

September 6, 2024

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244 CMS-1809-P

Re: CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1809-P)

Dear Administrator Brooks-LaSure:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities" proposed rule.

In the rule, the Centers for Medicare and Medicaid Services (CMS) proposes modifications to the existing emergency services Condition of Participation (CoP) due to reports it has heard that ED "readiness can be suboptimal, especially for obstetrical, geriatric, and pediatric populations, among others." Thus, the current Emergency Services CoP is not sufficient in ensuring optimal delivery of emergency care. A major indicator of this is the emergency department (ED) boarding and overcrowding crisis. "Boarding" in the ED is a result of dangerous health system overload that puts patients in a holding pattern as they wait for an inpatient bed or transfer after their initial care. Boarding in the ED is a symptom of a hospital operating at or over its capacity, limiting its ability to absorb the ED workload.

In terms of overall readiness, the boarding crisis poses both a threat to public health and to national security, as many emergency physicians are deeply concerned about the system's ability to respond to a large-scale crisis when the frontline is already at a breaking point on any given "normal" day. The impact of another significant disease outbreak or mass casualty event while our health care safety net is already strained beyond its limits may have serious, life-threatening consequences for millions of patients. Thus, we support CMS' goal in modifying the emergency services CoP "to

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improve the health and safety of all emergency services patients," through enhancements to the Emergency Services Readiness section of the existing emergency services standards for hospitals and CAHs as proposed in this rule, and we request that additional language (see Appendix) be added to the proposed enhancements to protect emergency patients from the hazards of boarding.

With that context in mind, we offer the following additional comments on the OPPS that pertain to emergency physicians and the patients they serve.

HOPD Payment for Telemedicine Evaluation and Management Services

For calendar year (CY) 2025, CMS proposes *not* to recognize the 17 new codes describing audio/video and audio-only telemedicine evaluation and management (E/M) services that were created by the Current Procedural Terminology (CPT®) Editorial Panel effective January 1, 2025. Given the similarities between the new telemedicine E/M code set and the office/outpatient E/M code set, CMS believes that the new telemedicine codes fall within the scope of the hospital outpatient clinic visit policy because the predecessor codes (office/outpatient E/M codes 99201-99205 and 99211-99215) would be reported using code G0463.

CMS seeks comments on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for G0463. CMS also requests feedback on whether the agency should finalize separate payment for these new telemedicine E/M codes under the Physician Fee Schedule, on the resource costs that would be associated with these services for hospitals, and whether the agency should develop separate coding to describe the resource costs associated with a telemedicine E/M service.

ACEP appreciates CMS' recognition of the work that the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) put into drafting the telemedicine E/M services codes, as we were one of the specialty societies involved in this process, and we support the future valuation of these services. We look forward to engaging with CMS and other stakeholders as we continually evaluate the important role telehealth services can play providing timely, quality care to Medicare patients.

Request for Comment on Payment Adjustments under the IPPS and OPPS for Domestic Personal Protective Equipment (PPE)

In the rule, CMS states that although the payment adjustments for domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 respirators under the OPPS and the inpatient prospective payment system (IPPS) have applied to cost reporting periods beginning on or after January 1, 2023, use of the payment adjustments has been limited. CMS is requesting comment on potential modifications to the payment adjustment in order to reduce reporting burden and achieve the policy goal to maintain a baseline domestic production capacity of PPE in order to ensure that quality PPE is readily available to health care personnel when needed. Specifically, CMS is seeking comment on payment adjustment methodology and eligibility, types of N95 respirators used by hospitals, potential modification to include coverage of nitrile gloves, and other PPE types and medical devices that could be appropriate for a similar payment adjustment.

Current standards established by the Occupational Safety and Health Administration (OSHA) around PPE require employers to implement "PPE programs." These programs should "address the hazards present; the selection, maintenance, and use of PPE; the training of employees; and monitoring of the program to ensure its ongoing effectiveness." Unfortunately, as learned during the COVID-19 public health emergency (PHE), some emergency physicians have found that the PPE programs instituted by hospitals have failed to protect them. Many hospitals did

not supply their employees with a sufficient level or amount of PPE, requiring health care workers to reuse PPE beyond their intended use. While supply chain issues contributed to this practice initially, the reuse of PPE continued even after these supply issues were resolved. To mitigate the impact of supply chain faults, there should be investment in a renewable national stockpile to avoid reliance on donations or inadequate stock.

The COVID-19 PHE highlighted the need for the entire emergency health care workforce to have comfortable, reusable, reliable protection for the airway, eyes, and skin. Current PPE can hamper the ability of health care workers to communicate, feel, breathe, or move. Current PPE also does not allow for accommodation for body differences; most PPE is only available in two sizes, and often the small size is impossible to find. In addition, current eyewear is limited to goggles, which are very uncomfortable and fog easily.

Further, there is a need for investment in research in airborne particle distribution and production of adequate protective equipment. Practices that are known to mitigate the distribution of airborne particles from other disciplines (i.e., strategies that the OSHA has recommended in response to asbestos) should be explored in relation to airborne microbes. Research regarding proper ventilation practices is necessary.

