SHEA
The Society for Healthcare Epidemiology of America

June 10, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1785-P
P.O. Box 8013
Baltimore, MD 21244-8013
Submitted via http://www.regulations.gov

RE: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Administrator Brooks-LaSure,

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to submit comments on the on the Centers for Medicare and Medicaid Services' (CMS) Fiscal Year (FY) 2025 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) proposed rule (herein referred to as "proposed rule").

SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology, infection prevention and antibiotic stewardship. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality and the cost of care linked to healthcare-associated infections (HAIs) and antibiotic resistance.

SHEA respectfully submits comments on the following sections of the proposed rule:

- **Crosscutting Quality Program Proposals and Request for Comment;**
- **Hospital Inpatient Quality Reporting (IQR) Program;**
- **Medicare Promoting Interoperability Program; and**
- **Conditions of Participation Requirements for Hospitals and Critical Access Hospitals to Report Acute Respiratory Illnesses.**

Thank you in advance for your consideration of our comments. Please do not hesitate to reach out with questions to Lynne Batshon, Director of Policy and Practice, at (703) 684-0761 or lbatshon@shea-online.org.

Sincerely,

President
SHEA

Crosscutting Quality Program Proposals and Request for Comment

Proposed Adoption of the Patient Safety Structural Measure Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination for the Hospital Inpatient Quality Reporting (IQR) Program and the CY 2025 Reporting Period/FY 2027 Program Year for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

On p. 36284, CMS states:

> *"We propose to adopt the Patient Safety Structural measure in the Hospital IQR Program beginning with the CY 2025 reporting period/FY 2027 payment determination and the PCHQR Program beginning with the CY 2025 reporting period/FY 2027 program year."*

On p. 36288, CMS states:

> *"The Patient Safety Structural measure comprises a set of complementary statements (or, attestations) that aim to capture the most salient, systems-oriented actions to advance safety. These statements should exemplify a culture of safety and leadership commitment to transparency, accountability, patient and family engagement, and continuous learning and improvement…"*

SHEA supports the proposed adoption of the Patient Safety Structural measure in the Hospital IQR Program and the PCHQR Program. We support measuring hospitals' commitment to fostering a system-level culture that prioritizes patient safety through measurable action and progress toward zero preventable harm. SHEA agrees that annual attestations are an appropriate method for assessing whether hospitals demonstrate having a structure and culture that prioritizes patient safety. We appreciate that CMS will publicly report the hospital's measure performance score on an annual basis beginning in fall 2026 on Care Compare and on the Provider Data Catalog for the PCHQR Program. The Patient Safety Structural measure sets the stage for substantive quality improvement.

Advancing Patient Safety and Outcomes Across the Hospital Quality Programs—Request for Comment

On pp. 360304-36305, CMS states:

> *"The Hospital Readmissions Reduction Program was implemented to reduce excess readmissions effective for discharges from applicable hospitals… However, studies have found a concurrent increase in patients who, after being discharged from an inpatient stay, visit the emergency department (ED), or receive observation services as an outpatient. As a result, we are concerned that our hospital quality reporting and value-based purchasing programs may not be adequately incentivizing hospitals to improve quality of care by accounting for more types of post-discharge events, such as a return to the ED or the receipt of observation services."*

On p. 36305, CMS states:

> *"Therefore, we are seeking ways to build on current measures in several quality reporting programs that account for unplanned patient hospital visits to encourage hospitals to improve*

discharge processes. Current measures include three Excess Days in Acute Care (EDAC) measures currently in the Hospital Inpatient Quality Reporting (IQR) Program, which estimate days spent in acute care within 30 days post discharge from an inpatient hospitalization for a principal diagnosis of the measure's specified condition. The acute care outcomes include ED visits, receipt of observation services, and unplanned readmissions. The measures are:

- *Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI), adopted in the FY 2016 IPPS/LTCH PPS final rule beginning with the FY 2018 payment determination (80 FR 49680 through 49682);*
- *Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF), adopted in the FY 2016 IPPS/ LTCH PPS final rule beginning with the FY 2018 payment determination (80 FR 49682 through 49690); and*
- *Excess Days in Acute Care (EDAC) after Hospitalization for Pneumonia, adopted in the FY 2017 IPPS/LTCH PPS final rule beginning with the FY 2019 payment determination (81 FR 57142 through 57148)."*

On p. 36306, CMS states:

"The EDAC measures currently in the Hospital IQR Program only cover patients with a primary discharge of AMI, HF, or Pneumonia. Meanwhile, the Hospital Visits After Hospital Outpatient Surgery measure only covers patients discharged from outpatient surgeries. Furthermore, since both the Hospital IQR and Hospital OQR Programs are quality reporting programs, a hospital's performance on these measures is not tied to payment incentives.

