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Epidemiology of America

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U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW, Room 445-G
Washington, D.C. 20201
Submitted via <http://www.regulations.gov>

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation

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) 2023 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.

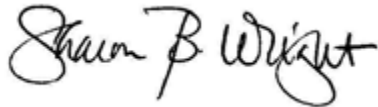
SHEA respectfully submits comments on the following sections of the proposed rule:

- **Hospital Value-Based Purchasing (VBP) Program;**
- **Hospital-Acquired Condition (HAC) Reduction Program;**
- **Hospital Inpatient Quality Reporting (IQR) Program;**
- **PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;**
- **Long-Term Care Hospital Quality Reporting Program (LTCH QRP);**

- **Medicare Promoting Interoperability Program; and**
- **Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements to Address Any Future Pandemics and Epidemics as Determined by the Secretary**

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,

A handwritten signature in black ink that reads "Sharon B. Wright". The signature is written in a cursive style with a large, stylized initial "S".

Sharon B. Wright, MD, MPH, FIDSA, FSHEA
President, SHEA

Hospital Value-Based Purchasing (VBP) Program

Flexibilities for the Hospital VBP Program in Response to the Public Health Emergency (PHE) Due to COVID-19

- Measure Suppression Policy for the Duration of the COVID-19 PHE

On p. 856, CMS states:

“In the FY 2022 IPPS/LTCH PPS final rule, we finalized a measure suppression policy and several Measure Suppression Factors for the duration of the COVID-19 PHE (86 FR 45266 through 45269).”

Specifically, on p. 857, CMS delineates the measure suppression factors corresponding to the above domains that it finalized to suppress for the FY 2022 program year:

- *Measure Suppression Factor 1: Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.*
- *Measure Suppression Factor 2: Clinical proximity of the measure’s focus to the relevant disease, pathogen, or health impacts of the PHE for COVID-19.*
- *Measure Suppression Factor 3: Rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.*
- *Measure Suppression Factor 4: Significant national shortages or rapid or unprecedented changes in healthcare personnel; medical supplies, equipment, or diagnostic tools or materials; or patient case volumes or facility-level case mix.*

On p. 858, CMS states:

“We continue to strongly believe that publicly reporting these data will balance our responsibility to provide transparency to consumers and uphold safety while ensuring that hospitals are not unfairly scored or penalized through payment under the Hospital VBP Program...We are not proposing any changes to the measure suppression policy in this proposed rule.”

SHEA appreciates CMS’ continued recognition of the significant and ongoing effects of the COVID-19 pandemic on the provision of health care, including pervasive health workforce shortages and supply chain issues, and evolving safety guidelines. The impact of these factors, many of which are outside of providers’ control, reiterate the need for continued flexibility in quality programs.

SHEA continues to support CMS’ PHE-driven measure suppression policy and, specifically, its proposal to maintain this policy for the remainder of the PHE. Doing so will help to ensure consistency in measure evaluations in the HRRP and other VBPs given the adverse effects of the pandemic on certain quality measures and data timeframes – factors that undoubtedly undermine or distort hospital performance reporting. Once the measure suppression policy is lifted post-PHE, SHEA urges CMS to carefully consider updates to the baseline period for certain measures

excluding, for example, quarters impacted by the ongoing COVID-19 pandemic (e.g., Q1 2022 data is just as concerning as previous quarters earlier in the pandemic).

The pandemic has had an unequal impact on hospitals across the country. In addition, current calculation of the baseline period does not adjust for hospital size, patient acuity, patient safety indicators, and other factors. For these reasons, applying the same methodology to the baseline period would result in an inaccurate measure of quality. Instead, SHEA encourages CMS to focus on year over year improvements for preventable infections rather than comparisons to performance prior to the pandemic that could result in inappropriate penalties to hospitals for COVID-19-related illnesses and complications. Data shows the dramatic impact of COVID-19 on the steady decreases in the incidence of six routinely tracked infections prior to the pandemic. The significantly higher rates of infections are attributed to factors related to the COVID-19 pandemic, including more and sicker patients requiring more frequent and longer use of catheters and ventilators as well as staffing and supply challenges.¹ The approach outlined in this proposal would align with the “Goal 5: Strengthen Resiliency” of the recently unveiled CMS National Quality Strategy as it would promote sustainable improvements in patient safety and health care quality.²