Given these issues with PPE programs, ACEP does not think that providing a payment adjustment to account for the increased cost of domestically made PPE would entirely solve the problem. While this policy may help address any PPE supply challenges that may come about in future PHEs, it would not address the other issues unrelated to the supply chain that health workers have experienced receiving high quality PPE from their hospitals. Therefore, ACEP encourages CMS to work with OSHA to ensure that healthcare workers have the flexibility they need to feel properly protected during surges. In addition, current payment adjustments only account for disposable, single-use items, and do not provide for higher-quality, more protective equipment such as powered air purifying respirators. CMS should consider these, along with other reusable PPE items, for a similar payment adjustment.

Non-Opioid Treatments for Pain Relief

Section 4135 of the Consolidated Appropriations Act (CAA), 2023, provides for temporary separate payments for certain non-opioid treatments for pain relief in both the hospital outpatient department (OPD) and ambulatory surgical center (ASC) settings from January 1, 2025, through December 31, 2027. These separate payments are available for qualifying drugs, biologicals, and devices that, among other requirements, have their individual payment packaged into payment for a covered OPD service (or group of services). Under the law, these temporary separate payments must be made in a budget neutral manner. Under the provisions in the CAA, 2023, CMS is proposing to make temporary separate payments to six drugs and one device for non-opioid treatment of pain relief.

ACEP supports the concept of separately paying for the use of non-opioid alternatives for pain management under the OPPS and ASC payment system—and encourages CMS to expand the policy going forward to include coverage and payment of non-opioid treatments in the ED setting.

As emergency physicians, we are on the front lines of the opioid epidemic. 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.¹ 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.²

In terms of payment, the additional cognitive work involved in implementing an ALTO program is not currently recognized or reimbursed in most settings, including the ED. The individual procedures may be reimbursed depending on the other services the patient receives, but many nerve blocks for example are bundled with the primary surgical procedure. Given the importance of using non-opioid treatments for pain as a means to help address the opioid crisis, we strongly recommend that CMS pay separately for both the facility *and* professional components of these critical treatments. We also urge CMS to consider introducing a payment model or grant funded by the Center for Medicare & Medicaid Innovation (CMMI) to help spread best practices for using non-opioids to treat pain.

Hospital Outpatient, ASC and Rural Emergency Hospital (REH) Quality Reporting Programs

Outpatient Quality Reporting and ASC Quality Reporting Programs

The Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Programs are pay-for-reporting quality programs. Providers must meet quality reporting requirements or receive a two percent reduction in their annual payment update.

CMS proposes several new quality measures focusing on health equity and social determinants of health (SDOH): (1) the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period; (2) the Screening for Social Drivers of Health measure beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period; and (3) the Screen Positive Rate for Social Drivers of Health measure, beginning with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period. CMS is likewise proposing these measures and implementation timelines for the REH Quality Reporting Program.

Emergency physicians proudly serve as the country's safety net, treating all patients regardless of their insurance status or ability to pay, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. It is well documented that racial and ethnic minorities represent a disproportionate share of patients in the ED and are more likely to rely on emergency care for both time-sensitive and non-urgent care needs. We also recognize that much more work needs to be done to address these disparities. Thus, we appreciate CMS' ongoing effort to assess how best to measure health care disparities and report those results to clinicians.

When developing new measures that assess social risk, a critical consideration is measure attribution, or the process of selecting a patient population for which a group or entity will be held accountable for providing appropriate health services and achieving adequate health outcomes. ACEP encourages evaluation at the clinician group level in order

¹ Wang HL. No joke: N.J. Hospital uses laughing gas to cut down on opioid use. NPR. April 2016.

² Stader D. Opioid Initiative Wave I: ALTO – The Colorado Experience.

 $https://www.acep.org/contentassets/7c78d4de4f174ecb966efb8fd58aab28/webinar_opioidsw1_5coloradoalto.pdf$

³ Richardson LD, Norris M. Access to Health and Health Care: How Race and Ethnicity Matter: ACCESS TO HEALTH AND HEALTH CARE. Mt Sinai J Med. 2010;77(2):166-177. doi:10.1002/msj.20174.

to ensure that gaps are fairly attributed to entities with adequate agency to be responsible and accountable for outcomes.

There should also be sensitivity, and perhaps an actual formulaic coefficient applied, when evaluating under-resourced facilities to ensure some congruency between their quality performance relative to facilities with more resources. CMS should consider adjusting programmatic requirements to ensure that reporting on quality measures is feasible for all facilities and that under-resourced facilities do not face undue difficulty or burdensome penalties that could affect access to care for vulnerable populations.

Public Reporting

In the CY 2011 OPPS/ASC final rule (75 FR 72086), CMS adopted the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure beginning with CY 2013 payment determination. The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time from ED arrival to departure, also known as ED throughput time. The measure data are stratified into four separate calculations: a) Median Time for Discharged ED Patients – Overall Rate; b) Median Time for Discharged ED Patients – Reporting Measure, which excludes psychiatric/mental health and transfer patients; c) Median Time for Discharged ED Patients – Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; and d) Median Time for Discharged ED Patients – Transfer Patients, which includes information only for patients transferred from the ED.