Therefore, we invite public comment on how these programs could further encourage hospitals to improve discharge processes, such as by introducing measures currently in quality reporting programs into value-based purchasing to link outcomes to payment incentives. We are specifically interested in input on adopting measures which better represent the range of outcomes of interest to patients, including unplanned returns to the ED and receipt of observation services within 30 days of a patient's discharge from an inpatient stay."

SHEA is concerned the Excess Days in Acute Care (EDAC) after Hospitalization for Pneumonia (PN) measure may be capturing severe complications that require more intensive care rather than preventable hospital care. An increased number of days in the hospital after readmission suggests more severe disease and that can likely not be managed as an outpatient. Thus this metric would not be the right outcome to measure if the goal is to prevent excess utilization or to move care to outpatient settings. Additional clarification on the specifications of this measure how it would be used is needed.

Hospital Inpatient Quality Reporting (IQR) Program

Proposal to Adopt the CAUTI-Onc Measure Beginning with the CY 2026 Reporting Period/FY 2028 Payment Determination

On p. 36312, CMS states:

"We are proposing to adopt the CAUTI-Onc measure for the Hospital IQR Program beginning with the CY 2026 reporting period/FY 2028 payment determination."

SHEA supports the proposed adoption of the CAUTI-Onc measure. We believe that stratifying the Catheter-Associated Urinary Tract Infection (CAUTI) measure for oncology locations is an important first step in evaluating the potential for success of an existing measure that is being modified for expanded performance measurement. SHEA looks forward to the ability to report this measure using patient level risk adjusted data when FHIR based interface is more widely available. SHEA recommends CMS provide additional clarity on how SIRs will be calculated at the unit level. For example, additional clarity on how to stratify data for ICU and med surge, and cancer patients in a community hospital setting who may have a CAUTI would be helpful.

Proposal to Adopt the CLABSI-Onc Measure Beginning with the CY 2026 Reporting Period/FY 2028 Payment Determination

On p. 36315, CMS states:

> *"We are proposing to adopt the CLABSI-Onc measure to the Hospital IQR Program beginning with the CY 2026 reporting period/FY 2028 payment determination."*

SHEA supports the proposed adoption of the CLABSI-Onc measure. We believe that stratifying the Central Line-Associated Bloodstream Infection (CLABSI) measure for oncology locations is an important first step in evaluating the potential for success of an existing measure that is being modified for expanded performance measurement. SHEA looks forward to the ability to report this measure using patient level risk adjusted data when FHIR based interface is more widely available. SHEA recommends CMS provide additional clarity on how SIRs will be calculated at the unit level. For example, additional clarity on how to stratify data for ICU and med surge, and cancer patients in a community hospital setting who may have a CLABSI would be helpful.

Medicare Promoting Interoperability Program

Proposal to Modify the AUR Surveillance Measure Beginning with the EHR Reporting Period in CY 2025

On p. 36353, CMS states:

> *"Specifically, we are proposing to separate the AUR Surveillance measure into two measures, beginning with the EHR reporting period in CY 2025:*
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> - *AU Surveillance measure: The eligible hospital or CAH is in active engagement with CDC's NHSN to submit AU data for the selected EHR reporting period and receives a report from NHSN indicating its successful submission of AU data for the selected EHR reporting period.*
> - *AR Surveillance measure: The eligible hospital or CAH is in active engagement with CDC's NHSN to submit AR data for the selected EHR reporting period and receives a report from NHSN indicating its successful submission of AR data for the selected EHR reporting period."*

SHEA supports the proposed separation of the Antimicrobial Use and Resistance (AUR) Surveillance measure into two measures, an Antimicrobial Use (AU) Surveillance measure and an Antimicrobial Resistance (AR) Surveillance measure. The proposed distinction of two measures for reporting AU and AR data acknowledges that the measures rely on different data sources and therefore entail different challenges. We agree with CMS that separating the AUR Surveillance measure into two measures would more appropriately target the availability of exclusions for participants who have difficulty with data transmission. The availability of two measures, an AU Surveillance measure and an AR Surveillance measure, would incentivize greater data reporting and promote antimicrobial stewardship. SHEA is committed to fostering strategies to improve the use of antimicrobial medications with the goal of enhancing patient health outcomes, reducing resistance to antibiotics, and decreasing unnecessary costs.

