proposing that beginning in CY 2019, in order to be an Advanced APM, the APM must require that at least 75 percent of eligible clinicians in each APM Entity use CEHRT to document and communicate clinical care with patients and other health care professionals. ACEP agrees with CMS that the use of CEHRT is a fundamental component of any Advanced APM. We believe that these models can only be successful if physicians are able to receive information on their patients in a seamless manner.

Nominal Risk

Under the nominal financial risk standard, there is both a revenue and benchmark standard. With respect to the revenue standard, CMS proposes to maintain the current threshold of 8 percent of the average

estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities through QP Performance Period 2024. CMS seeks comment on whether it should consider raising the nominal amount standard to 10 percent. With respect to the benchmark standard, CMS also proposes to maintain the current threshold of 3 percent of the expected expenditures for which an APM entity is responsible under the APM. CMS seeks comment on whether the agency should increase the Expenditure-based Standard to 4 percent for QP performance period 2025 and later.

ACEP is very pleased that CMS is proposing to maintain the current revenue and benchmark standards for the next few years. As we have noted in the past, emergency physicians have little or no experience in taking financial risk (aside from uncompensated care due to EMTALA duties) as a component of their medical practices and our current efforts to develop APMs represent a significant investment with yet unknown results. We would therefore encourage CMS to maintain both thresholds at their current levels for the foreseeable future and NOT increase them.

In our view, the MACRA requirement that an Advanced APM have “nominal” financial risk implies that Congress’ intent was that these models have a limited amount of risk and that this amount does not necessarily have to increase over time. Increasing the amount of financial risk an Advanced APM must have above current levels could result in discouraging certain specialties from making the necessary investments to successfully participate.

All-Payer Combination Option

CMS proposes that beginning with the 2019 and 2020 submission periods, a payer, APM Entity, or eligible clinician that submits a multi-year payment arrangement that CMS determines is an Other Payer Advanced APM would not have to go back to CMS every year to get the model re-approved, but would only need to submit information on relevant changes to the payment arrangement for the remaining duration of the payment arrangement. ACEP is appreciative that CMS listened to stakeholder feedback and is not requiring payers, APM entities, or eligible clinicians to have to get a model re-approved every year when nothing about the model has changed.

ACEP also supports the proposal to align the Payer Initiated Process for commercial/private payer with the previously finalized provisions for the Payer Initiated Process for Medicare, Medicare Health Plans, and CMS Multi-Payer Models. In order to encourage continued private payer innovation, ACEP believes that all payer types should be able to submit models in the first available submission year under the Payer Initiated Process.

Request for Information on Interoperability

ACEP supports the Trump Administration’s commitment to reducing information blocking and supporting the interoperability of EHRs. Emergency physicians play a very important role in our health care system, serving as the safety net in our communities. In many cases, we see patients with acute conditions who we have never seen before. With limited information, we deal with life and death situations and must make near-instantaneous critical decisions about how to treat our patients. Therefore, we are particularly anxious to work with hospitals toward the goal of interoperable EHRs that will open

the door to more comprehensive patient information sharing across sites of care. Linking previously stand-alone EHRs will allow us to make more informed decisions and will greatly enhance timely communication with patients, community physicians, and other caregivers. To that end, we support Medicare policies that promote our ability to receive and exchange information about our patients. However, as CMS considers future policy options, including potential changes to conditions of participation for hospitals and other providers, we urge the agency to carefully assess the impact these policies may have on small and/or rural providers that may not be able to meet the interoperability standards that other larger and/or urban providers can more easily achieve.

Request for Information on Price Transparency

CMS is requesting comments on a number of issues related to price transparency. In the rule, CMS encourages “all providers and suppliers to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.” ACEP appreciates CMS’ willingness to better understand the costs of health care and improve price transparency and accountability for patients and would like to respond directly to the questions posed by CMS.