In the CY 2024 OPPS/ASC final rule (88 FR 81995 and 81996), CMS finalized that data for the Overall Rate, Reporting Measure, and Transfer Patients strata would be publicly reported both on data.medicare.gov in downloadable data files and on Care Compare (or subsequent CMS-designated websites). Data for the Psychiatric/Mental Health Patients stratum are not currently publicly reported on the Care Compare site, though these data are published on data.medicare.gov in downloadable data files (82 FR 59438).

However, in this year's proposed rule, CMS is proposing to publicly report data for the Psychiatric/Mental Health Patients stratum due to "routine monitoring and evaluation of the CY 2024 performance period" showing a median ED throughput time of 4.7 hours for psychiatric/mental health patients compared to 2.6 hours for non-psychiatric/mental health patients, "suggesting this is an area that may benefit from additional quality improvement efforts." CMS suggests that public reporting of this data "will be useful for patients choosing a care location, as well as researchers and hospital staff as they attempt to address health disparities and improve the timeliness of care for mental health patients."

ACEP supports the concept of providing quality-related information to consumers. However, we are concerned that public reporting of this data could discourage patients from coming to the ED when they have a psychiatric emergency because of extended throughput times that may be due to factors outside of emergency physicians' and the ED's control.

Customarily, patients who arrive at the ED via walk-in are checked in and either directed to a treatment area or the waiting room to wait until space is available, depending on the severity of illness. Once space becomes available, they are taken back into the treatment area for completion of the clinical assessment and any needed treatment. A decision

is then made that the patient is either well enough to go home or requires admission to the hospital for continued treatment.

In many cases, when people with mental health disorders come to the ED, there are no places where they can be safely discharged or transferred, as there is an ongoing, severe shortage of inpatient psychiatric beds and staffing for psychiatric units. Research shows that psychiatric patients' length of stay in the ED is 3.2 times longer than that of non-psychiatric patients who are awaiting inpatient placement.⁴ This is not the fault of the emergency clinicians; rather, it is due to the lack of available psychiatric facilities. Therefore, the measure may not accurately reflect the efficacy of the ED itself, but rather the impact that outside influences have on ED throughput time.

Prior Authorization Process for Certain Services

Beginning with CY 2020, CMS established a process through which hospitals must submit a prior authorization request for a provisional coverage affirmation before an outpatient service is furnished to a beneficiary and before a claim is submitted. The change applied initially to only five categories of services. In CY 2021 and 2023, CMS expanded the services subject to prior authorization.

For CY 2025, consistent with its approach in CY 2022 and 2024, CMS proposes no changes to the list of service categories subject to prior authorization. However, CMS proposes to change its timeline for review for non-urgent services from 10 days to seven days to be consistent with the CMS Interoperability and Prior Authorization final rule that was finalized in February 2024.

ACEP supports this proposal and urges the agency to finalize it as proposed. However, we do note that a more expedited prior authorization timeline does not solve the root problem of prior authorization waits and denials and the effect that these have on our patients' ability to receive necessary services.

As emergency physicians, we still see how prior authorization can affect the ability of our patients to receive the most appropriate treatment in the most appropriate care setting. Emergency services are primarily exempt from prior authorization. Every second counts when it comes to treating patients with potentially life-threatening conditions, and therefore, both public and private payers recognize how it unsafe and impracticable it would be to require patients in the ED to receive prior authorization before being able to receive critical services. However, we have experienced numerous occasions where patients who are unable to receive services in other care locations because of a prior authorization wait or denial come to the ED to receive those services (sometimes at the direction of their clinician). The patient comes to the ED because the patient and their provider recognize that the patient can receive the service without undergoing prior authorization. This clearly is not an appropriate reason for a patient to receive treatment in the ED, but it reflects a fundamental flaw in the health care system resulting from extremely stringent prior authorization protocols.

Therefore, while ACEP supports this proposal, we believe that more comprehensive reforms to prior authorization are necessary. CMS must do more to streamline and automate the prior authorization process.

⁴ Nicks, BA & Manthey, David. (2012). The Impact of Psychiatric Patient Boarding in Emergency Departments. Emergency medicine international. 2012. 360308. 10.1155/2012/360308.

Continuous Eligibility in Medicaid and the Children's Health Insurance Program (CHIP)

Medicaid and CHIP provide critical health coverage to more than 82 million Americans. However, many beneficiaries who may be still eligible for Medicaid lose their coverage each year because of the cycle of enrollment and disenrollment, temporary changes in income levels, or administrative issues. The CAA, 2023 required that states permanently provide 12 months of continuous coverage in Medicaid and CHIP for children under the age of 19. (Prior to the CAA 2023, states had the option to provide children with 12 months of continuous coverage through Medicaid and CHIP.) This proposed rule codifies the CAA, 2023 requirement to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP.