- Proposals to Suppress Specific Measures for the FY 2023 Program Year: The Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) Survey Measure (NQF #0166); and six Hospital Acquired Infection (HAI) Measures

On p. 860, CMS states:

“Since the publication of the FY 2022 IPPS/LTCH PPS final rule, we have conducted analyses on all Hospital VBP Program measures to determine whether and how COVID-19 has impacted the validity of the data used to calculate these measures for the FY 2023 program year. We discuss our findings from these analyses that follows. Based on those analyses, we are proposing to suppress the following measures for the FY 2023 program year.”

Specifically, on p. 860, CMS delineates the measures corresponding to the above domains that it proposes to suppress for the FY 2023 program year:

- HCAHPS (NQF #0166)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons (ACS)-Centers for Disease Control and Prevention (CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)

¹ Weiner-Lastinger, L., Pattabiraman, V., Konnor, R., Patel, P., Wong, E., Xu, S., . . . Dudeck, M. (2022). The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. *Infection Control & Hospital Epidemiology*, 43(1), 12-25. doi:10.1017/ice.2021.362

² “The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality.” CMS.gov, <https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>. Accessed June 15, 2022

- *NHSN Facility-wide Inpatient Hospital-onset*
- *Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)*

SHEA supports CMS' proposal to suppress the HCAHPS and five NHSN HAI Safety Measures (CLAUTI, CLASBI, Colon and Hysterectomy SSI, MRSI, and CDI) for the FY 2023 program year based on its analysis of the COVID-19 pandemic on the validity of data to assess these measures. We appreciate that hospitals would continue to report the measure data to CDC and CMS to ensure ongoing quality improvement monitoring. It is important that, despite COVID-19, we not lose critical traction to prevent and, ultimately, eliminate HAIs. Further, through this process, we continue to urge CMS to assess whether variability in reporting (e.g. due to relief extended to providers during implicated COVID-19 reporting periods), versus variability in actual performance, could be driving variability in HAI rates.

Hospital-Acquired Conditions (HAC) Reduction Program

Flexibility for Changes that Affect Quality Measures During a Performance or Measurement Period in the HAC Reduction Program

- Cross-Program Measure Suppression Policy Proposal for Duration of COVID-19 PHE (Applicable to VBP, HAC)

Please refer to SHEA's comments regarding this broader CMS proposal in the VBP section of our comment letter. SHEA supports CMS' proposal that facilities requiring measure suppression not have a Total HAC Score calculated (i.e., a Total HAC Score of zero with no penalty). Doing so could inadvertently skew toward rewarding these facilities when compared to facilities whose data was not suppressed. Moreover, this process could add a layer of subjectivity relative to CMS' determination of whether certain outlier data is attributed to the COVID-19 PHE versus data that is not attributed to the PHE.

- Proposal to Apply the Measure Suppression Policy to FY 2023 and FY 2024 HAC Reduction Program Years

On p. 904, CMS states (re: FY 2023):

"In this proposed rule, we are proposing two updates for the FY 2023 HAC Reduction Program's measure suppression policy: (1) We are proposing to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thereby not penalizing any hospital under the HAC Reduction Program FY 2023 program year; and (2) For the CMS PSI 90 measure, we are proposing to not calculate or report measure results for the HAC Reduction Program FY 2023 program year."

On p. 918, CMS states (re: FY 2024):

"We therefore are proposing to suppress CY 2021 CDC NHSN HAI data from the FY 2024 HAC Reduction Program under Measure Suppression Factor 1, "significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years"; and the Measure

Suppression Factor 4 subfactor, “significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix.”

