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June 10, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

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 Program Requirements; and Other Policy Changes

Dear Administrator Brooks-LaSure,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the fiscal year (FY) 2025 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule. IDSA represents over 13,000 infectious diseases physicians, scientists and other public health and health care professionals specializing in the prevention, diagnosis and treatment of infectious diseases. Our members care for patients with a wide variety of serious infectious diseases, including COVID-19, antimicrobial-resistant infections, HIV, viral hepatitis and infections associated with cancer care, solid organ transplantation and injection drug use. Our members also lead hospital programs charged with antimicrobial stewardship, infection prevention and control, and emergency preparedness and response. We are pleased to support several components of the FY 2025 IPPS Proposed Rule as well as offer suggestions to strengthen some provisions, as detailed below.

Changes to the Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d), hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase. The Hospital IQR Program must first adopt measures and publicly report them on the Compare tool for at least one year before the Hospital Value-Based Purchasing Program is able to adopt them.

Proposal to Adopt Two Healthcare-Associated Infection (HAI) Measures Beginning With the Calendar Year (CY) 2026 Reporting Period/FY 2028 Payment Determination

In support of the Administration's Cancer Moonshot Program, CMS proposes to adopt the Catheter-Associated Urinary Tract Infection (CAUTI) Standardized

Infection Ratio (SIR) Stratified for Oncology Locations and the Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations (hereinafter referred to as the CAUTI-Onc measure and CLABSI-Onc measure, respectively), beginning with the CY 2026 reporting period/FY 2028 payment determination. These measures would supplement, not duplicate, the existing hospital CAUTI and CLABSI measures, which are used in the Hospital-Acquired Condition (HAC) Reduction Program and the Hospital Value-Based Purchasing Program and include most major inpatient care wards at acute care hospitals, including inpatient psychiatric facilities, hospice, inpatient acute care facilities, and inpatient rehabilitation facilities hospital inpatients, but not oncology wards. The CAUTI-Onc and CLABSI-Onc measures look only at patients in oncology wards. **IDSA agrees with the implementation of these measures to supplement existing measures at acute care hospitals.** Infectious disease physicians work closely in collaboration with oncologists to ensure that cancer patients receive fully comprehensive and coordinated care.

Long-Term Care Hospital Quality Reporting Program (LTCH QRP) Quality Measure Concepts Under Consideration for Future Years: Request for Information (RFI)

CMS is seeking input on the importance, relevance, appropriateness and applicability of concepts under consideration for future years in the LTCH QRP. In the FY 2024 LTCH PPS Proposed Rule, CMS published a request for information on the set of principles for selecting and prioritizing LTCH QRP measures, identifying measurement gaps and suitable measures for filling these gaps. Within this proposed rule, CMS also sought input on data available to develop measures and approaches to identify challenges with data collection. As a result of this RFI, CMS convened a Technical Expert Panel (TEP) in December 2023 to obtain expert input on future measure concepts that could fill the measurement gaps identified in this RFI. In consideration of the feedback from both the TEP and the RFI, CMS has proposed a measure concept for the LTCH QRP that includes a composite of vaccinations that could represent the overall immunization status of LTCH patients. **IDSA supports the development of a measure concept that includes a full composite of vaccinations.**

Proposal to Change the Antimicrobial Use and Resistance (AUR) Surveillance Measure Beginning With the EHR Reporting Period in CY 2025

CMS previously finalized the requirement for eligible hospitals and critical access hospitals CAHs to report the AUR Surveillance measure beginning with the EHR reporting period in CY 2024. Under the AUR Surveillance measure, eligible hospitals and CAHs report two kinds of data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN): antimicrobial use (AU) data and antimicrobial resistance (AR) data. Separate data elements and technical capabilities are required for reporting the AU data and AR data. Eligible hospitals and CAHs that report a “yes” response indicate that they have submitted data for both AU and AR and will receive credit for reporting the measure, unless they claim an exclusion for which they are eligible. Eligible hospitals and CAHs must also use technology certified to the criterion at 45 CFR 170.315(f)(6), “Transmission to public health agencies – antimicrobial use and resistance reporting” for data submission.

