



June 17, 2022

Ms. Chiquita Brooks-LaSure, MPP  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Baltimore, MD

**RE: RIN 0938-AU84**

Dear Ms. Brooks-LaSure,

I write to you today on behalf of Sepsis Alliance, the nation's first and leading sepsis organization, which works in all 50 states to educate about sepsis – the body's overwhelming response to infection – and advocate to save lives. I am writing to strongly urge the Centers for Medicare & Medicaid Services to **make publicly available the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) data for FY 2023**. I also strongly urge CMS to **finalize provisions in the FY 2023 Hospital Inpatient PPS Proposed Rule (CMS-1771-P) that would require expanded reporting on antimicrobial use and resistance into the CDC's National Healthcare Safety Network (NHSN)**.

CMS should take these affirmative steps, which match the seriousness of known patient safety and public health problems. Federal officials recently warned the American public about a significant spike in rates of harm: leaders at CMS and the CDC reported that, since 2020, federal data show a significant increase in the number of common hospital infections and patient safety mistakes. This is of particular concern for sepsis, which remains the leading cost of care and cause of death in U.S. hospitals and can often develop from hospital-acquired infections or errors including missed or delayed diagnosis. What's more, antimicrobial resistance (AMR) is a growing threat to public health, and to effective sepsis care, as sepsis treatment often requires effective antimicrobials. We must strive to better understand these public health threats, and we cannot do so without better, publicly available, data. Federal agencies and elected officials have a responsibility to make available health data that could enable researchers to better understand the health landscape and empower the public to be more informed consumers of healthcare services. More data, more widely available, is the best medicine for these problems – not less.

**Sepsis Alliance supports publication of PSI 90 information for the following reasons:**



- **Lives lost and patients harmed:** Nearly 25,000 people die, and another 94,000 suffer injuries, each year from the ten preventable medical and surgical complications covered in these data. These deaths and injuries occur from unacceptable complications from surgery, such as blood leakage, kidney harm, breathing failure, sepsis, wounds that split open, and accidental cuts and tears, as well as preventable complications from medical care such as deep bed sores, lung collapse, falls that break a hip, and blood clots. As a nation, we already contend with a lack of consistent reporting and public transparency around sepsis, which is why Sepsis Alliance seeks to create a [National Sepsis Data Trust](#). We cannot afford to exacerbate the existing data deficiency and make it more difficult for researchers, public health professionals, and the public to understand sepsis, which constitutes a hidden epidemic in the U.S.
- **CMS is the only source for this data:** Data on these complications is not available to the public from any other source. If CMS does not make this data available, America’s families will be in the dark regarding which hospitals put us most at risk. Yet we all shoulder the burden of these dangerous preventable complications: lost life, pain and suffering, lost productivity, and avoidable health costs.
- **Health equity implications:** In a groundbreaking report, Urban Institute researchers found that hospitalized Black patients were far more likely than their white counterparts to experience these medical and surgical complications at the same hospital, and the results were “clinically large.” For example, Black patients had 27% higher rate of experiencing sepsis after an operation and 15% higher rate of experiencing a kidney injury requiring dialysis. Black patients also bear twice the burden of sepsis deaths, relative to the size of the Black population, as compared to white patients. PSI 90 data is particularly impactful for populations traditionally the victims of bias.
- **Transparency is important to public trust – especially in times of crisis:** Policymakers have warned the public that dangerous complications increased during the COVID-19 pandemic. Publishing the CMS PSI 90 data will help to rebuild public trust in a precarious public health moment.

**We support the proposed mandatory requirement for NHSN reporting, as described in the FY 2023 IPPS Proposed Rule, for the following reasons:**

- **AMR is one of the greatest public health threats of our time:** Drug-resistant infections sicken at least 2.8 million people and kill at least 35,000 people in the United States each year. In 2019, there were more deaths worldwide caused by antibiotic-resistant bacteria than those caused by either HIV or malaria.
- **Effective antimicrobials are essential to modern medicine as we know it:** Clinicians rely heavily on antimicrobials such as antibiotics to treat infections that



can complicate procedures such as cancer chemotherapy, dialysis, Cesarean deliveries, care of wounds and burns, joint replacements, transplants, and other surgeries. Without effective drugs, the risk of developing life-threatening sepsis from routine procedures – even a trip to the dentist – skyrockets.

- **Widespread reporting is essential to tracking emerging threats and evaluating our interventions:** Widespread reporting of antibiotic use and resistance data improves clinical decision-making and informs antimicrobial stewardship practices. Without these data, clinicians and public health departments are left in the dark.

#### Recommendations:

1. **Publish New PSI 90 Data in 2023:** CMS should publish its PSI 90 data on its regular schedule.
2. **Continue to Maintain Publication of Previous PSI 90 Data:** It is important that employers, public health experts, and policymakers have access to all previous PSI 90 data from Calendar Year 2019 and years previous.
3. **Continue to Invite Public Comment:** The American public deserves to have access to lifesaving data about hospital quality and safety, especially as it relates to the care hospitals provide for conditions as common and as dangerous as sepsis. At all relevant opportunities in decisionmaking processes about data sharing, CMS should allow the public to comment and share feedback.
4. **Finalize provisions in the FY 2023 Hospital Inpatient PPS Proposed Rule (CMS–1771–P) that would require hospitals and critical access hospitals to report antimicrobial use and resistance (AUR) data into the CDC’s National Healthcare Safety Network (NHSN):** The first U.S. National Action Plan for Combating Antibiotic Resistant Bacteria, released in 2015, included a goal of 95% of hospitals reporting antimicrobial use data to NHSN by 2020. While improvements have been made, we remain far from this goal, with about 1,600 hospitals reporting antibiotic use or resistance data (or both) to NHSN as of February 2020. This new requirement is crucial to advance progress in this area.

We are grateful for the opportunity to provide our comments on these pressing issues.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Heymann".

Tom Heymann  
President & CEO  
Sepsis Alliance