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September 5, 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-1809-P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, proposed rule

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 CY 2025 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (OPPS/ASC) 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.

Proposal To Adopt the Hospital Commitment to Health Equity (HCHE) Measure for the Hospital Outpatient Quality Reporting (OQR) and Rural Emergency Hospital Quality Reporting (REHQR) Programs and the Facility Commitment to Health Equity (FCHE) Measure for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination or Program Determination

AND

Proposal To Adopt the Screening for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning with Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting for the CY 2026 Reporting Period/CY 2028 Payment or Program Determination

APIC recognizes that the complex intersection of health equity and infection prevention can have a profound influence on patient outcomes. We applaud CMS's efforts to make health equity a strategic priority and its commitment to supporting healthcare organizations in building a culture of safety and equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. It is incumbent on all providers of healthcare to ensure that patients receive the right care, at the right time, in the right setting for their condition(s), regardless of individual characteristics and/or the

patient's ability to pay for the services. We further applaud CMS's efforts to align health equity measures and assessment of social drivers of health (SDOH) as appropriate across both inpatient and outpatient settings.

We acknowledge health equity is unattainable without the use of standardized screening tools, collection and reporting of meaningful data that is standardized and validated, and organizational commitment to advancing health equity. CMS acknowledges that there are currently no consensus-based entity (CBE)-endorsed measures that address screening for SDOH in the outpatient setting. While APIC agrees that there is urgency in achieving health equity, and that screening for SDOH is certainly valuable, we advise caution in using unendorsed metrics for making inferences and decisions.

We agree with Chowkwanyun and Reed that "Disparity figures without explanatory context can perpetuate harmful myths and misunderstandings that actually undermine the goal of eliminating health inequities."[1] The details matter. While such demographic factors can be collected and reported, the ability to analyze the data and use it for meaningful healthcare improvement still provides the greatest challenge.

APIC Recommendations:

- APIC supports the health equity measures as positive steps toward improving health equity.
- APIC supports the need for measurement of equity and disparity across CMS quality programs but cautions that the data must be standardized, validated, and measure collection should be incorporated into broader healthcare surveillance systems in a way that minimizes administrative burden to facility staff.
- APIC looks forward to partnering with CMS in using data on race, ethnicity, and other social determinants of health to find evidence-based, measurable solutions to address healthcare disparities and provide equitable care to all sectors of our population.

Endorsement of Pass-Through Payment Status for Ambu aScope Gastroscope

APIC appreciates the opportunity to comment on the Ambu® aScope™ Gastro and its application for a new device category for transitional pass-through payment status for CY 2025.

APIC emphasizes the importance of supporting devices that mitigate infection risks, particularly in outpatient and ambulatory surgical settings. These locations often face challenges with the tools, space, and staffing required for high-level disinfection of gastrointestinal endoscopes.

Gastrointestinal endoscopes are known to acquire significant levels of microbial contamination during routine use.[2] Historical data shows that from 1966 to 1992 there were 281 reported instances of pathogen transmission linked to gastrointestinal endoscopes and 96 related to bronchoscopes.[3] Additionally, there have been more outbreaks of infections (> 130 outbreaks) associated with GI endoscopes (and bronchoscopes) in healthcare than any other reusable medical or surgical device. Furthermore, biofilm can persist within an endoscope despite reprocessing, potentially leading to ongoing contamination. Because of the high burden of contamination and risk of biofilm, the process for high level disinfection (HLD) of these scopes is quite complex, involving multiple steps.[4] The complexity

of the process inevitably leads to errors in cleaning and disinfection, contributing to infection transmission and death.[5]

Single-use devices eliminate the need for high-level disinfection, reduce the risk of biofilm development, and relieve facilities from the burdensome tasks of cleaning and disinfection. It is crucial to evaluate how this product will contribute to enhancing patient safety in outpatient and ambulatory surgery settings; therefore, APIC supports the company's application for a new device category for transitional pass-through payment status for CY 2025.

APIC Recommendation

- APIC supports incentives to replace high-risk, difficult to process instruments with disposable, single-use items and supports the application for a new device category for transitional pass-through payment status for CY 2025.