In response to public feedback, CMS proposes to separate the AUR Surveillance measure into two measures, beginning with the EHR reporting period in CY 2025:

- 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.

Under the proposal, eligible hospitals and CAHs would be required to report AU Surveillance measure data to CDC’s NHSN and to report AR Surveillance measure data to CDC’s NHSN. Eligible hospitals and CAHs must report a “yes” response or claim an exclusion, separately, to receive credit for reporting the AU Surveillance measure and the AR Surveillance measure. The Certified Electronic Health Records Technology (CEHRT) requirement under both measures would remain the same.

CMS believes that separating the AUR Surveillance measure into two measures would encourage participation from eligible hospitals and CAHs that could report data for only the AU measure or for only the AR measure that might previously have been excluded because of their inability to report both AU data and AR data as required by the AUR Surveillance measure.

IDSA supports the separation of the AUR Surveillance measure into two separate measures as this separation would result in better data capture methods for health care systems. These measures align with other NHSN reporting requirements (e.g., related to bloodstream infections and urinary tract infections) that are currently part of other CMS quality reporting and value-based payment programs, such as the Hospital Value-Based Purchasing Program and the HAC Reduction Program. IDSA has long promoted a multifaceted federal response to antimicrobial resistance that includes improved data collection and reporting, as well as antimicrobial stewardship, infection prevention, research and innovation. **We thank CMS for identifying AUR reporting as a priority.**

Conditions of Participation (CoP) Requirements for Hospitals and CAHs to Report Acute Respiratory Illnesses

In the FY 2023 IPPS final rule, CMS finalized revisions to 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) to require that, beginning at the conclusion of the COVID-19 public health emergency (PHE) declaration and continuing until April 30, 2024, hospitals and CAHs must electronically report information about COVID-19 and seasonal influenza virus, influenza-like illness and severe acute respiratory infection in a standardized format specified by the Secretary. CMS noted that this approach provides a path toward ending the overall reporting of COVID-19-related data.

Proposal to Continue Respiratory Illness Reporting in a Modified Form

In light of continued utility of respiratory illness data, CMS proposes to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs CoPs to extend a modified form of the current COVID-19 and influenza reporting requirements that will include data for RSV and reduce the frequency of reporting for hospitals and CAHs. Specifically, CMS proposes 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 Oct. 1, 2024, hospitals and CAHs electronically report information about COVID-19, influenza and RSV in a standardized format and frequency specified by the Secretary. 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.

Outside a declared national PHE for an acute respiratory illness, CMS proposes that hospitals and CAHs would have to report these data on a weekly basis (either in the form of weekly totals or snapshots of key indicators) through a CDC-owned or supported system.

These proposals are scaled back and tailored from the current post-COVID-19 PHE requirements, continuing the collection of the minimal necessary data to maintain a level of situational awareness that would benefit patients and hospitals across the country while reducing reporting burden on hospitals and CAHs. While hospitals and CAHs are encouraged to voluntarily continue reporting these data in the interim, CMS recognizes that there would be a 5-month gap between the sunset date for current reporting requirements (April 30, 2024) and the proposed implementation date for these new requirements. **IDSA recommends that CMS conduct a targeted educational campaign to encourage hospitals to continue reporting these data points during the transition period.**

IDSA agrees with CMS' proposal to continue reporting outside of the COVID-19 pandemic as it is critical for hospitals to continue reporting respiratory infection data outside of an emergency situation. However, hospitals were previously required to report total deaths among patients, ventilator use and capacity, staffing shortages and COVID-19 vaccine administration data of patients and staff. These data elements are still important to maintain outside of a declared national PHE. Although allowing hospitals and CAHs to report fewer data points than were required during the pandemic and allowing hospitals to submit data on a weekly basis will greatly reduce administrative burden for hospital systems, **IDSA encourages CMS to consider maintaining these previously required data reporting points as they are important to improve patient outcomes.**

Proposal to Collect Additional Elements During a PHE

CMS proposes that:

- During a declared federal, state, or local PHE for an infectious disease, the Secretary may require hospitals to report data up to a daily frequency without notice and comment rulemaking.
- During a declared PHE for infectious disease, the Secretary may require the reporting of additional or modified data elements relevant to infectious disease PHE including but not limited to: confirmed infections of the infectious disease, facility structure and infrastructure operational status; hospital/ED diversion status; staffing and staffing shortages; supply inventory shortages (e.g., equipment, blood products, gases); medical countermeasures and therapeutics; and additional, demographic factors.