As CMS considers any potential changes to provider requirements, we urge you to keep in mind issues that are unique to emergency medicine. Like you, we strongly believe that a patient’s concern should be focused on receiving the appropriate care, rather than choosing their emergency care based on cost. In the emergency department (ED), minutes and seconds matter and emergency physicians are often required to exercise their best clinical judgement quickly. Patients who have life-threatening illnesses and injuries obviously do not have the ability to shop around for the “lowest cost” provider. Furthermore, in delivering acute care, knowing what patients’ total out-of-pocket costs will be before they are diagnosed and stabilized is nearly impossible until a proper course of medical care and progression is followed. 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. This is very different from being able to figure out total costs for an urgent care patient with a small, clean, superficial laceration or a sore throat. Further complicating the issue is the fact that emergency care is billed in two separate components, the facility fee and the professional fee. Therefore, patients must sort through costs included in at least two different bills, each of which may have different cost-sharing obligations associated with it.

Emergency physicians have been significantly impacted by two laws that are not entirely aligned – the Emergency Medical Treatment and Labor Act (EMTALA) that guarantees access to emergency medical care for everyone, regardless of insurance status or ability to pay, and the Affordable Care Act (ACA), which includes emergency services as an essential benefit. Taken together, both laws have had the effect of increasing overall volume, while discouraging incentives for health plans to enter into fair and reasonable contracts to provide services at reasonable in-network rates. The majority of emergency

physicians would prefer to practice in-network and ensure that patients are not subject to gaps in their insurance coverage that could lead to unexpected bills and high out-of-network rates. However, the current environment leaves both emergency physicians and their patients subject to the practices of insurance companies, which we believe in some instances have been inappropriate and interfered with patient access to care. These companies must be held accountable to negotiate and establish reasonable in-network agreements with hospitals and hospital-based providers.

The requirements of EMTALA are mandatory and are unaffected by in-network or out-of-network insurance status or payment considerations. In fact, EMTALA stipulates that a hospital may not place any signs in the emergency department regarding prepayment of fees or payment of co-pays and deductibles which can have the chilling effect of dissuading patients from “coming to the emergency department.” To do so could lead patients to leave prior to receiving a medical screening examination and stabilizing treatment without regard to financial means or insurance status, which is a fundamental condition for satisfying EMTALA, and one of the most foundational principles of an important patient protection that was enacted three decades ago. If we attempt to get pricing information to patients prior to stabilizing them, not only would that be an EMTALA violation, but it could also potentially cause the patient’s health to deteriorate since it could delay the patient from receiving critical care. The last thing we want to do is put our patients in a position of making life-or-death health care decisions based on costs.

It is also important to note that people who think they are having an emergency have every right to go to the ED without worrying about whether the services they receive will be covered by their insurance. A provision in federal law called the “Prudent Layperson Standard” (PLP) states that payers must cover any medical condition “manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: 1) placing the health of the individual (or a pregnant woman or her unborn child) in serious jeopardy; 2) serious impairment to bodily functions, or 3) serious dysfunction of any bodily organ or part.” First established under the Balanced Budget Act of 1997, the PLP originally applied to all of Medicare and to Medicaid managed care plans, and then was extended under the ACA to all insurance plans regulated under the Employee Retirement Income Security Act of 1974 (ERISA) and qualified health plans in the state Exchanges. Furthermore, 47 states (all except Mississippi, New Hampshire, and Wyoming) have passed their own laws making some kind of prudent layperson standard mandatory in their state.

Once again, we appreciate your focus on improving price transparency for the benefit of our patients. We are grateful for the opportunity to share our responses to your questions. To better inform your request for input, our responses that follow for the most part address only emergency medical care, rather than the entire health care system.

How should we define “standard charges” in various provider and supplier settings? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should “standard charges” be defined to mean: average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as

determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should “standard charges” be defined and reported for both some measure of the average contracted rate and the chargemaster, price list or charge list? Or is the best measure of a provider’s or supplier’s standard charges its chargemaster, price list or charge list?