SHEA supports suppressing CY 2021 CDC NHSN HAI and from the Total HAC Score calculation for the FY 2023 and FY 2024 HAC Reduction program years due to ongoing disruptions due to COVID-19 (e.g., staffing and supply issues, among others). HAI outcomes during this period are less of an indicator of quality as much as they reflect unanticipated disruptions due to COVID-19. The impact of COVID-19 on each hospital varies considerably; thus, to inadvertently penalize hospitals that disproportionately treat COVID-19 patients is counterintuitive to the goal of the VBP program. SHEA supports the evolution of new quality metrics and suggests they undergo National Quality Forum (NQF) review and endorsement.

Further, SHEA appreciates CMS’ decision to continue to provide the measure results for the CDC NHSN HAI measures to hospitals via their hospital-specific reports (HSRs), as well as publicly via the Medicare Care Compare tool and Provider Data Catalog. We furthermore agree with CMS’ proposal that, due to the inherent impact of the COVID-19 pandemic on hospital performance, all hospitals receive a Total HAC Score of zero (i.e., no penalty), with those measure scores confidentially and publicly reported as “N/A.” However, it is unclear based on CMS’ proposal whether the five CDC NHSN HAI measure results would be publicly presented in aggregate form (i.e., de-identified). SHEA supports public reporting of the CDC NHSN HAI measures, with appropriate caveats regarding limitations, only if such scores are presented in aggregate form.

- Proposed Updated CMS PSI 90 Measure Specifications

On p. 918, CMS states:

“To account for the impact of the COVID-19 PHE on CY 2021 data in the CMS PSI 90 measure, we are updating the measure specifications to risk-adjust for COVID-19 diagnoses, as described in section V.J.3.c.(2). of this proposed rule, beginning with the FY 2024 program year.”

SHEA broadly supports CMS’ proposal to update the CMS PSI 90 software to include COVID-19 diagnosis as a risk-adjustment parameter for the FY 2024 program year and subsequent years. SHEA agrees that adjusting for COVID-19 at the patient level mitigates incremental risk associated with this diagnosis. However, SHEA would appreciate more information from CMS on the specificity of its proposal, including whether COVID-19 diagnosis, for purpose of risk-adjustment, pertains to a patient’s primary or secondary diagnosis, whether there has been a history of diagnosis, and so forth.

Finally, SHEA supports CMS’ proposal not to calculate measure results for CMS PSI 90 due to the potential for distorted measure results (i.e., discrepancies in the reference and applicable periods) among hospitals impacted by COVID-19. Given this discrepancy, we furthermore agree with CMS’ decision not to provide the CMS PSI 90 measure results to hospitals via their HSRs and not to publicly report these measure results on Care Compare and other public measure reporting tools.

HAC Reduction Program Requests for Information

- Digital CDC NHSN Measures

On p. 924, CMS states:

“...we request information on the potential future adoption of two digital NHSN measures, the NHSN Healthcare-associated Clostridioides difficile Infection Outcome Measure and the NHSN Hospital-Onset Bacteremia & Fungemia Outcome Measure, into the Hospital IQR Program, PCHQR Program, and the LTCH QRP. In addition, we request information on the potential inclusion of these digital CDC NHSN measures in the HAC Reduction Program. This request for information supports our goal of moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, including the HAC Reduction Program.”

SHEA appreciates CMS’ request for information regarding the potential future adoption of two digital NHSN measures in CMS quality reporting and VBPs, including the HAC Reduction Program, namely: (1) the NHSN Healthcare-associated *Clostridioides difficile* Infection (CDI) Outcome Measure; and (2) NHSN Hospital-Onset Bacteremia (HOB) & Fungemia Outcome Measure. SHEA supports CMS’ goal of broader digitization of quality measurement in CMS quality reporting and VBPs.