- If the Secretary determines that an event is significantly likely to become a PHE for an infectious disease, the Secretary may require hospitals to report data up to a daily frequency without notice and comment rulemaking.

CMS invites comments on the following:

- If, during a PHE, there should be any limits to the data the Secretary can require without notice and comment rulemaking, such as limits on the duration of additional reporting or the scope of the jurisdiction of reporting (that is, state or local PHEs).
- Whether and how the Secretary should still seek stakeholder feedback on additional elements during a PHE without notice and comment rulemaking and how HHS should notify hospitals of new required infectious disease data.
- The evidence HHS should provide to demonstrate: (1) that an event is “significantly likely to become a PHE”; or (2) that the increased scope of required data will be used to protect patient and community health and safety.
- Whether hospitals should be incentivized for this data if the burden of collecting and reporting reaches a certain threshold of cost or time

Although IDSA agrees with the proposal that the Secretary should expand data reporting during a PHE, the data points collected during a PHE should be aligned with infectious disease priorities. **The importance and value of collecting these critical data points during a PHE outweighs the administrative burden that can be associated with collecting additional data.** Accordingly, small and/or rural hospitals should be provided with technical assistance and other resources to help them meet expanded requirements for data reporting. Without this assistance, a two-tiered system may result, with the most highly resourced hospitals providing data and benefiting from analysis of their patient population while small and rural hospitals do not have access to this analysis. Additionally, skewed national data could result, which would provide inaccurate assessments and would mask the challenges specific to smaller, rural hospitals and their patient populations. IDSA stresses that resources should be prioritized for this effort, and lack of resources should not be used as a reason to prevent or delay reporting.

RFI on Health Care Reporting to the National Syndromic Surveillance Program

CDC’s National Syndromic Surveillance Program (NSSP) is a collaboration among CDC, other federal agencies, local and state health departments, and academic and private sector partners that have formed a Community of Practice. They collect, analyze and share electronic patient encounter data received from emergency departments, urgent and ambulatory care centers, inpatient health care settings and laboratories. The electronic health data are integrated through a shared platform, the BioSense Platform. Public health officials use these timely and actionable data to detect, characterize, monitor and respond to events of public health concern. Syndromic surveillance relies on the secondary use of EHR data that supports delivery of care, enabling an efficient and cost-effective way to identify and characterize public health threats. The provision of these data requires no ongoing action from a health care provider, with data exchange automated from the EHR.

Syndromic surveillance is not a part of any condition of participation under this program, but CMS believes the continued growth of national syndromic surveillance would benefit hospitals, health care

and public health. The goal of this RFI is to better understand what else can be done to ensure that this effort can continue to make progress and that this critical data source is available at all levels of public health to support health care preparedness, public health readiness and responsiveness to existing and emerging health threats. CMS seeks input on the following:

- How can CMS further advance hospital and CAH participation in CDC's NSSP?
- Should CMS require hospitals and CAHs to report data to CDC's NSSP, whether as a condition of participation or as a modification to current requirements under the Promoting Interoperability Program?
- Should CMS explore other incentive or existing quality and reporting programs to collect this information?
- What would be the potential burden for facilities in creating these connections in state and local public health jurisdictions that have not yet established syndromic programs and/or where state and local public health are not presently exchanging data with CDC's NSSP? Are there unique challenges in rural areas that CMS should take into consideration?
- Data reported as part of syndromic surveillance requirements could serve as an alternative source for the COVID-19, influenza, and RSV hospitalization reporting requirements proposed in this rule — and even support eventual evolution towards an all-hazards approach for monitoring inpatient hospitalizations for conditions of public health significance. Should CMS consider a future requirement or otherwise incentivize facilities to expand-based reporting currently provided for emergency department visits to include data collected from inpatient settings as defined in the HHS COVID-19 reporting guidance, or a subset of these? If the latter, should a subset of inpatient locations be subject to such a requirement? What would be the potential value and burden tradeoffs to facilities? And, should any requirement specify that reporting also be to CDC's NSSP (in addition to more general reporting to state/local syndromic surveillance systems)?
- How can CMS leverage its authorities and programs to improve the quality of data reported to CDC's NSSP, especially for key elements that are sometimes incomplete, including discharge diagnoses, discharge disposition, and patient class?
- In addition to its value for public health, how could CDC's NSSP serve as a tool to directly improve clinical practice, patient safety, and overall situational awareness?