We applaud CMS for the implementation of the CAA, 2023 requirement to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP. Expanded access to Medicaid and CHIP coverage will likely result in better health and health outcomes both for affected individuals as well as others in our country. As emergency physicians, we see every day the positive effect that insurance coverage has on our patients and their overall health—and this correlation is supported by a plethora of research. The Kaiser Family Foundation found in a 2019 study that twenty percent of uninsured adults went without needed care in the previous year because of cost, as opposed to eight percent of publicly insured adults. Further, 19 percent of uninsured adults said they delayed or did not get a needed prescription drug due to cost.⁵

Losing health care coverage hampers the financial stability of families and creates a burden to receiving necessary care. When people become uninsured, they may delay or avoid seeking vital care. Deferring or delaying care will often result in the exacerbation of a person's condition or symptoms, and eventually result in a trip to the ED. At this point, due to the progression of their condition, the person's care in the ED will be much costlier and more complex than if he or she had earlier access to more routine care in a physician's office. An increase in the uninsured percentage leads to an overall worsening of health outcomes, including increased prevalence of obesity and malnutrition and reduced prescription adherence. It also affects patients' SDOH leading to increased rates of poverty and housing instability and reduced productivity and educational attainment.

If finalized, these provisions may also help maintain the financial viability of the emergency care safety net. Emergency physicians proudly serve as the country's safety net, treating all patients regardless of their insurance status or ability to pay. As a result of this vital role that we play, we incur unique financial risks, which include higher rates of uncompensated care than other clinicians. We depend on adequate reimbursement from public and private payers to allow for the recruitment and retention of sufficient numbers of qualified providers with sufficient staffing 24 hours a day, seven days a week. By eliminating coverage gaps, which we anticipate would increase the number of Medicaid and CHIP beneficiaries, uncompensated care costs could decline, guaranteeing the viability of the emergency care safety net.

⁵ Kaiser Family Foundation, "The Uninsured and the ACA: A Primer – Key Facts about Health Insurance and the Uninsured amidst Changes to the Affordable Care Act," January 2019, available at: https://www.kff.org/report-section/the-uninsured-and-the-aca-a-primer-key-facts-about-health-insurance-and-the-uninsured-amidst-changes-to-the-affordable-care-act-how-does-lack-of-insurance-affect-access-to-care/.

Hospital Conditions of Participation

Currently, there are no baseline care requirements specific to maternal-child services for Medicare and Medicaid certified hospitals, critical access hospitals and rural emergency hospitals. Given ongoing concerns about maternal health, in the FY 2025 Inpatient Prospective Payment System (IPPS) proposed rule, CMS sought public comment on multiple detailed questions, ultimately seeking potential solutions that can be implemented through the hospital CoPs to address concerns regarding maternal morbidity, mortality and access in the United States. In that proposed rule, CMS stated that it would use feedback from the request for information to inform a new CoP for obstetric services that it would plan to propose in the OPPS rule. CMS goes forward with such a proposal in this rule and outlines proposed requirements for a new obstetrical care CoP.

CMS is also proposing revisions to the existing emergency services CoP related to emergency readiness for hospitals and critical access hospitals (CAHs) that provide emergency services, as well as revisions to the Discharge Planning CoP for all hospitals and CAHs related to transfer protocols.

ACEP has extensive comments on the proposed modification to the emergency readiness CoP, including recommending an addition that would help address the significant crisis of ED boarding.

Obstetrical Care Condition of Participation (§ 482.59 and § 485.649)

Overall Comments

ACEP agrees with CMS that all women who receive labor and delivery services should receive care that meets high standards of quality. We also share CMS' commitment to reducing maternal health disparities and improving maternal and neonatal health outcomes during pregnancy, childbirth, and in the postpartum period. Over the last decade, we have seen a substantial reduction in maternity care services within rural communities to the extent that maternity care deserts have developed and continue to expand. This is one reason why the maternal mortality rate has increased over the same time frame, which has been more acutely pronounced in rural communities, especially those with higher percentages of minorities.⁶

However, while we support CMS' overall effort to help to alleviate the mounting trend of pregnant patients without maternity care, we are concerned about CMS' specific approach with respect to the proposed creation of a new obstetrical CoP and timeline. We believe that hospitals and CAHs will struggle to implement the requirements in this new CoP—especially rural hospitals, CAHs, and facilities that provide care to underserved communities. Many of these requirements involve intensive efforts and infrastructure development to meet the minimum standard expected by CMS. We are particularly concerned that the new CoP as currently proposed could lead to adverse consequences—including closure of labor and delivery units in under-resourced hospitals that are unable to come into compliance—therefore leading to an exacerbation of the existing maternal health care access challenges and a worsening in the current trends in poor health outcomes that are resulting in growing maternity care deserts.

⁶ Health Resources and Services Administration. Maternal and Obstetric Care Challenges in Rural America. May 2020. https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2020-maternal-obstetric-carechallenges.pdf.

Rural Emergency Hospitals

CMS also solicits comments on whether the proposed requirements for the Obstetrical CoP should also apply to REHs going forward.

As we stated previously, ACEP is concerned about the adversity of some hospitals and facilities to come into compliance with the proposed obstetrical care CoP. For REHs, not only are their resources even more limited, but coming into compliance with these requirements may prove to be nonviable as several of the proposed details of the CoP are not applicable to REHs. CMS should thus allow for a meaningful open public comment period for the subsequent interpretive guidance that would be associated with the proposal to extend these requirements to REHs.