While we strongly support the collection of AU and AR data, we wanted to share feedback from our members who are responsible for submitting these data. The frequency of the data submission requirements – either on an ongoing basis or monthly reports – can pose challenges, particularly when vendors of electronic health records (EHRs) require time to update technology to support new reporting requirements. SHEA urges CMS to consider providing hospitals with a grace period to account for any delays in EHR vendor updates that are outside the control of hospitals. Additionally, we encourage CMS to consider requiring quarterly data submissions to provide hospitals sufficient time to complete data extractions and address any issues outside their control with EHR vendors.

Proposal To Adopt Exclusions for the AU Surveillance Measure and the AR Surveillance Measure Beginning With the EHR Reporting Period in CY 2025

On p. 36354, CMS states:

> *"We believe an exclusion that applies to eligible hospitals and CAHs that lack discrete electronic access to required data elements, including interface or configuration issues beyond their control, would address the difficulties for eligible hospitals and CAHs engaging in manual data collection to conduct AU or AR reporting. Therefore, we are proposing to add a new exclusion to account for scenarios where eligible hospitals or CAHs lack a data source containing discrete electronic data elements that are required for reporting the AUR Surveillance measure, meaning an eligible hospital or CAH cannot query, extract, or download the data elements in a discrete, structured manner from the systems to which it has access. Specifically, under this new exclusion, an eligible hospital or CAH would be excluded from reporting the AUR Surveillance measure when it does not have a data source containing the minimal discrete data elements that are required for reporting."*

SHEA supports the proposed adoption of an exclusion for an eligible or CAH when it does not have a data source containing the minimal discrete data elements that are required for AU or AR reporting. We encourage CMS to support hospitals that lack the data capabilities to report AU or AR data. CMS should provide a pathway for these hospitals to fully submit both AU and AR data.

Conditions of Participation Requirements for Hospitals and Critical Access Hospitals to Report Acute Respiratory Illnesses

Proposal to Continue Respiratory Illness Reporting in a Modified Form

On p. 36505, CMS states:

> *"Specifically, we propose to replace the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs at § 482.42(e) and (f) and § 485.640(d) and (e), respectively, with a new standard addressing respiratory illnesses to require that, beginning on October 1, 2024, hospitals and CAHs electronically report information about COVID–19, influenza, and RSV in a standardized format and frequency specified by the Secretary. To the extent determined by the Secretary, we propose that the data elements for which reporting would be required at this time include—*
>
> - *Confirmed infections of respiratory illnesses, including COVID–19, influenza, and RSV, among hospitalized patients;*
> - *Hospital bed census and capacity (both overall and by hospital setting and population group [adult or pediatric]); and*
> - *Limited patient demographic information, including age"*

SHEA supports the intent of the proposal to require hospitals and CAHs to report acute respiratory illnesses, but we are concerned that gaps in data infrastructure would make these requirements overly burdensome. Reporting confirmed infections of COVID-19, influenza, and RSV; hospital bed census and capacity; and patient demographic information is a heavily manual and labor-intensive process. As a result, the proposed requirement for weekly reports would divert limited time and resources away from vital infection prevention and control activities, especially at under-resourced hospitals.

We encourage CMS to consider leveraging data collected through the Emerging Infections Program (EIP), a pilot program in 12 states administered by the Centers for Disease Control and Prevention (CDC).[1] EIP sites collect extensive data related to healthcare associated infections, respiratory viruses, foodborne illnesses, and other emerging infectious diseases.

Additionally, we strongly urge CMS to advocate for adequate funding to complete improvements to the National Healthcare Safety Network (NHSN). As part of CDC's Data Modernization Initiative, federal investments are supporting pilot projects in states to automate pathogen-agnostic hospital bed capacity reporting to provide more timely, actionable reporting data while reducing reporting burden.[2] This initiative is an example of ongoing efforts towards data capabilities necessary for the proposed reporting requirements. The majority of hospitals do not have the infrastructure to submit respiratory illness reports as proposed by CMS beginning October 1, 2024.

If CMS finalizes the proposed measure, SHEA asks that the agency clarify whether the requirement to report confirmed infections of respiratory illnesses is limited to only COVID-19, influenza, and RSV. Relatedly, we request CMS to clarify whether the proposed measure would allow CMS to require the reporting of confirmed infections of respiratory illnesses that are not COVID-19, influenza, and RSV without completing notice-and-comment rulemaking.

[1] https://www.cdc.gov/emerging-infections-program/php/network-activities/index.html
[2] https://www.cdc.gov/nhsn/pdfs/NHSN-FactSheet-508.pdf

Conclusion

SHEA thanks CMS again for the opportunity to provide feedback on the Hospital IPPS LTCH PPS proposed changes. We would be happy to provide CMS with any additional detail or address any questions you may have as you work to finalize the rule.