IDSA believes that syndromic surveillance requirements could benefit the tracking of outbreaks for unusual illnesses. However, smaller, rural health care systems that do not have established syndromic programs may face increased administrative burden. To reduce administrative burden for these health care systems, CMS should work with other federal agencies and Congress to provide adequate resources that can cover both adult and pediatric populations.

The Transforming Episode Accountability Model (TEAM) Mandatory Alternative Payment Model (APM) Proposed Model

CMS proposes a new mandatory alternative payment model to test whether episode-based payments for five procedures — coronary artery bypass graft (CABG), lower-extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion – reduce Medicare expenditures while preserving or enhancing the quality of care. Building on lessons learned from previous models, the mandatory Transforming Episode Accountability Model (TEAM) would

incentivize coordination between care providers during a surgery, as well as the services provided during the 30 days that follow, and require referral to primary care services to support continuity of care and drive positive long-term health outcomes. This model, aimed at incentivizing higher value care across the inpatient and post-acute care settings for specific episodes, would complement other CMS value-based care initiatives by promoting collaboration with accountable care organizations.

Overview

The model is scheduled to start Jan. 1, 2026, and run for five performance years (12-month calendar years). The model will be mandatory for the hospitals that are required to participate in “selected geographic areas.” These will be Core-Based Statistical Areas (CBSAs), and CMS estimates that about 200 will be selected (25% of the around 800 CBSAs that have not been excluded). The CBSAs will be randomly selected across 17 stratifications based on the following characteristics of the CBSAs: the average historical episode spending; the number of hospitals; the number of safety net hospitals; and the CBSA’s exposure to prior CMS bundled payment models. CMS considered making participation voluntary, but they are concerned that a fully voluntary model would not lead to meaningful evaluation findings. Because the episodes being tested in this model have been used on a voluntary basis in BPCI-A and BPCI, CMS has significant data on the performance of these episode categories in a voluntary structure.

IDSAs recognize that mandatory models can address participation challenges inherent in voluntary models, such as provider attrition and selection bias; improve the generalized outcomes of model findings; and capture a wider variety of providers from across the country. At the same time, we are concerned that small, rural and safety net hospitals, as well as hospitals that do not have previous experience participating in a value-based payment model, will be disproportionately burdened and penalized under this model. Model participants will face unique financial pressures, which could result in perverse incentives to skimp on necessary care or to avoid higher risk patients. Similarly, we are concerned about the competitive advantage that providers outside of the mandatory participation areas might have over participants. IDSA recommends that CMS reconsider the use of mandatory models. However, if CMS insists on moving ahead with a mandatory model, we request that it adopt policies to address our concerns above.

Episodes and Pricing

The TEAM proposed model will have 30-day episodes centered around episode-based payments that are triggered by a hospital stay (either inpatient or outpatient) for the following procedures:

- Lower-extremity joint replacement
- Surgical hip femur fracture treatment
- Spinal fusion
- Coronary artery bypass graft
- Major bowel procedure

CMS proposes that the TEAM participant (the hospital) would be financially responsible for the episode. CMS would offer three participation tracks to provide a glide path to risk:

- Track 1 would be available only in the first performance year (PY) for all TEAM participants and would have only upside financial benefit with quality adjustment applied to positive reconciliation amounts.
- Track 2 would be available in PYs two through five to a limited set of TEAM participants, including safety net hospitals, and would have two-sided financial risk with quality adjustment to reconciliation amounts.
- Track 3 would be available in PYs one through five for all TEAM participants and would have two-sided financial risk with quality adjustment to reconciliation amounts.