Although CMS is not requiring REHs to abide by the new CoP initially, ACEP reiterates our request made when the REH CoPs were first proposed to make it a requirement that a physician with experience in emergency medicine (either a board-certified emergency physician or a family physician with significant expertise in emergency medicine) provide the care or oversee the care delivered by non-physician practitioners. Emergency physicians are fully qualified to manage obstetrical emergencies, and many are qualified to do deliveries. Emergency physicians who are competent in obstetrical care should be credentialed to do deliveries, especially those who are trained in family medicine. While non-physician providers may have some exposure to obstetrical conditions, their training and scope of practice does not provide significant depth to meet the requirements outlined in this proposal.

Discharge Planning CoP; Transfer Protocols § 482.43

CMS notes that existing CoPs for CAHs and REHs include requirements related to the transfer of patients in the event that the facility is unable to deliver needed services for a patient or the patient requires a higher level of care than can be provided there. However, CMS believes that a comprehensive discharge planning CoP for hospitals, including documented requirements for transfer protocols, will enhance the existing requirements and "better protect the health and safety needs of all patients, including pregnant, birthing, and postpartum women. CMS is therefore proposing § 482.43(c), "Standard: Transfer protocols" to require that hospitals have written policies and procedures for transferring patients under their care. CMS believes this would ensure patients are transferred to the appropriate level of care promptly and without undue delay, in order to meet their needs. CMS also proposes to require the hospital to provide training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care. CMS encourages all hospitals receiving transfers to have policies and procedures in place regarding the acceptance of transfers and remind hospitals of their obligations to comply with the Emergency Medical Treatment and Active Labor Act (EMTALA) and Federal civil rights laws.

CMS seeks comment on these proposals as well as other questions around appropriate staff training, transfer criteria, and policies and procedures.

To meet the obligations under EMTALA, which requires hospitals to provide a medical screening exam to every individual who "comes to the emergency department," larger hospitals in urban areas usually accept rural ED transfers. Both facilities have an incentive to communicate about this relationship ahead of needing to transfer patients. However, rural hospitals often experience difficulty finding destination hospitals to accept patients with needs that extend beyond the capabilities of their rural hospital due to the ongoing boarding crisis (described in detail below). Thus, though a transfer decision may be made in a timely and appropriate manner, there are circumstances

outside of the rural ED's control that make it impossible to ensure that the transfer is carried out "promptly and without undue delay." Hospitals bear the responsibility of ensuring the prompt care coordination of interfacility transfer patients and should develop appropriate mechanisms to meet increased patient needs. Thus, CMS should require that hospitals and CAHs develop and maintain procedures not only for transferring patients under their care, but also for accepting patients from other facilities.

ACEP believes that the transfer of patient care responsibilities between physicians and facilities must be orderly, clearly defined, and properly documented. Having a transfer agreement in place is a key check to make sure that both the discharging and the accepting hospital manage patient care appropriately and that the accepting hospital offers evidence-based treatments and has staff able to take care of all possible patient complications. Although ACEP understands that EMTALA requires the hospital to respond to any emergency regardless of a transfer agreement, the transfer agreement itself provides value because it holds both sides to a set of quality standards that allows the hospital to know what it can expect in terms of emergent transfers in the future. Without a transfer agreement, other hospitals may also not know for certain whether there are appropriate specialists available at the accepting hospital, thereby leading to multiple transfers in some cases. This scenario could be devastating for patients, as their care would be significantly delayed. In all, the transfer agreement provides a necessary check on the quality of care that is delivered to patients and therefore must continue to be required. Therefore, for hospitals that do not have adequate services, documented partnerships with another hospital would ensure that transfers are appropriately carried out, for more comprehensive obstetrical and fetal medicine and all other types of services as well.

Rural Emergency Hospitals

As with the obstetrical CoP, CMS is proposing that the addition of the transfer protocol standard apply only to hospitals and CAHs. ACEP does believe that REHs would benefit from such a standard, and it would be especially impactful if a physician with experience in emergency medicine (either a board-certified emergency physician or a family physician with significant expertise in emergency medicine) is required to provide the care or oversee the care delivered by non-physician practitioners. ACEP therefore believes that the transfer protocol standard addition should extend to REH CoPs as well.

Emergency Services Readiness (§ 482.55; § 485.618)

Overall Comments

As background, EMTALA requires Medicare-participating hospitals with EDs to always be ready to provide individuals with an appropriate medical screening exam and stabilizing treatment if an emergency medical condition is found or, under certain circumstances, appropriately transfer such individuals to receive stabilizing care at another facility with higher treatment capabilities not available at the originating hospital. CMS has heard reports that ED "readiness can be suboptimal, especially for obstetrical, geriatric, and pediatric populations, among others." CMS is therefore proposing a new standard entitled "Emergency Services Readiness" within the existing emergency services CoP for hospitals and CAHs (§ 485.618) at (c) to "set clear expectations as well as improve facility readiness in caring for emergency services patients, including pregnant, birthing, and postpartum patients." These requirements would apply to all hospitals and CAHs offering emergency services.