Modification to the Overall Hospital Quality Star Rating Methodology

APIC has commented previously on concerns about Quality Star Rating methodology, specifically regarding concerns with creating a composite rate of multiple patient harm events, each with distinct and separate risk factors and impact.

Do you support reweighting the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care as described in option 1?

> APIC applauds CMS for its commitment to emphasizing the importance of patient safety. As several healthcare-associated infection (HAI) measures are included within the Safety of Care grouping, we would support reweighting the Overall Hospital Quality Star Rating to place a larger emphasis on this important safety concern. However, as APIC has commented in the past, we do not support groupings of measures as HAI measures should stand alone to allow for easy comparison of like measures, rather than having measures lost within a grouping that may include a variety of different safety measures with facilities selecting which measures they include within the grouping. Therefore, while it is the best of the three options, we find it difficult to wholeheartedly endorse this option.

Do you agree with the potential new weights for each measure group (as shown in Table 103)?

> While APIC agrees with placing a greater emphasis on Safety of Care, we do not support composite measures because composite data does not direct patients or consumers to precise, meaningful information related to their care, and therefore, can be misleading and difficult to interpret, and/or not apply to the type of care they are seeking.

Do you support reducing the Star Rating for hospitals with a low Safety of Care score as described in option 2?

> APIC does not support reducing the Star Rating for hospitals with a low Safety of Care score, as this score is a complex grouping of a variety of measures and does not allow for direct comparison across hospitals for the same metric.

Do you agree with the potential policy to apply a 1-star reduction to all hospitals in the lowest quartile of Safety of Care?

There will always be a bottom 25% quartile; therefore, even if improvement is made, a double penalty for performance is applied that does not allow the hospital to be accurately compared to others across all measures. A blanket 1-star reduction to all hospitals in the lowest quartile does not reward areas of improvement or exceptional performance that may be of particular interest to a patient or consumer. The overall reduction would place some hospitals with superior performance in other measure groups on the same level as hospitals who are both performing poorly with Safety of Care AND other measure groups.

Do you support a combination of reweighting the Safety of Care measure group with a 4-star maximum on Star Rating as described in option 3?

APIC does not support the proposal to reweight the Safety of Care measure group with a combined 4-star maximum rating as this will likely result in an overcorrection and further penalize hospitals that are performing well in other areas but are not improving Safety of Care measures at the same rate.

Do you have feedback or preference towards an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2?

Because the overall scores are based on measure groupings, rather than individual measures, we do not believe most hospitals can easily be labeled as “high performers” or “low performers” without additional explanation. Therefore, an automatic “up-score” or “down-score” based on composite measure groupings would likely mislead consumers, who are the intended beneficiaries of the star rating system.

What are other methodological approaches that could be used to emphasize the Safety of Care measure group?

APIC recommends that HAI measures stand alone as a separate measure group and are not grouped together with other safety measures. This will allow for more accurate comparison across hospitals with similar Safety of Care measures instead of a composite score that may include very different variables.

With respect to the potential changes to the Overall Hospital Quality Star Rating methodology, are there any special considerations for small, rural or safety net hospitals (including Critical Access hospitals)?

To receive a star rating, hospitals must report on three measures in each of at least three measure groups, one of which must specifically be Safety of Care or Mortality. Small, rural, or safety net hospitals report fewer Safety of Care measures. With an increased weight to the Safety of Care measure group, they may choose to report these measures even less often, which will in turn skew CMS data and potentially create misleading benchmarks for facilities opting to report.

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

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[1] Chowkwanyun, M, Reed, AL Racial Health Disparities and Covid-19 — Caution and Context N Engl J Med 2020; 383:201-203 DOI: 10.1056/NEJMp2012910.

[2,3] Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med* 1993;118(2):117–28.

[4] Rutala WA, Weber DJ. Reprocessing semicritical items: outbreaks and current issues. Am J Infect Control 2019;47S:A79–89.

[5]McCafferty CE, Aghajani MJ, Abi-Hanna D, Gosbell IB, Jensen SO. An update on gastrointestinal endoscopy-associated infections and their contributing factors. Ann Clin Microbiol Antimicrob. 2018 Oct 10;17(1):36. doi: 10.1186/s12941-018-0289-2. PMID: 30314500; PMCID: PMC6182826.