ACEP believes the best measure of standard charges is the usual and customary physician charge (“U&C charge”) procured from a not-for-profit, independently owned and operated entity. This entity should maintain an open and transparent database that collects physician charge data from actual claims information and makes that data commercially available to the public for consumption. The information itself must be statistically stratified, geographically adjusted, and specialty specific. The “gold standard” for databases is the FAIRHealth database²⁶, which was found to be the best national U&C charges database to determine out of network (OON) reimbursements in two separate studies by the non-partisan and objective research organization (NORC) at the University of Chicago.²⁷

The mission of FAIRHealth is to provide transparency to the health care and health insurance marketplaces. It was established in 2009 as the result of health plan litigation settlements facilitated by then Attorney General of New York, Andrew Cuomo, in response to an investigation he had conducted against Ingenix and its parent company UnitedHealth Group. In 2008, Attorney General Cuomo found that rates of health care charges maintained by Ingenix were lower than the actual costs of certain medical services and that the Ingenix charge data had been manipulated by certain health plans, resulting in greater than necessary out-of-pocket costs to patients and consumers. After the Attorney General sued, the major health plans settled the litigation over their use for many years of the Ingenix database for over \$1 billion including 35 BCBS plans, Aetna, CIGNA, Humana, UnitedHealth (UNH) & Anthem. Ingenix and Attorney General Cuomo reached a settlement agreement that UNH and Ingenix would help fund a non-profit entity that would develop a new healthcare pricing database. Out of this agreement came the creation of FAIRHealth.

The FAIRHealth database includes data on claims from 150 million covered lives and billions of medical procedures, and these figures are growing. The database contains claims from private insurance in all 50 states, and, through the Qualified Entity Program, has access to all Medicare Parts A, B, and D claims data. Twice a year, the database is updated with claims for the most recent 12 months available. FAIRHealth provides analytical resources and tools that serve the full spectrum of healthcare stakeholders: payers, hospitals and healthcare facilities, physicians, the Government, and consumers. Importantly for patient educational purposes, FAIRHealth has an extensive glossary of terms and definitions that would benefit patients in today’s high deductible health plan (HDHP) environment.

FAIRHealth has been designated by the state as the benchmark tool for determining out-of-network reimbursement in Alaska (since 2004 by DOI regulation), New York (by DFS regulation) and Connecticut (by statute for emergency medicine). In New York, the State Department of Financial Services, which

²⁶ More information on the FairHealth database is available at <https://www.fairhealthconsumer.org/>.

²⁷ NORC at the University of Chicago, Qualitative Assessment of Databases for Out-of-Network Physician Reimbursement, April 18, 2018.

provides oversight to insurance companies, issued guidance implementing Part H of Chapter 60 of the Laws of 2014 that identifies FAIRHealth as an authorized, “independent source” for health plans to determine the “usual and customary cost” for out-of-network services. If health plans in New York choose to use a source other than FAIRHealth for determining the usual and customary cost, they must seek approval from the State Department of Financial Services.

With regard to consumers and their ability to access this information in an easy and transparent manner, FAIRHealth maintains a website and mobile app that use data from its vast database to help consumers understand the costs of medical and dental services and procedures in their specific geographic area. For example, if a person wanted to know the cost of getting a gall bladder removed, he or she could find an estimate of the in-network and out-of-network cost in that person’s zip code.

Beyond the FAIRHealth database, there is little to no price data available to consumers that is provided in a clear, consistent, informative, and easily-accessible manner with data for geozips for the entire United States. While there are some attempts to rectify this product offering, including state-sponsored all payer claims databases (APCDs) or insurers’ own proprietary offerings to members such as price estimation tools, it is widely accepted that none of the currently available tools fully explain the costs of care and none of the state-based APCDs contain national data by geographical zip codes. Further, not all of these state-based tools are available to all consumers. The availability, requirements, and capabilities of APCDs, for example, vary widely from state to state. Determining prices, out-of-pocket costs, and quality represents a significant burden on the consumer. Currently, the FAIRHealth database represents the most consumer-friendly tool to ascertain regional costs for procedures, both in-network and out-of-network.

What types of information would be most beneficial to patients, how can providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?

Insurers, including CMS, should be responsible for clearly providing information to consumers about the potential costs of seeking care under their particular coverage. Providers can participate by helping patients interpret their cost-sharing responsibilities (of note not during the emergency but rather at a non-emergent time such as upon purchase of a policy) but the onus should be on insurers to make these costs transparent to patients. We believe that patients today truly do not understand their “high deductible” health plans and there is a dearth of information on “co-insurance,” “deductibles,” and “co-pays.”