As CMS states, ED readiness can currently be suboptimal. Thus, the current emergency services CoP is not sufficient in ensuring optimal delivery of emergency care. A major indicator of this is the ED boarding and overcrowding crisis. "Boarding" in the ED is a result of dangerous health system overload that puts patients in a holding pattern as they wait for an inpatient bed or transfer after their initial care. Boarding has become its own public health emergency. Our nation's safety net is on the verge of breaking beyond repair; EDs are gridlocked and overwhelmed. And this breaking point is entirely outside the control of the highly skilled emergency physicians, nurses, and other ED staff doing their best to provide equitable, high quality and safe care. Boarding in the ED is a symptom of a hospital operating at or over its capacity, limiting its ability to absorb the ED workload.

ACEP supports CMS' enhancements to the Emergency Services Readiness section of the existing emergency services standards for hospitals and CAHs as proposed in this rule. But given that CMS' goal in this is "to improve the health and safety of all emergency services patients" ACEP requests that additional language (see below) be added to the proposed enhancements to protect emergency patients from the hazards of boarding.

Boarding is a systemic problem that hinders patients' access to care. Any emergency patient can find themselves boarded, regardless of their condition, age, insurance coverage, income, or geographic area. Patients in need of intensive care may board for hours in ED beds (or even waiting room chairs) not set up for the extra monitoring they need. Those in mental health crisis, often children or adolescents, can board for months in chaotic EDs while waiting for a psychiatric inpatient bed to open anywhere. Patients may delay or avoid emergency care and risk their physical and mental health because of these systemic bottlenecks.

ED boarding and crowding are not caused by ED operational issues or inefficiency; rather, they stem from broader health system dysfunction. This dysfunction also leads to negative patient outcomes, as a substantial body of evidence has shown that ED boarding and crowding lead to increased cases of mortality related to downstream delays of treatment for both high and low acuity patients.^{7, 8, 9} Boarding can also lead to ambulance diversion, increased adverse events, preventable medical errors, lower patient satisfaction, violent episodes in the ED, emergency physician and staff burnout, and higher overall health care costs.^{10, 11}

This is not a new problem. According to a 2002 national U.S. survey, more than 90 percent of large hospitals reported EDs operating "at" or "over" capacity. However, historically, the majority of hospitals have failed to implement full capacity protocols, even among the most crowded quartile. Though CMS has implemented measures related to ED

⁷ Hsuan C, Segel JE, Hsia RY, Wang Y, Rogowski J. Association of emergency department crowding with inpatient outcomes. Health Serv Res. 2023 Aug;58(4):828-843. doi: 10.1111/1475-6773.14076. Epub 2022 Oct 12. PMID: 36156243; PMCID: PMC10315392.

⁸ do Nascimento Rocha HM, da Costa Farre AGM, de Santana Filho VJ. Adverse Events in Emergency Department Boarding: A Systematic Review. J Nurs Scholarsh. 2021 Jul;53(4):458-467. doi: 10.1111/jnu.12653. Epub 2021 Mar 31. PMID: 33792131.

⁹ Boudi Z, Lauque D, Alsabri M, et al. Association between boarding in the emergency department and in-hospital mortality: a systematic review. PLoS One. 2020;15(4):e0231253. doi:10.1371/journal.pone.0231253

¹⁰ Viccellio A, Santora C, Singer AJ, Thode HC, J., Henry MC. The association between transfer of emergency department boarders to inpatient hallways and mortality: A 4-year experience. *Ann Emerg Med.* 2009;54(4):487-491. https://www.annemergmed.com/article/S0196-0644(09)00238-8/fulltext.

¹¹ Epstein SK, Huckins DS, Liu SW, et al. Emergency department crowding and risk of preventable medical errors. *Intern Emerg Med.* 2012;7(2):173-180. https://link.springer.com/article/10.1007/s11739-011-0702-8.

¹² Trzeciak S, Rivers EP. Emergency department overcrowding in the United States: an emerging threat to patient safety and public health. Emerg Med J. 2003; 20:402-5.

¹³ Warner LS, Pines JM, Chambers J, et al. The most crowded US hospital emergency departments did not adopt effective interventions to improve flow, 2007-2010. Health Aff. 2015;34(12):2151-2159.

throughput in the Hospital OQR program, including OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients, OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and OP-22: Left Without Being Seen, our ability to take action on ED overcrowding, wait times, and boarding based on the performance of these measures is limited.

