

June 5th, 2023

CMS-1785-P

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

Re: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership

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 Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership." Our comments are limited to the sections that pertain to emergency physicians and the patients we serve.

Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2024

Starting in Fiscal Year (FY) 2014, Medicare disproportionate share hospitals (DSHs) receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period. In this proposed rule, CMS is proposing to update estimates of the factors used to determine uncompensated care payments for FY 2024. CMS estimates that adopting these changes would result in a decrease of \$167 million in total (or 2.4 percent) across all 2,395 hospitals that would be eligible to receive DSH payments in FY 2024.

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ACEP is extremely concerned with the effect the payment cuts would have on the financial viability of hospitals. According to a study conducted by Chartis, an estimated 143 rural hospitals have closed from 2010 through January 2023, peaking with a high of 19 in 2020 just as the pandemic hit. Another 453 are vulnerable to closure.¹ When a hospital closes, mortality rates and readmission rates increase at hospitals near to where the hospital closed, particularly at high-occupancy bystander hospitals that are sensitive to changes in the availability of emergency care in neighboring communities.² In other words, access to emergency care decreases especially for time-sensitive cases. Patient outcomes also decline with hospital closures, with one study indicating that inpatient mortality increases for time-sensitive conditions such as stroke and acute myocardial infarction patients (4.4 percent increase in inpatient mortality), and within these diagnoses, Medicaid patients and racial minorities had the highest mortality increases (11.3 percent and 12.6 percent, respectively).³ Finally, hospital closures cause long-term staffing and recruitment issues, limiting patient access and choice in the surrounding area. Given the impact that this proposal could have on hospitals in both rural and underserved communities, *ACEP urges CMS not to finalize the proposal*.

Payment for Indirect and Direct Graduate Medical Education Costs

The Consolidated Appropriations Act (enacted on December 27, 2020) included a provision that would allow critical access hospitals (CAHs) and small rural hospitals (those with less than 50 beds) to convert to rural emergency hospitals (REHs) starting on January 1, 2023. In order to enable residency training to begin at newly designated REHs, CMS is proposing to allow hospitals to include full-time equivalent (FTE) residents training at an REH in its direct graduate medical education (GME) and indirect GME (IME) FTE counts for Medicare payment purposes. REHs may also have the option to incur direct GME costs and be paid based on reasonable costs for those training costs.

ACEP strongly supports this proposal. We understand the workforce challenges that exist in rural areas. To ensure quality emergency care, it is critical that a physician with training and/or experience in emergency medicine provide the care or oversee the care delivered by non-physician practitioners. Emergency patients represent some of the most complex and critically ill patients in medicine, and effective management of these patients requires years of specialized training. Therefore, providing funding to REHs to ensure that residents can be trained in these facilities is critical.

Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

CMS is proposing to adopt the Severe Sepsis and Septic Shock: Management Bundle measure in the VBP program. CMS believes that the adoption of this measure aligns with the Core Principles outlined in the HHS National Healthcare System Action Alliance to Advance Patient Safety, including the focus on demonstrating and fostering commitments to safety as a core value and the promotion of the development of safety cultures. The agency also believes the adoption of the Sepsis and Septic Shock: Management Bundle measure will contribute toward CMS' goal of advancing health equity, as outlined in the CMS National Quality Strategy.

ACEP has significant concerns about the adoption of the Sepsis and Septic Shock: Management Bundle and again requests that CMS NOT adopt the measure. If CMS adopts this measure under the VBP Program, it would represent

¹ The full report can be found at

https://www.chartis.com/sites/default/files/documents/chartis_study_rural_health_safety_net_under_renewed_pressure_as_pandemic_f_ades.pdf.

² Hsai R. and Shen Y. Emergency Department Closures And Openings: Spillover Effects On Patient Outcomes In Bystander Hospitals. Health Affairs VOL. 38, No. 9 September 2019. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00125.

³ Gujral K. and Basu A. Impact of Rural and Urban Hospital Closures on Inpatient Mortality. The National Bureau of Economic Research. NBER Working Paper No. 26182. August 2019, Revised in June 2020. https://www.nber.org/papers/w26182.

a major shift in accountability from pay-for-reporting that was based at least in part on a flawed measure, to pay-for*performance* based on a flawed measure, which is significantly more alarming. We believe this shift will not enhance care and may create unintended threats to the health of those with sepsis or other conditions that can mimic sepsis.

Found below is a summary of our major concerns about this measure, some of which were previously outlined in a 2021 position paper and in public comments during the National Quality Forum re-endorsement process.⁴

1. Despite massive investments by US hospitals to implement, assess compliance with, and report data on the SEP-1 core measure, rigorous analyses indicate that implementation of SEP-1 has not improved outcomes for patients.

- Careful analyses using interrupted time series models and clinical data from hundreds of hospitals demonstrate that implementation of SEP-1 led to changes in *processes* of care (including lactate checks, fluids, and in some studies, broad spectrum antibiotics) but *not* to improvements in sepsis-associated mortality.⁵⁶⁷⁸ These data support the concern that SEP-1 forces clinicians and hospitals to focus on a set of processes and interventions that have not been shown to lead to better outcomes for patients.
- The only study that suggests a possible benefit of SEP-1 is one that retrospectively compared outcomes for patients who received SEP-1 compliant vs non-compliant care.⁹ Despite attempting to adjust for baseline risk using propensity matching, however, this study is at high risk for confounding because the patients who do not receive SEP-1 compliant care tend to be very different from those who do (including more severe illness, more ambiguous clinical presentations, higher rates of hospital vs community-onset sepsis, and higher rates of septic shock which requires more steps required to pass the measure.)¹⁰ When assessing compliance just among patients with septic shock (a fairer comparison than combining patients with sepsis and septic shock), mortality rates for SEP-1 compliant versus non-compliant care in this study were not statistically different (and in fact numerically higher for those who received compliant care, 38% vs 35%).¹¹
- 2. SEP-1's requirement to immediately administer antibiotic therapy to all patients with possible sepsis, regardless of severity-of-illness, risks increasing excessive and unwarranted antibiotic administration. This concern will be magnified if SEP-1 shifts from pay-for-reporting to pay-for-performance.