CMS proposes to use three years of baseline data, trended forward to the performance year, to calculate target prices at the level of MS-DRG/HCPCS episode type and region. CMS would risk-adjust episode-level target prices. CMS proposes to apply a 3% discount factor to the benchmark price to serve as Medicare's portion of reduced expenditures from the episode. CMS proposes to conduct an annual reconciliation, where CMS would compare spending for a TEAM participant's beneficiaries in episodes against the reconciliation target price in order to determine whether CMS owed the TEAM participant a reconciliation payment, or if the TEAM participant owed CMS a repayment (for all Track 3 participants and beginning in performance year two for Track 2 hospitals). CMS would conduct the annual reconciliation of each TEAM participant's actual episode payments against the target price(s) six months after the end of the performance year. CMS proposes an appeal process for TEAM participants to contest matters related to payment or reconciliation.

The target pricing includes the following services:

- Physicians' services
- Inpatient hospital services, including services paid through IPPS operating and capital payments
- Inpatient psychiatric facility (IPF) services
- Long-term care hospital (LTCH) services
- Inpatient rehabilitation facility (IRF) services
- Skilled nursing facility (SNF) services
- Home health agency (HHA) services
- Hospital outpatient services
- Outpatient therapy services
- Clinical laboratory services
- Durable medical equipment
- Part B drugs and biologicals except for those excluded under §512.525 (f) as proposed
- Hospice services
- Part B professional claims dated in the three days prior to an anchor hospitalization if a claim for the surgical procedure for the same episode category is not detected as part of the hospitalization because the procedure was performed by the TEAM participant on an outpatient basis but the patient was subsequently admitted as an inpatient

However, CMS proposes that episodes would **exclude** costs associated with delivery of services in the following categories:

- Hospital admissions and readmissions for oncology, trauma medical admissions, organ transplant and ventricular shunts (identified by specific MS-DRGs) and all admissions related to the

following excluded Major Diagnostic Categories (MDC): MDC 02 (Diseases and Disorders of the Eye); MDC 14 (Pregnancy, Childbirth and Puerperium); MDC 15 (Newborns); MDC 25 (Human Immunodeficiency Virus)

- IPPS new technology add-on payments for drugs, technologies and services
- Outpatient Prospective Payment System (OPPS) transitional pass-through payments for medical devices
- Drugs or biologics that are paid outside of the MS-DRG, specifically hemophilia clotting factors
- Certain Part B payments for high-cost drugs and biologics, low-volume drugs and blood clotting factors for hemophilia patients

Overall, IDSA supports the goal of the TEAM model to align financial incentives to improve care coordination and achieve better health outcomes. The model could help to better manage episodes as standard practice in traditional Medicare and may reduce costs while enhancing the overall care experience for Medicare beneficiaries. TEAM model participants will be able to share incentives downstream with providers and suppliers when they achieve higher quality care and, in turn, work more collaboratively. However, **we are concerned that the efforts of clinically relevant physicians, including ID physicians, are not meaningfully accounted for in the model.** ID physicians lead and manage infection prevention and control (IPC) and antimicrobial resistance (AMR) activities in health care delivery systems, as well as manage patient complications from surgeries, procedures and transplants, which are critical for the long-term care of patients. Inadequate accounting of clinical and non-clinical effort threatens to exacerbate already existing challenges in recruitment to the specialty of ID and access to ID care and program management for Medicare recipients. To address this oversight, IDSA makes the following recommendations:

- **Adopt a mechanism to ensure that clinically relevant physicians have the option to be integrated into leadership and governance roles within this proposed model and to share in the savings generated by the model, which would ensure the provision of clinically appropriate care and ensure fair mechanisms for distributing payments to specialists under the TEAM model.**
- **Direct participants to allot a meaningful portion of the shared savings payment within the model to ID physicians to account for their leadership and management of IPC and AMR activities.**

IDSA thanks you for your attention to these important issues impacting our hospitals' approach to preventing, tracking and reporting on infectious diseases. We hope that our comments are useful as you work to finalize the FY 2025 IPPS rule. If you have any questions or if we may be of any assistance to you, please do not hesitate to contact Amanda Jezek, IDSA senior vice president for public policy and government relations, at ajezek@idsociety.org.

Sincerely,



Steven K. Schmitt, MD, FIDSA, FACP
IDSA President