Simply put, though hospital throughput measures and boarding proxy measures exist, the boarding and crowding problem persists and continues to grow worse. Therefore, we believe that modifying the emergency services CoP to try address these issues is a more effective tool. The specific language that CMS is proposing is proposing to add is as follows:

- (c) Standard: Emergency services readiness. In accordance with the complexity and scope of services offered, there must be adequate provisions and protocols to meet the emergency needs of patients.
 - (1) Protocols. Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.
 - (2) Provisions. Provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions must include the following:
 - (i) Drugs, blood and blood products, and biologicals commonly used in life-saving procedures;
 - (ii) Equipment and supplies commonly used in life-saving procedures; and
 - (iii) Each emergency services treatment area must have a call-in-system for each patient.
 - (3) Staff training. Applicable staff, as identified by the hospital, must be trained annually on the protocols and provisions implemented pursuant to this section.
 - (i) The governing body must identify and document which staff must complete such training.
 - (ii) The hospital must document in the staff personnel records that the training was successfully completed.
 - (iii) The hospital must be able to demonstrate staff knowledge on the topics implemented pursuant to this section.
 - (iv) The hospital must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

Recommended Addition and Rationale

ACEP proposes to add a fourth provision under (c) that would be as follows:

- (4) Readiness. Hospitals must have an actionable protocol developed and in place to move emergency patients deemed to need inpatient admission or observation out of the emergency service or department when that service or department's capacity for such patients is exceeded.
 - (i) This protocol should be implemented when the number of patients requiring inpatient hospitalization or observation exceeds 25% of the emergency service's dedicated treatment areas at any given time.

- (ii) The protocol shall include a load balancing plan for moving such patients out of the emergency department or other dedicated emergency service areas; alternative staffing plans for inpatients by non-ED staff and contingency plans and arrangements with other hospitals and post-acute facilities to be able to transfer inpatients to the most appropriate site of care.
- (iii) The protocol should include a target goal for the return to normal operations.
- (iv) A hospital must report its performance and adherence to the protocol in a standardized method as part of its QAPI program and use findings from these performance reports to help inform any additions, revisions, or updates to the protocol on an ongoing basis.

As mentioned above, ED boarding due to inpatient overflow is a major contributor to delays in providing effective, humane, and life-saving care. It also increases the risk of preventable care management errors. ED patients must compete for a finite number of inpatient beds with those patients receiving elective admissions, being transferred from another hospital or facility, or undergoing major procedures/surgeries. Unfortunately, under current reimbursement structures, hospitals are incentivized to provide a bed for all these other patients over emergency patients. Patients can even frequently board in the ED in some hospitals despite inpatient beds being open, since those are being held for specialty patients or in anticipation of other desirable elective admissions or transfers. With so many inpatients waiting for a long-term bed, patients cannot leave the ED, and every new patient is stuck in the waiting room or hallway for hours. ED beds and other treatment areas are needed for acute emergency evaluation and management, and each one that is taken up by prolonged waits of these admitted or observation patients will further delay needed care for new ED patients, who are the least stable and most undifferentiated patients in the health system, as they are left to languish in the hallways and waiting rooms of the ED. Having care move sooner to the best setting (inside the hospital, out of the ED) ensures better outcomes – but due to a fundamental misalignment of incentives, this does not happen on its own.

Addressing this significant issue related to misaligned financial incentives would be extremely difficult and would likely require some actions that are outside the scope of government intervention. However, our proposed addition to the emergency services CoP readiness standard represents an actionable step <u>that can be taken now</u>. It would require hospitals to have protocol developed for when admitted or observation patients waiting to be moved out of the ED exceed the unit's capacity.

ACEP supports the Joint Commission's definition of boarding and recommendation that boarding time frames not exceed four hours in the interest of patient safety and quality of care.¹⁵ But the rising nature of emergency care makes it difficult to predict demand and allocate resources accordingly, so having a mandated time limit would be difficult to operationalize through a CoP. Our proposed standard instead states that the hospital's protocol would need to require the hospital to move admitted emergency patients out of the ED when the hospital reaches a **specific capacity threshold**.

When more than 25 percent of that ED's dedicated treatment spaces are taken up by admitted patients waiting to be moved to inpatient or transfer, the hospital's own developed protocol should be activated. The denominator for that 25 percent threshold should be limited only to dedicated treatment areas for that ED (e.g., an individual room or curtained cubicle); the use of hallways, closets, and more is now the norm in EDs rather than the exception due to

¹⁴ Institute of Medicine. Hospital-based emergency care: At the breaking point. Washington, D.C.: The National Academies Press; 2007.

¹⁵ The Joint Commission. EP6: https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3 report issue 4.pdf.

the boarding crisis, but these ad hoc spaces should *not* be considered as part of the denominator as these are not appropriate to the provision of high quality, emergency care.

The protocol itself should include a load balancing plan for moving admitted patients out of the ED or another dedicated emergency service area. The patient cannot simply be 'admitted' to any space physically located in the ED. Furthermore, no ED beds may be converted to inpatient or observation beds to attempt to avoid the physical transfer out of the department requirement. Instead, patients can be moved to temporary care spaces outside the ED, such as inpatient hallways, with the goal of safely sharing the burden of inpatients without assigned beds throughout the hospital. Mortality and ICU transfer rates have shown to be less among patients placed in inpatient hallway beds compared to those awaiting standard bed placement from the ED. ¹⁶ As well, 85 percent of admitted ED patients who experienced boarding in the ED hallway and then were subsequently transferred to inpatient hallways actually preferred the inpatient hallway. ¹⁷