Regarding the CDI measure, further clarity is needed with respect to the definition of treatment, given that clinical decisions regarding whether to treat a patient for CDI is often subjective and dependent on patient co-morbidities. SHEA recommends patients with negative toxin tests should be excluded from the denominator. Further consultation with the CDC’s Emerging Infections Program (EIP) could help to illuminate definitional considerations, as well as determine whether the measure is appropriate for inclusion in the HAC Reduction Program. Since CDC intends to submit the CDI measure for NQF review and endorsement, as noted on p. 1223, SHEA asks CMS to wait for NQF to assess the CDI measure before proceeding with a formal proposal. Moreover, appropriate goal-setting is important to bear in mind, given that a goal of zero HACs may move the needle too far in its potential to cause harm, e.g., if its inclusion ultimately results in insufficient testing for clinicians to make appropriate diagnostic and treatment decisions.

Regarding the HOB and fungemia outcome measure, with some anticipated refinement, its adoption in CMS quality reporting and VBPs is a step in the right direction. Similarly, SHEA requests that CMS postpone release of a formal proposal for adoption of the HOB and fungemia outcome measure until after NQF review. Upon adoption of this measure in a future rulemaking, CMS should take steps to avoid duplicative measures by prioritizing the HOB and fungemia outcome measure over CLABSI and MRSA LabID measures. Like the CDI measure, appropriate goal-setting for this measure is paramount given that zero HACs is unattainable and may ultimately cause harm. Notably, CMS referenced a study in the proposed rule, on p. 1227, finding “two-thirds of all HOB events and half of nonskin commensal HOB events were judged as potentially preventable.”³ SHEA asks how CMS plans to address non-actionable HOB events.

Moreover, the proposed HOB measure still uses outdated facility-level risk adjustment. Two papers show that patient-level risk adjustment is more accurate in determining CLABSI risk.^{4,5} The second of these two papers

³ Dantes RB, Rock C, Milstone AM, Jacob JT, Chernetsky-Tejedor S, Harris AD, Leekha S. Preventability of hospital onset bacteremia and fungemia: A pilot study of a potential healthcare-associated infection outcome measure. *Infect Control Hosp Epidemiol.* 2019 Mar;40(3):358-361. doi: 10.1017/ice.2018.339. Epub 2019 Feb 18. PMID: 30773166.

⁴ Pepin CS, Thom KA, Sorkin JD, et al. Risk factors for central-line-associated bloodstream infections: a focus on comorbid conditions. *Infect Control Hosp Epidemiol.* 2015;36(4):479-481. doi:10.1017/ice.2014.81

⁵ Jackson SS, Leekha S, Magder LS, Pineles L, Anderson DJ, Trick WE, Woeltje KF, Kaye KS, Stafford K, Thom K, Lowe TJ, Harris AD. The

showed that patient-level risk adjustment that can be extracted from the EMR was better able to predict CLABSI risk than the current model. COVID-19 and advancements in hospital design have further reduced the accuracy of facility and unit-level risk adjustment. Specifically, newer hospitals have flexible units that can provide care across the spectrum of acuity, from that of a medical-surgical unit to ICU level. During COVID-19 surges, many hospitals with these flexible units transitioned medical-surgical units into ICUs. Unit-level risk adjustment during these surges would underestimate true CLABSI (and likely HOB) risk. Rather than replicating the outdated CLABSI risk adjustment model for HOB, SHEA recommends that CMS take the opportunity to refine risk adjustment. Specifically, for the first year of HOB, CMS could require that hospitals report the numerator and denominator data as proposed, and additionally report electronically-available comorbidities to help in developing/refining risk adjustment models. Clinical variables might include such comorbidities as:

- Active chemotherapy
- Immunosuppression
- ABD trauma
- Coagulopathy
- Drug abuse
- Paralysis
- HIV/AIDS
- Lymphoma
- Malignancy
- Metastatic cancer
- Liver disease
- Obesity
- Renal disease
- Weight loss (malnutrition)

For this first year, during this data collection, CMS would use this data to refine risk adjustment. There would be no payment impact during this first year.

Furthermore, SHEA encourages CMS to consider parallel monitoring of complimentary metrics for the CDI measure and HOB and fungemia outcome measures developed by CDC to identify and discourage gaming.