¹⁰ Rhee C, Filbin MR, Massaro AF, et al. Compliance with the National Sep-1 Quality Measure and Association with Sepsis Outcomes: A Multicenter Retrospective Cohort Study. *Crit Care Med.* 2018;46(10):1585-1591.

⁴ Rhee C, Chiotos K, Cosgrove SE, et al. Infectious Diseases Society of America Position Paper: Recommended Revisions to the National Severe Sepsis and Septic Shock Early Management Bundle (Sep-1) Sepsis Quality Measure. *Clin Infect Dis.* 2021;72(4):541-552.

⁵ Barbash IJ, Davis BS, Yabes JG, Seymour CW, Angus DC, Kahn JM. Treatment Patterns and Clinical Outcomes after the Introduction of the Medicare Sepsis Performance Measure (Sep-1). *Ann Intern Med.* 2021.

⁶ Rhee C, Yu T, Wang R, et al. Association between Implementation of the Severe Sepsis and Septic Shock Early Management Bundle Performance Measure and Outcomes in Patients with Suspected Sepsis in Us Hospitals. *JAMA Netw Open.* 2021;4(12):e2138596.

⁷ Pakyz AL, Orndahl CM, Johns A, et al. Impact of the Centers for Medicare and Medicaid Services Sepsis Core Measure on Antibiotic Use. *Clin Infect Dis.* 2021;72(4):556-565.

⁸ Anderson DJ, Moehring RW, Parish A, et al. The Impact of Centers for Medicare & Medicaid Services Sep-1 Core Measure Implementation on Antibacterial Utilization: A Retrospective Multicenter Longitudinal Cohort Study with Interrupted Time-Series Analysis. *Clin Infect Dis.* 2022;75(3):503-511.

⁹ Townsend SR, Phillips GS, Duseja R, et al. Effects of Compliance with the Early Management Bundle (Sep-1) on Mortality Changes among Medicare Beneficiaries with Sepsis: A Propensity Score Matched Cohort Study. *Chest.* 2022;161(2):392-406.

¹¹ Townsend et al.

- SEP-1 stipulates the same time-to-antibiotic goals (3 hours) for sepsis and septic shock, but the association between time-to-antibiotics and mortality in the largest and highest-quality observational studies is much stronger for septic shock than for sepsis.^{12,13} The only randomized controlled trial to compare differential timing of antibiotics in patients with suspected sepsis (the vast majority of whom did not have septic shock) did not show any differences in 28-day mortality despite antibiotics being administered a median of 96 minutes earlier in the intervention arm.¹⁴
- The signs and symptoms of sepsis are non-specific and mimicked by many non-infectious conditions. At least one third of patients treated with antibiotics for possible sepsis turn out to have viral infections or non-infectious conditions.^{15,16} The impact of the SEP-1 implementation on others who seem initially to have sepsis but later discovered *not* to have this was unassessed in the supportive trial ¹⁷; this is not a trivial issue as sepsis care steps may not help and can harm those without sepsis, something seen decades earlier with a community acquire pneumonia measure.
- Immediate empiric antibiotics are appropriate in patients with suspected septic shock, but the perception that any delays in antibiotic therapy led to worse outcomes for patients with suspected sepsis, regardless of severity-of-illness, leads to inappropriate antibiotic prescribing and is the wrong message for clinicians.
- External pressures to rush to treatment will further expose many patients without infection or with very low likelihood of infection to the risk of antibiotics (including direct toxicities, *C. difficile* infection, and development of antibiotic resistance) without benefit and potentially exacerbate the public health crisis of antibiotic resistance.¹⁸
- 3. There are no high-quality data supporting the 3-hour 30 cc/kg threshold for crystalloid fluids in patients with sepsis-induced hypotension or repeat lactate measurements as an approach to reduce sepsis mortality, yet both are common causes of SEP-1 failure.¹⁹ Hospitals should not be denied payment for not complying with these bundle elements that have both been labeled as "weak recommendations with low quality of evidence" in the latest version of the Surviving Sepsis Campaign Guidelines.²⁰

¹² Weinberger J, Rhee C, Klompas M. A Critical Analysis of the Literature on Time-to-Antibiotics in Suspected Sepsis. *J Infect Dis.* 2020;222(Suppl 2):S110-S118.

¹³ Im Y, Kang D, Ko RE, et al. Time-to-Antibiotics and Clinical Outcomes in Patients with Sepsis and Septic Shock: A Prospective Nationwide Multicenter Cohort Study. *Crit Care.* 2022;26:19.

¹⁴ lam N, Oskam E, Stassen PM, et al. Prehospital Antibiotics in the Ambulance for Sepsis: A Multicentre, Open Label, Randomised Trial. *Lancet Respir Med.* 2018;6(1):40-50.

¹⁵ Klein Klouwenberg PM, Cremer OL, van Vught LA, et al. Likelihood of Infection in Patients with Presumed Sepsis at the Time of Intensive Care Unit Admission: A Cohort Study. *Crit Care*. 2015;19:319.

¹⁶ Shappell CN, Klompas M, Ochoa A, Rhee C, Program CDCPE. Likelihood of Bacterial Infection in Patients Treated with Broad-Spectrum Iv Antibiotics in the Emergency Department. *Crit Care Med.* 2021;49(11):e1144-e1150.

¹⁷ Kang et al.

¹⁸ Carignan A, Allard C, Pepin J, et al. Risk of Clostridium difficile infection after perioperative antibaterial prophylaxis before and during an outbrak of infection due to a hypervirulent strain. Clin Inf Dis 2008;46:

¹⁹ Pepper DJ, Jaswal D, Sun J, Welsh J, Natanson C, Eichacker PQ. Evidence Underpinning the Centers for Medicare & Medicaid Services' Severe Sepsis and Septic Shock Management Bundle (Sep-1): A Systematic Review. *Ann Intern Med.* 2018;168(8):558-568.

