PREMIER TRANSFORMING HEALTHCARE TOGETHER®

June 6, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1808-P

Submitted electronically to: http://www.regulations.gov

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 Programs Requirements; and Other Policy Changes [Docket Number: CMS-1808-P]

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2025 Inpatient Prospective Payment System (IPPS) proposed rule, which was published in the May 2, 2024 *Federal Register*.

In our detailed comments below, Premier urges CMS to:

- Adopt new or supplemental data sources, such as PINC AI™ data, to ensure labor costs are adequately reflected in the Medicare hospital payment update in the final rule. Premier also strongly urges CMS to apply a one-time adjustment to course correct for its significantly lower estimates of the hospital market basket for FYs 2021-2024. At a minimum, CMS must address the gross underpayment that occurred in FY 2022 via a one-time adjustment of at least 3 percent.

- Solicit input from the hospital community on reforms to the wage index and efforts to improve the sustainability of workforce, especially in rural and underserved communities.

- Finalize its reclassification of the Z-codes representing housing insecurity/instability and consider ways to address persistent issues that may limit how accurately these and other Z-codes are capturing the significant resource use involved in providing care to underserved populations.
- Modify its buffer stock of essential medicines proposal to instead focus on establishing a differential reimbursement for domestically manufactured essential medications.

- Not finalize an increase to mandatory electronic clinical quality measure (eCQM) reporting requirements under the Hospital Inpatient Quality Reporting (IQR) and Medicare Promoting Interoperability Programs and instead continue to work with stakeholders to address persistent challenges with eCQM reporting and develop a strategy around advancing digital quality measurement.

- Modify its proposal to require hospitals to continue reporting certain data related to acute respiratory illnesses, including not tying the policy to a condition of participation (CoP) and providing hospitals with additional time before the policy goes into effect.

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- Work with stakeholders to develop policies focused on improving maternal healthcare outcomes while ensuring CMS does not exacerbate access to care issues. As a result, Premier does not support the creation of a new CoP around obstetrics care, but rather offers feedback to help inform CMS' thinking of how it can improve data collection, standards, and other elements of obstetrical care in the United States.

Premier will be responding to the proposed mandatory Transforming Episode Accountability Model in a separate letter.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 hospitals and approximately 300,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 2.7 billion hospital outpatient and clinic encounters and 177 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. IPPS RATE UPDATES AND IMPACTS OF RISING LABOR COSTS

Background

The hospital market basket is an input price index that measures the average percentage change in the price of goods and services hospitals purchase to provide inpatient care. As a fixed-weight index, the hospital market basket measures changes in prices over time of the same mix of goods and services purchased during a base period. As a result, any changes in the mix of goods and services are not measured annually. CMS rebases the hospital market basket every four years. The current market basket, which was rebased for FY 2022, reflects hospital costs from Medicare cost reports that began on or after October 1, 2017 and before October 1, 2018.

CMS updates the market basket annually by forecasting costs using available historical data. To update the market basket for the FY 2025 proposed rule, CMS utilized the IHS Global Inc.'s (IGI's) fourth quarter 2023 forecast, which includes historical data through third quarter of calendar year (CY) 2023. Following

past practice, we anticipate the final rule will be based on more recent data and include historical data through second quarter of CY 2024.

Proposals and Premier's Recommendations

Based on its standard methodology for updating the hospital market basket, CMS proposes to update IPPS operating payments for FY 2025 based on a forecasted 3.0 percent increase to the hospital market basket. After accounting for the -0.4 percent adjustment for productivity, CMS estimates that operating payments will increase by 2.6 percent in FY 2025. ***Premier continues to have significant concerns that the proposed payment update does not adequately reflect the rising costs that hospitals have faced over the last few years, especially as it relates to labor costs.***

A PINC AI™ analysis found that labor costs have increased by more than 18 percent since the start of CY 2020 through CY 2023 and do not show signs of returning to a lower level. To determine changes in hospital labor costs, PINC AI™ analyzed the data within its workforce optimization solutions, one of the nation's largest and most robust sources for standardized geographically diverse payroll data and benchmarks. The data comes directly from a hospital's general ledger and is collected and validated by health system users daily.

Our analysis found that increased labor costs are significantly higher than what CMS has estimated and finalized over the last few years and is currently estimating as part of its market basket update for FY 2025. CMS updates labor costs using data from the U.S. Bureau of Labor Statistics' (BLS) Employment Cost Index (ECI).[1] Specifically, CMS uses a four-quarter rolling average of change in compensation and benefits as measured through the ECI survey of hospital workers. As noted above, there is a lag in the data that CMS uses to update the market basket annually, and the proposed update is based on historical data through third quarter of CY 2023. This compares to the Premier data that comes directly from hospital payroll in real time. Another critical difference between Premier's analysis and the ECI data is that the ECI survey of hospital employment costs only includes employed hospital staff, not contracted or contingent workers.[2]

The significant increases in labor expenses over the last several years are largely driven by two factors:

- *Increased utilization of contract staff:* Over the past few years, many hospitals have relied on contract staff – especially contract nurses – to help alleviate workforce shortages. Based on PINC AI™ data, the use of contract labor (as a percentage of total staff hours) nearly doubled from the start of 2021 through 2022. With increased demand, we also saw a significant increase in compensation for contract labor. According to PINC AI™ data, the average salary for contracted nurses nearly doubled between the start of FY 2020 and the first half of FY 2022, when salaries for contract labor peaked. Our data indicates that while salaries for contract nurses has decreased some from this peak in certain geographical areas, salaries remain nearly 60 percent higher as of the end of FY 2023 as compared to the start of FY 2020. While this increase in the use of contracted staff may be temporary, it does suggest a reason why the hospital market basket for FY 2021 and FY 2022 understated hospital increases in costs, as discussed in more detail below.