- Complementary Metrics for HOB:
 - Blood Culture Utilization;
 - Blood Culture Contamination;
 - Community-onset Bacteremia and Fungemia Event;
 - Matching Commensal Bacteremia Event; and
 - Non-Measure HOB Event

Effect of Adding Comorbidities to Current Centers for Disease Control and Prevention Central-Line-Associated Bloodstream Infection Risk-Adjustment Methodology. *Infect Control Hosp Epidemiol.* 2017 Sep;38(9):1019-1024. doi: 10.1017/ice.2017.129. Epub 2017 Jul 3. PMID: 28669363; PMCID: PMC5711399.

- Complimentary Metrics for CDI:
 - CDI Test Utilization;
 - CDI Test Positivity;
 - Outpatient CO-CDI Event;
 - Community-Onset Antibiotic Treated CDI Event;
 - Inpatient CDI Therapy Utilization; and
 - Positive CDI Test Without Therapy.

Hospital Inpatient Quality Reporting (IQR) Program

New Measures Being Proposed for the Hospital IQR Program Measure Set

- Proposed Adoption of Two Social Drivers of Health Measures Beginning with Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting Beginning with the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

On page 1080, CMS states:

“As a first step towards addressing the role of HRSNs in closing the health equity gap, we have developed two evidence-based measures—Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. These two proposed Social Drivers of Health measures will support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients.”

SHEA supports quality measures intended to screen for social drivers of health. Universal and consistent data collection in this area have been sparse to-date. Interventions cannot be implemented without individual level actionable data.

Potential Future Inclusion of Two Digital National Healthcare Safety Network (NHSN) Measures

- Cross-Program Request for Information on Potential Future Inclusion of Two Digital National Healthcare Safety Network (NHSN) Measures (Applicable to HAC, IQR, PCHQR, LTCH QRP)

Please refer to SHEA’s comments regarding this broader CMS proposal in the HAC section of our comment letter.

Additional Comments

SHEA recommends revisions to the Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) aimed at achieving a better balance between immediate antibiotic treatment for patients in need of such treatment and limiting antibiotic overuse. We are concerned that SEP-1, as stipulated, compels a “one-size-fits-all” approach for treating all patients with possible sepsis risk that can drive antibiotic overuse and contribute to the antibiotic resistance crisis. SHEA recommends the elimination of “sepsis without shock” from SEP-1 due to the dearth of evidence on the impact of antibiotics on survival for sepsis without shock and limiting SEP-1 to septic shock alone. To be clear, this recommendation intends to mitigate the risk of indiscriminately administering antibiotics to

patients who present with signs and symptoms resembling sepsis. Removing “septic without shock” from SEP-1 will allow clinicians to make a patient-centric determination based on the varied patient factors without the pressure to follow a single treatment pathway. Additional recommendations are outlined in “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.”⁶

PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR)

- Cross-Program Request for Information on Potential Future Inclusion of Two Digital National Healthcare Safety Network (NHSN) Measures (Applicable to Hospital IQR Program, PCHQR, LTCH QRP)

Please refer to SHEA’s comments regarding this broader CMS proposal in the HAC section of our comment letter.

Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

- Cross-Program Request for Information on Potential Future Inclusion of Two Digital National Healthcare Safety Network (NHSN) Measures (Applicable to Hospital IQR Program, PCHQR, LTCH QRP)

Please refer to SHEA’s comments regarding this broader CMS proposal in the HAC Program section of our comment letter.

Medicare Promoting Interoperability Program

Public Health and Clinical Data Exchange Objective

- Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective: Antimicrobial Use and Resistance (AUR) Surveillance Measure

On page 1329, CMS states:

“We are proposing the following new AUR Surveillance measure under the Public Health and Clinical Data Exchange Objective:

AUR Surveillance measure: The eligible hospital or CAH is in active engagement with CDC’s National Healthcare Safety Network (NHSN) to submit antimicrobial use and resistance (AUR) data for the EHR reporting period and receives a report from NHSN indicating their successful submission of AUR data for the EHR reporting period.