²⁰ Seymour CW, Gesten F, Prescott HC, et al. Time to Treatment and Mortality During Mandated Emergency Care for Sepsis. N Engl J Med. 2017;376(23):2235-2244.

- The largest observational study of sepsis bundle compliance (almost 50,000 patients treated in New York hospitals under the state health department's sepsis regulatory requirements) did not find an association between completion of the 30 cc/kg fluid bundle component and mortality.²¹
- The recent cessation of the CLOVERS trial which aimed to compare aggressive early fluid resuscitation versus earlier initiation of vasopressors in septic shock was stopped early for futility (<u>https://clinicaltrials.gov/ct2/show/NCT03434028</u>). This underscores the lack of data to support a one-size fit-all approach to fluid management.
- The lack of benefit of serial lactates is further supported by a recent randomized controlled trial of patients with septic shock that showed no difference in mortality between fluid resuscitation based on physical exam (capillary refill time) versus serial lactate measurements.²²

4. The current SEP-1 time-zero is complex, subjective, and not evidence based.

• The SEP-1 time zero definition requires documentation of suspected infection, SIRS criteria, and one of more than 8 potential organ dysfunction criteria within a limited time window. The complexity of the current time zero definition contributes to variability in abstraction and undermines the validity of the measure.²³

5. Pay-for-performance based on a flawed measure is likely to negatively and disproportionally affect safety-net healthcare systems.

• Hospitals caring for a high percentage of medically underserved patients have been shown to bear the brunt of financial penalties associated with CMS value-based purchasing programs.²⁴Before implementing a new measure in CMS's Hospital Value-Based Purchasing Program, or any other pay-for-performance program, its impact on the poorest hospital systems must be considered.

We would like to reiterate the concrete suggestions we have previously made to improve SEP-1, which include the following:

- 1. Focus the bundle on the subset of patients most likely to benefit from rapid and aggressive interventions, which are those with septic shock.
- 2. Minimize antibiotic overuse and adverse effects by eliminating patients with possible but unconfirmed sepsis who do not have shock from the bundle since many of these patients do not have infections and the data supporting immediate antibiotics for this population are weak.
- 3. Eliminate bundle elements that do not contribute to improved patient outcomes, such as measuring serial lactates and 30 cc/kg of fluids for hypotension.

²¹ Pakyz. et al.

²² Kang et. al

²³ Rhee C, Brown SR, Jones TM, et al. Variability in Determining Sepsis Time Zero and Bundle Compliance Rates for the Centers for Medicare and Medicaid Services Sep-1 Measure. *Infect Control Hosp Epidemiol.* 2018:1-3.

²⁴ Rosenbaum L. Reassessing Quality Assessment - the Flawed System for Fixing a Flawed System. N Engl J Med. 2022;386(17):1663-1667.

- 4. Streamline the reporting process to focus on clinical outcomes rather than process measures.
- 5. Make reporting electronic with data that is easily extractable from the electronic health record.
- 6. Get input and support for intended changes from all stakeholders, including the full array of professional organizations that routinely manage patients with possible sepsis.

In its current state, however, we do not believe that SEP-1 is appropriate for pay-for-reporting or pay-forperformance.

Hospital IQR Program

<u>Proposed Removal of Medicare Spending Per Beneficiary (MSPB)—Hospital Measure Beginning with the</u> <u>CY 2026 Reporting Period/FY 2028 Payment Determination</u>

In this proposed rule, CMS is proposing to remove the Medicare Spending Per Beneficiary (MSPB)—Hospital Measure beginning with the FY 2028 payment determination under measure removal factor 8 (the costs associated with a measure outweigh the benefit of its continued use in the program). This measure is being proposed for adoption by the Hospital VBP Program in section V.K. of the proposed rule, so CMS is proposing its removal from the Hospital IQR Program to reduce the burden that would arise from duplicative reporting of the measure in a quality reporting program and value-based program and to simplify administration of both programs. This proposed removal is contingent on finalizing the proposal to adopt the re-evaluated measure in the Hospital VBP Program beginning with the FY 2028 program year.

In general, ACEP continues to have significant concerns regarding the MSPB measure. We believe that the measure insufficiently adjusts for risk, which punishes physicians repeatedly for caring for the most vulnerable patients with high cost, multiple chronic conditions. Further, it does not appropriately reflect costs of services that are controlled by emergency physicians, as emergency physicians are not the physicians who are driving the cost of care during a hospital stay.

Potential Future Inclusion of Two Geriatric Care Measures

CMS believes that patient-centered care for aging patient populations with multiple chronic conditions should be prioritized by hospitals. Therefore, they are considering two attestation-based structural measures, the Geriatric Hospital measure and the Geriatric Surgical measure, for the Hospital IQR Program. These attestation-based structural measures apply evidence-based, concrete, actionable steps to improve patient-centered care in the hospital inpatient setting for older adults. CMS is also requesting public comment on the potential future proposal for a hospital designation focused on hospitals that participate in patient-centered geriatric care health system improvement initiatives.

ACEP General Comments

ACEP specifically worked on the Geriatric Hospital measure, so we will limit our comments to that measure. The Geriatric Hospital structural measure assesses hospital commitment to improving outcomes for patients 65 years or older through patient-centered competencies aimed at achieving quality of care and safety for all older patients. The measure includes 14 attestation-based questions across eight domains representing a comprehensive framework

required for optimal care of older patients admitted to the hospital or being evaluated in the emergency department (ED): (1) Identifying Goals of Care; (2) Medication Management; (3) Cognition and Delirium; (4) Preventing Delirium Related Events; (5) Function and Mobility; (6) Social Determinants of Health; (7) Care Transitions; and (8) Ensuring Quality Care for High-Risk Patients.