The protocol should also include alternative staffing plans for inpatients by non-ED staff. In other words, clinical staff (nurses, physicians, etc.) from the department or service to which the patient will ultimately be admitted to once a bed becomes available will come and provide care for the admitted patient in the ED. While this does not alleviate boarding itself, it helps free up already overburdened ED staff, and provides improved and more specific care for the boarded patients while they wait in the ED for an inpatient bed.¹⁸

Lastly, the protocol should include contingency plans and arrangements with other hospitals and post-acute facilities to be able to transfer inpatients to the most appropriate site of care. Hospitals should bear the responsibility of ensuring the prompt care coordination of interfacility transfer patients and should develop appropriate mechanisms to meet increased patient needs. Patients should not receive a lower quality of care because of inefficient hospital flow systems, staff shortages, insufficient beds, ineffective triage systems, or any other failure of planning that results in ED boarding. The need for contingency plans is especially critical in rural areas. Rural hospitals often experience difficulty finding destination hospitals to accept patients with needs that extend beyond the capabilities of their rural hospital.

We believe that our recommended modification to the emergency services CoP is flexible enough for hospitals of all sizes and those in both rural and urban areas to meet. It allows hospitals to create their own protocols that, while complying with the basic requirements of the standard, can be tailored based on their staffing arrangements and overall workforce and their physical location and presence in the community. Again, while we do not think that the proposed standard addresses the fundamental issue of misaligned financial incentives that drive boarding, it is a step that must be taken now to start to tackle this crisis.

¹⁶ Viccellio A, Santora C, Singer AJ, et al. The association between transfer of emergency department boarders to inpatient hallways and mortality: a 4-year experience. Ann Emerg Med. 2009;54(4):487-491.

¹⁷ Viccellio P, Zito JA, Sayage V, Chohan J, Garra G, Santora C, Singer AJ. Patients overwhelmingly prefer inpatient boarding to emergency department boarding. J Emerg Med. 2013 Dec;45(6):942-6. doi: 10.1016/j.jemermed.2013.07.018. Epub 2013 Sep 21. PMID: 24063879.

¹⁸ Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. NEJM Catalyst. 2021; 5(2).

We appreciate the opportunity to share our comments regarding modifications to the emergency services CoP and the OPPS proposed rule overall. If you have any questions, please contact Erin Grossmann, ACEP's Manager of Regulatory and External Affairs, at egrossmann@acep.org.

Sincerely,

Aisha T. Terry, MD, MPH, FACEP

ACEP President

Appendix:

Proposed Emergency Services Condition of Participation (CoP) Modification to Address ED Boarding

Key:

Black text = current CoP

Blue text = CMS' proposed addition in CY 2025 OPPS NPRM

Red text = ACEP's requested enhancement to that CMS proposed language

42 CFR § 482.55 - Condition of participation: Emergency services.

§ 482.55 Condition of participation: Emergency services.

The <u>hospital</u> must meet the emergency needs of <u>patients</u> in accordance with acceptable standards of practice.

- (a) Standard: Organization and direction. If emergency services are provided at the hospital—
 - (1) The services must be organized under the direction of a qualified member of the medical staff;
 - (2) The services must be integrated with other <u>departments</u> of the <u>hospital</u>;
 - (3) The policies and procedures governing medical care provided in the emergency service or <u>department</u> are established by and are a continuing responsibility of the medical staff.
- (b) Standard: Personnel.
 - (1) The emergency services must be supervised by a qualified member of the medical staff.
 - (2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.
- (c) Standard: Emergency services readiness. In accordance with the complexity and scope of services offered, there must be adequate provisions and protocols to meet the emergency needs of patients.
 - (1) Protocols. Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

- (2) Provisions. Provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions must include the following:
 - (i) Drugs, blood and blood products, and biologicals commonly used in life-saving procedures;
 - (ii) Equipment and supplies commonly used in life-saving procedures; and
 - (iii) Each emergency services treatment area must have a call-in-system for each patient.
- (3) Staff training. Applicable staff, as identified by the hospital, must be trained annually on the protocols and provisions implemented pursuant to this section.
 - (i) The governing body must identify and document which staff must complete such training.
 - (ii) The hospital must document in the staff personnel records that the training was successfully completed.
 - (iii) The hospital must be able to demonstrate staff knowledge on the topics implemented pursuant to this section.
 - (iv) The hospital must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.
- (4) Readiness. Hospitals must have an actionable protocol developed and in place to move emergency patients deemed to need inpatient admission or observation out of the emergency service or department when that service or department's capacity for such patients is exceeded.
 - (i) This protocol should be implemented when the number of patients requiring inpatient hospitalization or observation exceeds 25% of the emergency service's dedicated treatment areas at any given time.
 - (ii) The protocol shall include a load balancing plan for moving such patients out of the emergency department or other dedicated emergency service areas; alternative staffing plans for inpatients by non-ED staff and contingency plans and arrangements with other hospitals and post-acute facilities to be able to transfer inpatients to the most appropriate site of care.
 - (iii) The protocol should include a target goal for the return to normal operations.
 - (iv). A hospital must report its performance and adherence to the protocol in a standardized method as part of its QAPI program and use findings from these performance reports to help inform any additions, revisions, or updates to the protocol on an ongoing basis.