⁶ Chanu Rhee, Kathleen Chiotos, Sara E Cosgrove, Emily L Heil, Sameer S Kadri, Andre C Kalil, David N Gilbert, Henry Masur, Edward J Septimus, Daniel A Sweeney, Jeffrey R Strich, Dean L Winslow, Michael Klompas, for the Infectious Diseases Society of America Sepsis Task Force, 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, *Clinical Infectious Diseases*, Volume 72, Issue 4, 15 February 2021, Pages 541–552, <https://doi.org/10.1093/cid/ciaa059>

We are proposing to require eligible hospitals and CAHs to report this measure beginning with the EHR reporting period in CY 2023. Eligible hospitals and CAHs that report a “yes” response or an exclusion for which they are eligible would receive credit for reporting the measure. Eligible hospitals and CAHs that report a “no” response or fail to report any response would not receive credit for reporting the measure and would fail to satisfy the Public Health and Clinical Data Exchange Objective. No additional points would be associated with the reporting of this measure, but it would be one of five required measures required to satisfy the Public Health and Clinical Data Exchange Objective.”

SHEA supports the intent of requiring the AUR Surveillance measure, as it will incentivize the reporting of AUR data. Facilities could use this data to better benchmark prescribing performance as well as patterns of use and resistance. However, we are concerned with the proposed CY 2023 start date for implementation. SHEA asks CMS to consider delaying implementation to not before CY 2025 to provide hospitals and CAHs with additional time to establish the necessary reporting infrastructure. The addition of data elements, in conjunction with existing infection control reporting requirements, will require significant investment and time from facilities, especially those with limited resources. The specific nature of this new reporting requirement may require the procurement of additional modules and equipment upgrades from third-party vendors or internal capacity-building through the hiring and training of dedicated analyst support.

Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements to Address Any Future Pandemics and Epidemics as Determined by the Secretary

ICRs for Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements to Address Any Future Pandemics and Epidemics as Determined by the Secretary

- Continued COVID-19 and Seasonal Influenza-Related Reporting

On page 1461, CMS states:

“We are proposing to revise the regulations by adding provisions to the CoPs (§ 482.42 for hospitals and § 485.640 for CAHs) requiring hospitals and CAHs, after the conclusion of the current COVID-19 PHE, to continue COVID-19 and seasonal influenza-related reporting. The proposed revisions would continue to apply upon conclusion of the COVID-19 Public Health Emergency (PHE) and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date.”

SHEA supports the proposal to require COVID-19 and seasonal influenza-related reporting until April 30, 2024. We are encouraged that CMS “do[es] not expect that these categories of data elements would require hospitals and CAHs to report any information beyond that which they have already been reporting.” SHEA strongly urges CMS to adhere to this approach.

- Future Reporting in the Event of a PHE Declaration

On page 1464, CMS states:

“Specifically, when the Secretary has declared a PHE, we propose to require hospitals and CAHs to report specific data elements to the CDC’s National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, the categories of data elements that this report would include are as follows: suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total hospital bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.”

SHEA supports the proposal to require hospitals and CAHs to report specific data elements to NHSN in the event of a PHE declaration. We urge CMS to prioritize the use of NHSN, the nation’s most widely used surveillance system for tracking and collecting data on the prevalence of healthcare-associated infections (HAIs) and antibiotic prescribing trends. The NHSN is used by nearly 38,000 healthcare facilities along with the CDC, state and local public health departments, and medical researchers¹ and serves as the primary hub for healthcare data collection.⁷

Conclusion

SHEA thanks CMS again for the opportunity to provide feedback on the Hospital IPPS LTCH PPS proposed changes. As we noted, 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.

⁷ “National Healthcare Safety Network (NHSN).” CDC.gov, 25 Jan. 2021, <https://www.cdc.gov/nhsn/about-nhsn/index.html>. Accessed June 15, 2022.