To report on this measure, hospitals would respond to the eight domain attestations that encompass 14 corresponding statements. A hospital would receive one point for each domain where they attest to each of the corresponding statements (for a total of zero to eight points). For domain questions with multiple statements, positive attestation to each statement would be required to qualify for the corresponding domain attestation. The measure would be calculated as the number of complete attestations divided by the total number of questions.

ACEP supports this measure overall. We agree with CMS that our health care system struggles to care for older adults. Hospitals are increasingly faced with older patients who have complex medical, physiological, and psychosocial needs that are often inadequately addressed by the current health care infrastructure.

In response to this gap in care, we need to develop measures that identify clinical frameworks based on evidencebased best practices to provide goal-centered, clinically effective care for older patients. This measure accomplishes this goal. It puts an emphasis on the importance of defining patient (and caregiver) goals not only from the immediate treatment decision but also for long-term health and aligning care with what the patient values. The measure causes teams to transparently portray their quality and seek to continuously improve. It also can provide the public with information that reflects a care delivery team where the hospital and the related specialties are wired together in a meaningful way.

It is also important to note that the measure aligns with the standards that ACEP has put to place through the Geriatrics Emergency Department Accreditation (GEDA) framework. Geriatric emergency departments (GEDs) incorporate specially trained staff, assess older patients in a more comprehensive way, and take steps to make sure the patient experience is more comfortable and less intimidating for older adults. All of this allows for a better care experience for older adults while in the ED and safer transitions to a community setting for those who do not need medical admission. An accredited GED has four key areas of differentiation from a traditional ED. First, physicians and nurses receive additional education in geriatric emergency medicine that provides added expertise in the emergency care of older adults. Additional education focuses on:

- Geriatric specific syndromes and concepts (e.g., atypical presentation of disease, changes with age, transitions of care) relevant to emergency medicine,
- Clinical issues nearly exclusive to geriatric patients (e.g., end of life care, dementia, delirium, systems of care for older adults), and
- Issues common to all ED patients but focused on the unique factors found in older adults (e.g., trauma in older adults, cardiac arrest care for the geriatric patient)

Second, GEDs have enhanced screening processes. Patients receive additional screenings that can quickly uncover physical or mental health risks that are more common in older adults. For example, screening tools uncover geriatric syndromes (like falls, polypharmacy, delirium, dementia) as well as social vulnerabilities (like food scarcity or elder mistreatment).

Third, GEDs are often supported by interdisciplinary team members that help provide enhanced community connections for the most vulnerable older adults, as well as focus on transitions of care. Team members can reach

out to the local agency on aging, services like Meals on Wheels, physical therapy providers and home health agencies, or help facilitate direct to skilled nursing facility (SNF) transfers when an in-patient admission is not required.

Finally, a GED is usually not a separate space or standalone ED, but rather has structural enhancements to the physical environment that make the experience more conducive to older adults. Oftentimes this includes a designated, quieter, cordoned-off space within an ED, light dimmers, non-stick flooring to minimize falls, comfortable space for caregivers in the ED, or the inclusion of handrails.

In summary, the goals of GEDs are to improve transitions of care, avoid unhelpful hospital admissions or readmissions, identify unmet needs, and improve care quality and the patient experience. GEDs do this through the use of transitional care nurses or social workers by:

- Identifying underlying geriatric syndromes and social vulnerabilities through enhanced screenings
- Intervening upon findings
- Connecting to social services
- If appropriate and feasible, transitioning to home or community-based settings (hospital at home, primary care provider, etc.)

Though research in improving emergency care for older adults has been underway for decades, wide-scale adoption of geriatric emergency medicine care processes is relatively new. In 2013, <u>the Geriatric ED Guidelines</u> were created. In 2018, ACEP launched the <u>Geriatric Emergency Department Accreditation program</u>, which established criteria for three levels of GED accreditation. There are now over 425 accredited GEDs in the United States, along with an increasing international presence.

There is a growing body of literature that supports the outcomes of GEDs to lower cost, improve quality, and improve the patient experience:

- Up to 16.5 percent reduced risk of hospital admission²⁵ and 17.3 percent of readmission²⁶
- Up to \$3,202 savings per Medicare beneficiary after 60 days²⁷
- Decreased odds of 30- and 60-day fall-related ED revisit with PT services²⁸
- 3 percent increase with the clarity of discharge information and perceived wellbeing²⁹
- Multiple studies showcasing improved experience across a variety of interventions³⁰

²⁷ Hwang U, Dresden SM, Vargas-Torres C, et al. Association of a Geriatric Emergency Department Innovation Program With Cost Outcomes Among Medicare Beneficiaries. JAMA Netw Open. 2021;4(3):e2037334. doi:10.1001/jamanetworkopen.2020.37334
²⁸ Lesser A, Israni J, Kent T, Ko KJ. Association Between Physical Therapy in the Emergency Department and Emergency Department Revisits for Older Adult Fallers: A Nationally Representative Analysis. J Am Geriatr Soc. 2018 Nov;66(11):2205-2212. doi: 10.1111/jgs.15469. Epub 2018 Aug 21. PMID: 30132800.

²⁵ Hwang, U., Dresden, S.M., Rosenberg, M.S., Garrido, M.M., Loo, G., Sze, J., Gravenor, S., Courtney, D.M., Kang, R., Zhu, C.W., Vargas-Torres, C., Grudzen, C.R., Richardson, L.D. and (2018), Geriatric Emergency Department Innovations: Transitional Care Nurses and Hospital Use. J Am Geriatr Soc, 66: 459-466. <u>https://doi.org/10.1111/jgs.15235</u>

²⁶ Dresden SM, Hwang U, Garrido MM, Sze J, Kang R, Vargas-Torres C, Courtney DM, Loo G, Rosenberg M, Richardson L. Geriatric Emergency Department Innovations: The Impact of Transitional Care Nurses on 30-day Readmissions for Older Adults. Acad Emerg Med. 2020 Jan;27(1):43-53. doi: 10.1111/acem.13880. Epub 2019 Dec 1. PMID: 31663245.