While providers and hospitals may be able to provide raw pricing information upfront to patients, without accompanying information from insurers concerning the manner and methodology the insurer has utilized to adjudicate the patient’s benefits, little can actually be achieved in the form of true transparency. In fact, this information from insurers is an essential component to transparency. Further, knowing that an insurer paid a member benefit ‘at the usual and customary benefit level consistent with the member/patient’s plan benefits’ is not acceptable. Rather, the insurer must define in specific terms and in plain English the manner and methodology utilized by the insurer to adjudicate the patient’s plan benefits, notwithstanding an assertion by the insurer that the information is proprietary or confidential—which, more often than not, is an all too frequent insurer response. This often provides the patient with

a cryptic response and a limited understanding on what they're ultimately responsible for. Therefore, placing this responsibility exclusively on the shoulders of the hospital, physician, or patient is unfair and of little use in satisfying the objective of CMS' present request for true transparency. In order to truly enhance transparency, we believe that CMS should promote and educate Medicare beneficiaries about the non-biased independent pricing data provided by FAIR Health through www.fairhealthconsumer.org. It is free and easy for Medicare beneficiaries to access and understand. It also does not require any new systems to be set up or extra dollars spent to maintain

With respect to acute unscheduled emergency care, patients have the right to know from their insurers in advance if the physician treating them is in-network and, as required by the ACA, should pay the same cost-sharing if they receive care from an out-of-network clinician that they would have paid to an in-network physician. Insurers must meet appropriate network adequacy standards that include adequate patient access to care, including access to hospital-based physician specialties.

Should providers and suppliers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patients' choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers of healthcare services play any role in helping to inform patients of what their out-of-pocket obligations will be?

As stated above, EMTALA does not allow providers to discuss costs with patients in the ED before they are stabilized. ACEP believes that it is the responsibility of insurers to clearly provide information to consumers prior to the emergency about the potential costs of seeking emergency care under their particular coverage. Providers in the ED can participate by helping patients interpret their cost-sharing responsibilities after a medical screening exam has been performed, but the onus should be on insurers to make these costs transparent to patients. Ultimately, while providers and hospitals could provide raw charges upfront to patients, without information from insurers far prior to an emergency condition, it is of little use and could scare patients into not seeking emergency care when they need it most.

Patients should also be able to know in advance of an emergency if an emergency physician is in-network, and should not be financially penalized if they need to receive care from an out-of-network emergency provider. Insurers must meet appropriate network adequacy standards that include adequate patient access to care, including access to hospital-based physician specialties. Patients should also be provided with reasonable and timely access to in-network physicians for non-emergent care.

With respect to network adequacy, the ACA initially had very general, non-specific standards which – as recent years' surprise billing problems demonstrate – did not improve network adequacy among ACA plans. Rather than address this, though, in June of 2017, CMS relinquished virtually all responsibility for establishing and enforcing network adequacy standards for Federally-Facilitated Exchange plans and instead deferred this activity to private organizations and the States.²⁸

²⁸ See at the changes made to 45 CFR §156.230 at <https://www.regulations.gov/document?D=CMS-2017-0021-4021>.

Our experience with network quality and network adequacy standard development and enforcement in purely state-regulated insurance markets leaves us profoundly concerned about this framework. We hope CMS is at least looking closely at network conditions under it – in terms of the quality of plans being approved; the specific time/distance and patient-to-provider ratio standards in place, particularly for specialty physicians; and the enforcement of any applied network standards – and we would be delighted to see or hear what the Agency has learned.

Another barrier that affects our patients' access to high-quality, affordable care is that insurance companies do not release or make public their contracted, in-network rates for individual procedures or services, or even their out-of-network coverage rates. As such, under the current system what is actually charged is virtually never what is paid, leaving the consumer unable to compare costs and further distorting the true costs of care.

