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June 10, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Docket #CMS-1808-P: Medicare and Medicaid Programs: 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 Ms. Brooks-LaSure:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide input to the FY 2025 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) proposed rule. APIC is a nonprofit, multidisciplinary organization representing 15,000 infection preventionists (IPs) whose mission is to create a safer world through prevention of infection.

We are pleased that CMS continues to demonstrate its commitment to improving the quality of patient care across the healthcare continuum. We value the efforts to improve transparency through public reporting of important quality measures.

Updates to the Hospital Inpatient Quality Reporting (IQR) Program

Proposal To Adopt Two Healthcare-Associated Infection (HAI) Measures Beginning with the CY 2026 Reporting Period/FY 2028 Payment Determination

APIC notes the proposal would add to the current mandatory reporting requirements both the Catheter-Associated Urinary Tract Infection (CAUTI) and Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratios for Oncology Wards measures beginning with the CY 2026 reporting period/ FY 2028 payment determination following the same data collection, reporting and submission processes that are already established via the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for the current required reporting locations for CAUTI and CLABSI. APIC agrees that patients with cancer are particularly susceptible to infection, as they are often immunocompromised and may have many comorbidities. Post-surgery CAUTI incidence can be as high as 12.5 percent in certain cancer populations.[1] Additionally, the utilization of central venous access is often necessary in oncology patients undergoing treatment and this patient population has a mortality rate from CLABSI of 12 – 40 percent.[2] APIC recognizes the need to add oncology wards to the locations already included in the Hospital Inpatient Quality Reporting Program (IQR) and in the PPS-Exempt

Cancer Hospital Quality Reporting Program. However, we believe there can be challenges for some hospitals in defining true oncology locations as defined by the CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations due to the 80/20 rule. APIC cautions that many facilities may not be able to meet the NHSN 80/20 rule to identify an "oncology unit," and therefore, many oncology patients may be systematically excluded from this metric.

Recommendations:

- APIC supports the proposal to add both the CAUTI and CLABSI Standardized Infection Ratios for Oncology Wards measures to the IQR program beginning with the CY 2026 reporting period/FY 2028 payment determination.
- APIC suggests evaluating the ability of hospitals to identify "true" oncology units as defined by the CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations Document due to the 80/20 rule.
- While APIC supports the addition of CLABSI and CAUTI reporting for the oncology patient population, we ask for clarification on delineating the specific units that would be included in this new metric instead of a broad statement of "oncology wards." This may be open to interpretation and could potentially leave some oncology units out of the reporting requirement.

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

Proposal to continue respiratory illness reporting in a modified form

CMS is proposing to revise the hospital and critical access hospital (CAH) infection prevention and control and antibiotic stewardship programs CoPs by replacing the current COVID-19 and Seasonal Influenza reporting standards with a new standard that would require hospitals and CAHs to electronically report information about COVID-19, influenza, and RSV in a standardized format and frequency, effective October 1, 2024. Proposed data elements would include:

- Confirmed infections of respiratory illness including COVID-19, Influenza and RSV among hospitalized patients;
- Hospital bed census (both overall and by hospital setting and population group [adult and pediatric]); and
- Limited patient demographic information, including age.

APIC recognizes the importance of respiratory illness surveillance as an indicator for preventing outbreaks, creating proactive protective measures (source control, testing, isolation protocols) and driving future actions. Awareness of incidence of respiratory illness within communities is critical for rapid response to impending issues. However, we stress the importance of actionable data being available to the hospital in a timely manner so that infection preventionists can implement initiatives to ensure patient, staff and visitor safety (such as source control and visitation protocols). Reporting infections weekly in the absence of a PHE (as proposed) would reduce the burden on IPs but it would be

important that data is analyzed and distributed to hospitals rapidly so it can be used to identify trends and activate prevention protocols in real time.

Recommendations:

- APIC supports the collection of respiratory illness data (COVID-19, Influenza and RSV) for hospitalized patients.
- We request that CMS coordinate with public health and CDC in order to minimize duplicate reporting requirements across platforms that could yield the same results.

Soliciting Input on Collecting Data by Race and Ethnicity Proposal

APIC supports efforts to collect the data necessary to detect and respond to inequities in healthcare delivery. APIC agrees with CMS that complete data on racial and ethnic differences in hospitalizations are critical to meeting the commitment to protect patients in all communities and prevent inequities caused or exacerbated by respiratory viruses like COVID-19, influenza and RSV. While race and ethnicity demographic data can be collected, the ability to collect additional demographic factors, including socioeconomic or disability status, poses a challenge and would indicate greater administrative burden to facility staff.

Recommendations:

- APIC supports gathering race and ethnicity data to help illuminate health equity challenges.
- Since other demographic factors, like socioeconomic or disability status, may not be so readily available, we would request a longer phase-in period for reporting these data to allow hospitals to develop processes for collecting this information without stigmatizing patients.

Proposal to Collect Additional Elements During a Public Health Emergency (PHE)

APIC acknowledges there may be a need for requesting additional data elements from healthcare institutions to help forecast decision-making during a public health emergency (PHE) and appreciates the opportunity to comment on the process.

Recommendations:

- APIC supports the proposal to allow the Secretary of HHS, during a declared public health emergency, to require healthcare facilities to report data more frequently (including daily if necessary) and to require additional or modified data elements relevant to the infectious disease PHE. However, CMS should also note that the burden and stress on hospitals and healthcare providers during a PHE is significant and should not add to this stress by penalizing facilities when a reporting system or procedure may break down during a high traffic period.
- APIC recommends that new requirements should be announced via state health departments and CDC alert networks to facilitate a rapid phase-in period.