²⁹ Guttman A, Afilalo M, Guttman R, Colacone A, Robitaille C, Lang E, Rosenthal S. An emergency department-based nurse discharge coordinator for elder patients: does it make a difference? Acad Emerg Med. 2004 Dec;11(12):1318-27. doi: 10.1197/j.aem.2004.07.006. Erratum in: Acad Emerg Med.2005 Jan;12(1):12. PMID: 15576523.

³⁰ Berning MJ, Oliveira J E Silva L, Suarez NE, Walker LE, Erwin P, Carpenter CR, Bellolio F. Interventions to improve older adults' Emergency Department patient experience: A systematic review. Am J Emerg Med. 2020 Jun;38(6):1257-1269. doi: 10.1016/j.ajem.2020.03.012. Epub 2020 Mar 12. PMID: 32222314.

GEDs are a proven example of emergency medicine facilitating higher-value care for complex patients. They decrease the risk of unnecessary hospital admissions, improve patient experience in the ED and care transitions to the community, and decrease the need for repeat ED visits and re-hospitalizations by addressing the underlying risk factors (such as falls risks, polypharmacy, elder abuse, care giver fatigue, etc.) that may have precipitated the ED visit in the first place. EDs need to lead the charge to value-based care (and be supported for doing so), and GEDs demonstrate how this is possible.

Specific Comments: Applicability to the ED and Omission of Domain on Boarding in the ED

Applicability to the ED

In the rule, CMS states that the new measures would be "required for optimal care of older patients admitted to the hospital *or* being evaluated in the emergency department" (emphasis added). It is unclear from the preamble whether hospitals would be required to attest to the domains within the measure for all admitted geriatric patients AND all geriatric patients that are evaluated in the ED, or if the hospital could choose to only attest to the domains for admitted geriatric patients or choose to do so only for geriatric patients evaluated in the ED. CMS should clarify what the expectation is for hospitals as the measure is finalized.

While ACEP believes that hospitals should make it a focus to improve care for *all* geriatric patients evaluated in the ED, we do note that some of the domains and attestation statements may be more difficult than others to perform in the ED rather than the hospital inpatient setting. Please see the table below for our analysis of the relevance, importance, and feasibility of each of the domains and attestation statements for patients seen in the ED specifically.

Domain	Attestation Statement	Discussion of Relevance, Importance and Feasibility in the Emergency Department setting
Domain 1: Identifying Goals of Care	(1) Advance Care Planning	Under ideal circumstances, advanced care planning is a longitudinal process, best facilitated by an individual's outpatient physicians. However, eliciting information about prior advanced directives, including appointed health care proxies and prior decisions about life sustaining treatment, is an important and routine part of ED care for critically ill individuals. Some GEDs may facilitate completion of these documents for non-critically ill older adults and/or those with life-limiting illness who lack advanced care planning documentation.
	(2) Patient Goals	Understanding an individual's goals and values is an important component of code status discussions in critically ill older adults in the ED. Additionally, some GEDs routinely ask about patient priorities when they are frail and/or have advanced dementia, to ensure the care provided in the ED aligns with a patient's goals and values.
Domain 2: Medication Management	(3) Inappropriate Medication	Emergency physicians and other clinicians should and do minimize use of medications that may be inappropriate for older patients. This is often facilitated by electronic alerts and/or order sets in the electronic medical record. Additionally, many GEDs have specific processes to review the patient's existing medication and identify medications that may be inappropriate for older patients or may contribute to the patient's presenting complaint. Some GEDs have robust QI processes to monitor for prescribing of potentially inappropriate medications to older adults.

	(4) Pain Management	ACEP believes it is important for EDs to have opioid sparing multimodal pain management protocols in place. Additionally, emergency physicians and other clinicians should be aware of the need for dose adjustments of certain analgesics for older adults and/or those with renal or hepatic dysfunction. Many GEDs have specific order sets to optimize pain management in older adults.
Domain 3: Cognition and Delirium	(5) Delirium and Cognition Screening	Recognizing that a patient has delirium or dementia is an important aspect of ensuring a safe discharge. Many GEDs actively screen older adults for delirium and some GEDs actively screen older adults for cognitive impairment.
Domain 4: Preventing Delirium Related Events	(6) Delirium Prevention	Prolonged ED lengths stay, hallway length of stay and lack of mobilization in the ED have been associated with development of delirium after admission. Accordingly, it would be useful for EDs to establish protocols to minimize the risk of precipitating delirium through environment modifications, safe medication prescribing practices, and timely discharge/transfer of patients.
Domain 5: Function and Mobility	(7) Function and Mobility Screening	It may be challenging to perform a full function and mobility assessment for all older adults presenting to the ED. However, many EDs routinely screen patients for fall risk using validated screening tools, and many GEDs actively screen older adults for function and functional decline through structured screenings.
	(8) Assistance with Activities of Daily Living (ADLs) / Instrumental Activities of Daily Living (IADLs)	It may be challenging to perform an assessment of ADLs for all older adults presenting to the ED. However, many GEDs actively screen community dwelling older adults for ability to address ADLs and iADLs through structured screenings.
Domain 6: Social Determinants of Health	(9) Social Determinants of Health	EDs can and should assess patients for social determinants of health.
	(10) Elder Abuse, Neglect, and Exploitation	Most EDs actively screen for intimate partner violence. Most EDs have defined processes for addressing suspected elder abuse, neglect or exploitation. Some GEDs proactively screen for elder abuse and neglect using validated screening tools.
Domain 7: Care Transitions	(11) Identifying Needs at Hospital Discharge	It is important for there to be protocols in place to safely discharge patients from the ED or ED observation unit.
	(12) Post-Acute Care	For patients transferred to the ED from long term and post-acute care facilities, understanding the circumstances triggering the transfer is critical to ensure an appropriate ED diagnostic and treatment plan. Some GEDs have processes in place to improve communication with these transferring facilities.
		Some patients who present to the ED could be discharged directly to a skilled nursing or acute rehabilitation facility. Some GEDs have processes in place to facilitate direct transfers for patients with a recent 30-day qualifying inpatient stay and/or Medicare Accountable Care Organization or Advantage Plan that authorizes waivers to the requirement for a three-day qualifying inpatient hospitalization.