ACEP is particularly concerned about the lack of transparency around out-of-network rates for services, and has pushed for years for this to be improved. The current methodology that CMS uses to determine reasonable payments for out-of-network emergency services is called the “greatest of three” (GOT) methodology. This methodology was originally established by Obama Administration in an interim final rule (IFR) in 2010 and was most recently reaffirmed by the Trump Administration in a clarification to a final rule released on April 30, 2018. Under the methodology, when determining payment for out-of-network emergency services, an insurer must pay the greatest of the following:

- 1) the insurer's in-network amount;
- 2) the amount calculated by the same method the plan generally uses for out-of-network services, such as the usual, customary, and reasonable (“UCR”) amount; or,
- 3) the Medicare amount.

Ever since the IFR was promulgated in 2010, we have repeatedly voiced concern with the second of the GOT standards. We believe that the UCR amount is subject to insurer manipulation unless it is verifiable, and the term “usual, customary, and reasonable amount” is not an objective standard for calculating out-of-network payments because it is not defined. Accordingly, we have recommended that the data supporting the calculation be subject to independent verification. This issue is crucial because Medicare rates are some of the lowest in the industry, and in-network amounts are also depressed because in-network providers accept lower reimbursement in exchange for the volume and other benefits that accompany in-network status. Thus, the second of the GOT standards, if calculated fairly and accurately, will nearly always be the greatest of the three and will determine the out-of-network payment.

The current GOT regulation represents the greatest threat to the financial viability of the emergency medicine profession and to patient access to qualified emergency physicians and ED on-call specialists than any other federal regulation to date. In fact, emergency physicians have seen payments for out-of-network services drop significantly since the GOT regulation was issued in 2010. By giving insurers an incentive not to contract for emergency services, the GOT method may impact the ability of EDs to provide care to patients due to inadequate reimbursements that do not cover the cost of stabilizing and treating patients who present at the ED.

Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular service performed by that provider or supplier? If so, what changes would need to be made by providers and suppliers? What burden would be added as a result of such a requirement?

ACEP believes that insurers, including CMS, should make coverage terms and conditions available to their consumers. Emergency physicians do not know what the final cost of services provided to our patients will be, and it may be overly burdensome to expect them to figure this out given the myriad of different insurance policies and cost-sharing arrangements their patients could all have. For example, with respect to Medicare, quite often emergency physicians are faced with the tough decision of either sending a patient home or keeping the patient in the hospital for observation. Beyond the Medicare Outpatient Observation Notice (MOON) that hospitals are required to provide to beneficiaries, emergency physicians could potentially discuss the cost of keeping the patient in the hospital for observation as well. However, emergency physicians may not have all of the appropriate or accurate information easily accessible, including whether the patient is enrolled in Medicare Part B or has any supplemental insurance. The worst thing emergency physicians or any other physicians can do is give their patients incorrect information.

We also note that the Medicare physician fee schedule should not be used as a marker to assess appropriate payment for physicians. As noted earlier in our comment letter, the 2018 Medicare Trustees Report, acknowledges that annual updates for physician reimbursement do not keep pace with the increasing cost of providing physician services and that access to Medicare-participating physicians will become a significant issue in the long term.

How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

Like all health plans, Medigap plans should be required to provide the information described above to patients. How coordination of benefits may be achieved and issues of primary versus secondary or tertiary supplemental insurance policies are best described and explained by the health plans as they are the best source to turn to for adjudicating claims and providing sufficient transparent member benefit information pursuant to policies and procedures that they themselves have created, implemented and sold to consumers in the marketplace. Clinicians are often unknowing that a patient's secondary or tertiary supplemental policy is a Medigap policy nor its terms and conditions, and often do not know or have access to this information until after claims have been adjudicated by the supplemental insurer and the patient is well into the revenue cycle process. Requiring clinicians and hospitals to explain detailed terms

and conditions of Medigap policies before or during patient care would be an unreasonable regulatory burden.

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

Sincerely,

A handwritten signature in black ink that reads "Paul D. Kivela". The signature is written in a cursive, flowing style.

Paul D. Kivela, MD, MBA, FACEP
ACEP President