- APIC supports collecting, reporting, and analyzing various data elements that will contribute to creating a safe environment for patients and staff, but the data being requested must be relevant and actionable to improve outcomes and gain knowledge to prevent future PHEs.
- APIC supports reporting hospital bed census and capacity data and demographic information on a weekly basis in the absence of a PHE to continue to provide ongoing information on trends to proactively identify issues.

Collaboration

APIC appreciates efforts across agencies at all levels of government to collaborate on reporting systems and data to decrease the reporting burden on healthcare facilities while enabling information sharing across the healthcare continuum and at all levels of government. The ability of all parties to collect and act on accurate data provides the largest opportunity to protect a community from transmission of dangerous pathogens and bring public health emergencies to an end.

Recommendation:

- APIC appreciates collaboration between CMS, CDC, the Administration for Strategic Preparedness and Response (ASPR), and the Office of the National Coordinator for Health Information Technology (ONC), as well as the collaboration between these agencies and hospitals, health systems and state, territorial, local and tribal agencies to streamline federal, state, and local reporting burden, utilizing the least burdensome technical exchange mechanisms for reporting.

Request for Information on Healthcare Reporting to the National Syndromic Surveillance Program

APIC supports the use of CDC's National Syndromic Surveillance Program (NSSP) to capture data points from the emergency department, urgent and ambulatory care centers, laboratories, and (some) inpatient healthcare locations. This may be a platform that could provide additional data elements for respiratory illness reporting for hospitalized patients. The electronic data is integrated through a shared platform called the BioSense Platform and is primarily used by the public health community to analyze data. There is a benefit to utilizing the NSSP since the data is exchanged via the electronic health record, thereby removing any ongoing actions required for reporting from the healthcare teams.

Recommendations:

- APIC supports evaluating the full potential of the NSSP to capture and report respiratory illness infection data that could possibly allow for one reporting system for an all-hazards approach for monitoring inpatient hospitalization for conditions of PHEs.
- APIC would support requiring hospitals to participate in the NSSP if it would eliminate the other reporting needs previously discussed. APIC recognizes that there may be limitations for some hospitals that are not currently reporting through this system, and we recommend that CMS explore why these gaps exist, as well as opportunities to close them.
- APIC supports utilizing the electronic health record to capture data directly and removing the ongoing burden from the healthcare teams.

Proposal to Separate the Antimicrobial Use and Resistance (AUR) Surveillance Measure into Two Measures Beginning with the Calendar Year (CY) 2025 Reporting Period

APIC notes that currently the AUR measure requires eligible hospitals and CAHs to attest to submitting data for both Antimicrobial Use (AU) and Antimicrobial Resistance (AR) data to be compliant; however, if exclusion criteria are met for either AU or AR data then the hospital is excluded from the entire AUR surveillance measure. APIC supports creating two separate measures (AU and AR) to encourage additional reporting by a hospital or CAH that would have been previously excluded for being able to report only one measure. Compliance would be met by reporting one or both measures as there is no partial credit being offered.

Recommendation:

- APIC supports separating the AUR surveillance measure into two distinct measures (AU and AR), thus providing more reporting opportunities for eligible hospitals and CAHs.
- APIC recommends re-evaluating the need to offer partial credit if one measure is disproportionately being captured.

Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

APIC recognizes that shortages of critical medical products (including antibiotics) have persisted over the past several years and notes the proposal of a Medicare payment policy to provide a separate payment to hospitals under the IPPS for Medicare's share of the inpatient costs of establishing and maintaining access to a 3-month buffer stock of one or more of the 86 essential medications. APIC believes this is necessary to mitigate the impact of pharmaceutical shortages, including antibiotics and vaccines, and promote resilience in the supply chain to safeguard and improve the care in hospitals. Although medication prescribing and distribution is not within the normal responsibilities of an IP, APIC notes that the development of vaccines and antibiotics greatly improved the ability of healthcare providers to protect patients from serious illness or death from infections and enabled the development of complex procedures that previously would have been impossible because of the risk of serious complications from infections.

We understand the concerns expressed regarding such a policy exacerbating drug shortages through demand shock to the supply chain and support a phase-in approach to prevent demand shortages.

Recommendations:

- APIC supports providing a separate payment to hospitals under the IPPS for Medicare's share of the inpatient costs of establishing and maintaining access to a 3-month buffer stock of one or more of the 86 essential medications.
- APIC suggests evaluating the need to have this payment included in the cost of the medicines themselves and not only cover the cost of establishing the buffer stock.
- APIC understands the difficulty predicting drug shortages but agrees that establishing this 3-month buffer for medications deemed essential should temper shortages as they arise.

APIC commends CMS for its ongoing commitment to patient safety and healthcare quality improvement across all care settings and populations. We look forward to continuing to work with CMS to prevent healthcare-associated infections in healthcare facilities.

Sincerely,

Tania Bubb, PhD, RN, CIC, FAPIC
2024 APIC President

[1] Mercadel, A.J., Holloway, S.B., Saripella, M., & Lea, J.S. (2023). Risk factors for catheter associated urinary tract infections following radical hysterectomy for cervical cancer. American journal of obstetrics and gynecology, 228(6), 718.e1–718.e7. https://doi.org/10.1016/j.ajog.2023.02.019.

[2] Beaudry J, ScottoMiMaso K. Central Line Care: Reducing Central Line-Associated Bloodstream Infections on a Hematologic Malignancy and Stem Cell Transplant Unit. CJON 2020, 24(2), 148-152. DOI: 10.1188/20.CJON.148-152. Available at https://www.ons.org/pubs/article/243061/preview . Accessed 6/7/2024.