Domain 8: Ensuring Quality Care for High- Risk Patients	(13) Identification and Management of Seriously Ill patients	Early identification of unmet palliative care needs in seriously ill ED patients can improve inpatient care, prevent unwanted interventions, decrease hospital length of stay and decrease costs of care. Some GEDs have processes in place to identify seriously ill patients and/or those with unmet palliative care needs and facilitate early palliative care consultation.
	(14) Geriatric Leader and Quality Framework	It is important that all EDs have a quality framework in place for all patients, including those seen in the ED. All GEDs have ED physician and ED nurse geriatric champions and many GEDs have executive sponsors and patient advocates focused on improving the emergency care of older adults. All GEDs monitor the quality of specific geriatric care processes.

Omission of Domain on Boarding in the ED

Although ACEP generally supports the new measure, we believe that it has a glaring omission that must be incorporated before it is finalized: *"boarding" in the ED*. Boarding is a situation where patients are kept waiting in the ED for hours, days, or longer due to the lack of available inpatient beds or space in other facilities where the patient could be transferred. Boarding has hit crisis levels, and in November 2022, ACEP and 34 other organizations wrote a <u>letter</u> to President Biden asking his Administration to convene a summit on this issue with all impacted stakeholders so that we can together collaborate on near- and longer-term solutions.

Even with the worst of the COVID-19 pandemic now behind us, EDs all over the country are at, or even past, the breaking point, with no relief in sight. It led to <u>a nurse in Washington</u> calling 911 as her ED became completely overwhelmed with waiting patients and boarders. Her story is not unique – it is happening right now in EDs across the country, every day. To paint a broader picture of the distressing scope of the ED boarding problem, ACEP collected hundreds of firsthand accounts from emergency physicians who have <u>shared their stories</u> from the front lines.

Boarding affects patients of all kinds, regardless of their condition, age, insurance coverage, income, or geographic location. These excessive waits for needed care directly harm patients through worse outcomes, increased risk of medical errors, and even avoidable deaths.^{31,32} One emergency physician account <u>noted that</u> in addition to average boarding times of more than 70 hours at their hospital, "…we have patients who unfortunately have died in our waiting room while awaiting treatment. These deaths were entirely due to boarding."

Boarding in the ED also disproportionately affects more vulnerable and historically disadvantaged populations. One study found that Black patients wait for about one hour longer than non-Black patients before they are transferred to an inpatient bed.³³ Another found that cognitive stressors, specifically overcrowding and patient load, are associated with increased implicit bias that may affect patient care.³⁴ Those with acute psychiatric conditions, especially children and adolescents, are particularly hard hit by boarding and may board <u>for *months*</u> at a time in noisy, chaotic EDs as they wait for an available psychiatric inpatient bed to open up somewhere.

33 https://onlinelibrary.wiley.com/doi/10.1111/j.1553-2712.2009.00381.x

³¹ Morley C, Unwin M, Peterson GM, Stankovich J, Kinsman L. Emergency department crowding: A systematicreview of causes, consequences and solutions. *PLoS One*. 2018;13(8):e0203316. <u>https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0203316</u>. ³² Berg LM, Ehrenberg A, Florin J, Ostergren J, Discacciati A, Goransson KE. Associations between crowding and ten-day mortality among patients allocated lower triage acuity levels without need of acute hospital care on departure from the emergency department. Ann Emerg Med. 2019 Sep;74(3):345-356. <u>https://www.sciencedirect.com/science/article/pii/S0196064419303312?via%3Dihub</u>.

³⁴ https://onlinelibrary.wiley.com/doi/10.1111/acem.12901

All the above-described long wait times are entirely outside of the control of the ED; rather, they are the product of a multitude of factors, including decades' worth of misaligned economic incentives and systemic faults. These stressful working conditions only serve to accelerate the record levels of physician and nurse burnout as these professionals simply do not have the resources to keep up with the volume of patients coming in. As one emergency physician describes, "These kinds of working conditions are NOT sustainable, yet similar conditions continue all over the country. It's like a warzone everyday. No wonder doctors and nurses are leaving healthcare in droves and rates of depression and suicide are so high- working in those conditions day in and day out, not being able to provide the care and treatments we know patients need." The alarming health care workforce shortages that continue to worsen have been a major driver to the growing boarding crisis, which itself leads to more burnout, causing more to leave health care altogether and sending the nation's emergency care system further into its spiral towards collapse.

Boarding must be added as a key domain to this measure. One possible way to assess and improve boarding in the ED is to attest to a benchmark that monitors the length of time from patients arriving in the ED, to receiving a disposition from the emergency physician, to leaving the ED to be discharged home to the community, transferred to another facility such as skilled nursing, or admitted to the hospital. The Joint Commission recommends that boarding times stay below four hours to avoid delays in care or safety issues.

Potential Establishment of a Publicly Reported Hospital Designation to Capture the Quality and Safety of Patient-Centered Geriatric Care

In addition to potentially adding new Geriatric Hospital and Geriatric Surgical structural measures, CMS is also considering a geriatric care hospital designation to be publicly reported on a CMS website. This designation could initially be based on data from hospitals reporting on both Geriatric Hospital and Geriatric Surgical structural measures if they are proposed and finalized in the future. If proposed for future rulemaking, CMS could develop a scoring methodology for granting the designation, such as recognizing those hospitals that affirmatively attest to all domains in the Geriatric Hospital and Geriatric Surgical structural measures.

ACEP supports the concept of having a geriatric care hospital designation be publicly reported on a CMS website. As noted above, ACEP has developed a geriatric ED accreditation program called GEDA—and GEDA's framework already aligns closely with the domains included in the geriatric hospital measure. Going forward, ACEP would like to work with CMS on how to appropriately designate hospitals and ED that are providing high quality and cost-effective care to geriatric patients while minimizing additional reporting and attestation burdens.

Proposed Changes to the Medicare Promoting Interoperability Program

CMS previously finalized a 180-day reporting period starting in Calendar Year (CY) 2024. In this rule, CMS is proposing that the EHR reporting period in CY 2025 would be a minimum of any continuous 180-day period within CY 2025. A 180-day EHR reporting period would be the minimum length, and eligible hospitals and CAHs would be encouraged to use longer periods, up to and including the full CY 2025.

ACEP does not support CMS' plan to increase the reporting period to 180 days starting in CY 2024. We believe that a 90-day reporting period is the appropriate length of time needed to ensure that hospitals are meeting all the objectives of the program, while at the same time not posing an undue burden on these facilities. Thus, we strongly urge CMS to retain a 90-day reporting period for the foreseeable future.

Special Requirements for REHs

This proposed rule would codify requirements for additional information that an eligible facility would be required to submit when applying for enrollment as a Rural Emergency Hospital (REH), as specified in the Consolidated Appropriations Act (CAA), 2021. The establishment of REHs as a Medicare provider is intended to promote equity in health care for those living in rural communities by facilitating access to needed services, such as emergency, urgent, and observation care services, as well as other additional outpatient medical and health services that an REH might elect to provide.

CMS also proposes to revise the definition of "Provider of services or provider" at § 488.1. The proposed new definition of "provider of services or provider" would state that it refers to a hospital, critical access hospital, rural emergency hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services.

Finally, CMS proposes to require that any facility that submits an application for enrollment as an REH must also submit an action plan containing: (1) A plan for initiating REH services (including mandatory provision of emergency department services and observation care); (2) a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH; (3) a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and (4) information regarding how the provider intends to use the additional facility payment, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services and ambulance services).

ACEP supports all of these proposals and looks forward to seeing how REHs can serve as a viable option in rural areas to maintain access to high quality emergency services.

Safety Net Hospital Request for Information

CMS is interested in public feedback on the challenges faced by safety-net hospitals, and potential approaches to help safety-net hospitals meet those challenges. They ask the following questions to help facilitate feedback.

What are particular challenges facing rural safety-net hospitals?

Unfortunately, there are numerous barriers to providing equitable care in rural communities. Some of these barriers relate to:

- The inability to recruit qualified and sufficiently experienced, educated, and trained physicians, nurses, ancillary support staff, and other healthcare providers;
- Rural EDs, compared to their urban counterparts, are resource limited, financially stressed, and experience higher interfacility transfer rates;
- The inconsistent use of technologies such as telehealth and inadequate broadband in rural areas; and
- Beneficiaries' inability to reach hospitals due to transportation issues. Emergency medical services (EMS) in rural areas also experience significant transportation delays due to issues with crew availability.

Are there specific payment approaches to consider for rural safety-net hospitals, including acute care hospitals and CAHs, to address challenges?

Rural communities have a higher burden of uninsured and underinsured patients as well as a high burden of disease. Even with existing cost-based reimbursement, many rural CAHs struggle to support their operations. While ACEP does not represent CAHs, as emergency physicians working in rural areas (including in CAHs), we have noticed that in some cases, the cost-based reimbursement system has led to inaccurate accounting of what services are provided due incomplete data on claims and a lack of information about secondary diagnoses, procedures, or other services. Increasing incentives for accurate reporting of these services and providing funding for the study of these costs and the optimal reimbursement strategy for these services would be beneficial.

ACEP also notes that REHs will receive additional facility payments under the Outpatient Prospective Payment System (OPPS)—but not added reimbursement for physicians and other clinicians under the Physician Fee Schedule (PFS) who actually deliver the services in REHs. In order to incentivize physicians and other clinicians to work in rural areas and appropriately staff these newly-designated REHs, ACEP strongly recommends that CMS consider creating an add-on code or modifier that clinicians could append to claims for services delivered in REHs. CMS could consider setting the value of this add-on code or modifier at five percent of the PFS rate for each Current Procedural Terminology (CPT) code that is billed—consistent with the additional OPPS payment that the statute provides.

Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities—Applicability to Other Providers and Suppliers

In the February 15, 2023 Federal Register (88 FR 9820), CMS published a proposed rule titled "Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities" (hereinafter referred to as the Disclosures proposed rule) due to their concerns about the quality of care furnished by private equity company (PEC)-owned and real estate investment trust (REIT)-owned SNFs and the consequent need for transparency regarding such owners (88 FR 9822 and 9823). However, these concerns about PEC and REIT are not limited to SNFs but extend to other provider and supplier types. Given the linkage discussed in the Disclosure proposed rule between PEC and REIT ownership and a decline in nursing home quality, CMS believes it is very important to collect this information from all providers and suppliers that complete the Form CMS-855A so as to: (1) determine whether a similar connection exists with respect to non-SNF providers and suppliers; and (2) help CMS take measures to improve beneficiary quality of care to the extent such connections exist. CMS has already revised the Form CMS-855A application to require all owning and managing entities listed on any provider's or supplier's Form CMS-855A submission to disclose whether they are a PEC or a REIT.

CMS is now proposing in this rule that the definitions of PEC and REIT established in the Disclosures proposed rule would apply to all providers and suppliers completing the Form CMS-855A enrollment application. The definitions would not be limited to SNFs; however, as stated in the Disclosures proposed rule, these definitions may be modestly different from definitions of the same terms used in other settings. CMS seek comment on whether their proposed definition of PEC should include publicly-traded private equity companies and any other public feedback regarding any other types of private ownership besides PECs and REITs about which CMS should consider collecting information from providers and suppliers as part of the enrollment process.

ACEP supports this proposal, as we are increasingly concerned about the expanding presence of private equity and corporate investment in health care, including emergency medicine. In all, we believe that full transparency regarding private equity and corporate investment is essential in the health care industry and that objective data is critically

needed to measure the impact of private equity and corporate investment in health care on patient care and outcomes. Thus, we commend CMS for their efforts in increasing transparency by requiring disclosure of ownership information and making this information available to the public. We echo CMS' encouragement for states to establish reporting requirements in order to have accurate and updated information regarding nursing facilities' owners and operations.

We believe that there is a particular need for CMS to explore the role that private equity and consolidation plays in emergency medicine. In less than ten years, the number of emergency physicians working in large, national groups increased from one in seven in 2012 to one in four in 2020.³⁵ Coupled particularly with consolidation of hospitals and payers, ACEP has been hearing about labor-related impacts of the acquisitions and mergers and the effect they have had on physician wages, non-wage benefits and other aspects of emergency physicians' contracts with their employers, and physician autonomy in their medical decision-making. Our overall goal is to support emergency physicians and ensure that they are treated fairly by their employer and practice in an environment where they can serve their patients to the best of their abilities.

Emergency physicians serve the essential role of strengthening the health care safety net for our communities. They treat all patients who come through our doors, regardless of their insurance status or ability to pay. Over the years, certain laws have been put into place to help enforce and protect patients and the emergency health care safety net, including EMTALA, which requires hospitals to provide a medical screening examination to every individual who "comes to the emergency department" seeking examination or treatment. The "prudent layperson" (PLP) standard, first established under the Balanced Budget Act of 1997, is another such law which allows people who reasonably think they are having an emergency to come to the ED without worrying about whether the services they receive will be covered by their insurance. Given this vital responsibility that emergency medicine plays in our health care system, ensuring that EDs across the country are appropriately staffed so they can provide care 24 hours a day, 7 days a week, 365 days a year is essential. Hospitals and emergency medicine groups have tried to achieve this goal in different ways, and as described below, mergers and acquisitions have at times come into play.

Emergency physicians work in a variety of employment models. While some are employed directly by hospitals, many are employed by independent entities that contract with the hospital to provide 24/7 ED coverage. These independent entities range in size, from small, independent democratic (i.e., owned by the physicians) groups that serve only one or two local hospitals to larger groups that staff EDs (and sometimes service lines of other specialties) nationwide. In recent years, physician practices, including independent emergency medicine practices, have been acquired by hospitals, health systems, and corporate entities (such as private equity and health insurance companies) at a relatively high rate. A study in Health Affairs found that between 2014 and 2018, there was an 89 percent increase in hospital and health system ownership of physician practices. The pressures of staying financially viable during the COVID-19 pandemic seem to have accelerated this trend even further. According to a report from the Physicians Advocacy Institute (PAI), there was a sharp rise in the number of physician practices being acquired by hospitals and corporate entities throughout 2019 and 2020-especially in the first half of 2020 as the pandemic began. Now, PAI reports that 70 percent of physicians are employed by hospital systems or other private entities—meaning that only 30 percent of physicians practice independently. Further, according to a recent market report conducted by Ivy Clinicians, private equity-owned firms manage clinicians in roughly 25 percent of U.S. EDs. In aggregate, private equity-owned firms staff EDs that are in lower-income, higher uninsurance, and more rural counties. Although we understand the general trends of emergency medicine practice ownership, it has been difficult to find a

³⁵ Pollock JR, Hogan JS, Venkatesh AK, et al. Group Practice Size Consolidation in Emergency Medicine. Annals of Emergency Medicine. 2022;79(1):2-6. doi:10.1016/j.annemergmed.2021.07.122

comprehensive source of information about the parent organizations for individual practices. ACEP has attempted to study this issue itself with consultants, who determined that even among public and proprietary databases, any effort to collect data on ownership becomes outdated relatively quickly and would be inaccurate when attempting linkage to other metrics on quality, cost, and physician autonomy, due to the lack of standardization and the rapid pace of consolidation and contracts changing hands every month. The ever-changing nature of health care markets, like the emergency medicine market, may pose challenges for CMS as it attempts to collect data on consolidation.

Last year, in response to the Antitrust Division of the Department of Justice's (DOJ's) and Federal Trade Commission's (FTC's) joint <u>Request for Information on Merger Enforcement</u>, ACEP asked our members a series of both structured and open-ended questions to gain specific and up-to-date information on how mergers and acquisitions are impacting their lives, their jobs, and the care they provide. Specifically, for those members whose practice had undergone a merger recently, we asked questions about the merger, such as how they were notified about it, along with how that merger impacted their wages, non-cash benefits, right to due process, and autonomy for medical decision-making. We also asked for their general views about the labor-related impacts of mergers or acquisitions in emergency medicine. We received over 110 responses to this questionnaire.

Our survey results are summarized in our <u>response</u> to the CY 2023 Outpatient Prospective Payment System proposed rule. All in all, with some notable exceptions, the results clearly show that the current practice of consolidation in the emergency medicine marketplace, at the hospital system, insurer, and physician practice level, detrimentally affects physicians' interests and wellbeing, which in turn may impact their ability to serve their patients.

These results reinforce our strong belief that CMS should continue its efforts to increase transparency in health care. CMS should collect data that assesses the labor-related impacts of consolidation in health care and how changes to the labor market affect patient care. In addition, CMS should release data and reports to help the public better understand how mergers and acquisitions can lead to anti-competitive and harmful practices, including, but not limited to:

- Reduced wages and/or non-cash benefits;
- Infringement of the right to due process;
- Interference with clinician autonomy to make independent medical decisions that benefit their patients;
- Inability to find a job or undue imposed restrictions on ability to switch jobs; and
- Practices, such as the use of a less-skilled health care workforce, that put profits over quality of patient care.

We appreciate the opportunity to share our comments. If you have any questions, please contact Erin Grossmann, ACEP's Manager of Regulatory and External Affairs, at <u>egrossmann@acep.org</u>.

Sincerely,

Clarino

Christopher S. Kang, MD, FACEP ACEP President