[1] Approximately 67.6 percent of the market basket is related to labor costs, often referred to as the labor-related share. Wages and salaries and fringe benefits for civilian workers in hospitals – which is updated based on the BLS ECI data – account for 53 percent of the market basket. The remaining 14.6 percent of labor costs is accounted for by professional fees, administrative and facilities support, installation, maintenance and repair and all other labor costs.
[2] Per discussions with CMS Office of the Actuaries (OACT)

- *Growth in employee salaries:* Our data also indicates significant growth in salaries for employed workers over the last few years; this growth does not show signs of slowing as employers leverage increased salary and benefits as a retention strategy to address workforce shortages. According to PINC AI™ data, salaries for employed staff have increased by 14.3 percent overall since the start of CY 2020 through CY 2023, with employed nurses seeing a more than 18.3 percent increase in salaries on average overall.

The use of contract labor and overall increased labor costs have been driven by significant workforce shortages. Before the pandemic, many clinical staff were in short supply and growing closer to retirement age. According to pre-pandemic research published in 2018, healthcare was projected to be short more than 1 million nurses by 2020 as a result of nurse retirements, an aging U.S. population and a stagnant talent pipeline.[3] Since that time, the pandemic has only exacerbated matters, prompting a significant increase in clinician resignations and retirements; for example, more than 500,0000 nurse retirements were expected in 2022.[4] A recent analysis finds that by 2025, it is expected that the United States may have a gap of between 200,000 to 450,000 nurses available for direct patient care, equating to a 10 to 20 percent gap.

This significant and growing deficit in the workforce supply indicates that it is unlikely these increased labor costs are transitory, but rather a new normal that reflects shifting market dynamics. As talent shortages become more severe, providers are paying more to attract and retain scarce staff, and our analysis indicates it is likely that these wage increases have set a new floor. However, the BLS' ECI does not accurately reflect the increased and persistent labor costs resulting from these projected ongoing shortages.

Given the significant delta between the increased cost of labor calculated by PINC AI™ versus what CMS is estimating, ***Premier has significant concerns that CMS' data source for estimating the cost of labor does not capture current market dynamics and woefully underestimates the true cost of healthcare labor across the country.*** This gross underestimate by CMS will result in a fifth consecutive year where the IPPS payment update is not reflective of the actual cost increases hospitals are experiencing. This comes at a time when many acute care providers are struggling to stay afloat after years of COVID-related financial losses, high inflation and increased labor expenditures. ***Premier continues to strongly recommend that CMS use its exceptions and adjustments authority to adopt new or supplemental data sources, such as PINC AI™ data, to ensure labor costs are adequately reflected in the payment update in the final rule*****.** It is imperative that CMS diversify its data sources to ensure a more accurate, blended labor impact rate for FY 2025 and beyond.

In addition to updating the data sources for calculating the annual market basket update in FY 2025, Premier recommends that CMS reevaluate the data sources it uses for rebasing its market basket and calculating the annual market basket update, including labor costs. Premier strongly encourages CMS to adopt new or supplemental data sources in future rulemaking that more accurately reflect the costs to hospital, such as through use of more real time data from the hospital community. For example, in future years we would encourage CMS to utilize supplemental data sources to evaluate the accuracy of the ECI proxy and to modify methodologies, including adopting new or supplemental data, to calculate the payment update if its analysis determines that the ECI is not adequately capturing labor costs. Premier believes that the current

[3] Zhang, Ziaoming, et al., "United States Registered Nurse Workforce Report Card and Shortage Forecast: A Revisit,"*Americna Journal of Medical Quality,* 2018, Vol. 33(3) 229–236, https://edsource.org/wp-content/uploads/2019/02/Zhang-Daniel-Pforsich-Lin-2017-United-States-Registered-Nurse-Workforce-Report-Card-and-Shortage-Forecast_-A-Revisit.pdf
[4] American Nurses Association, "Nurses in the Workforce," https://www.nursingworld.org/practice-policy/workforce/

market basket does not account for the higher costs of contract labor which have become more common in hospitals in an era of clinical labor shortages.

In addition to ensuring the market basket update is accurately calculated moving forward, Premier is concerned that CMS has underestimated the hospital market basket update for the last few years, resulting in a permanent depression of payments for hospitals moving forward.

CMS finalized the following market basket updates over the last several years:

- FY 2021: 2.4 percent
- FY 2022: 2.7 percent
- FY 2023: 4.1 percent
- FY 2024: 3.3 percent

According to CMS' latest forecasts,[5] these updates are notably lower than what CMS is now estimating based on actual data. Of particular note, CMS now estimates that total hospital costs increased by 5.7 percent in FY 2022, which is *3 percentage points higher* than the market basket update that CMS finalized for that year (2.7 percent). In addition to FY 2022, CMS has also underestimated the last several years:

- *FY 2021*, CMS now estimates 3.0 percent growth (based on actuals), or 0.6 percentage points higher than the final market basket
- *FY 2023,* CMS now estimates 4.8 percent growth (based on actuals), or 0.8 percentage points higher than the final market basket
- *FY 2024,* CMS now *projects* 3.5 percent growth, or 0.2 percentage points higher than the final market basket.

As a result, Premier strongly urges CMS to use its exceptions and adjustments authority to apply a one-time adjustment to course correct for its significantly lower estimates of costs for FYs 2021-2024. Because the annual payment update builds on the prior year's payment rate, failing to correct CMS' gross underestimation of the payment updates during the pandemic will further perpetuate inaccuracies in the payment rate moving forward, resulting in a permanent cut to hospital payments. Given the unprecedented circumstances and the significant effect of the pandemic on hospital inflation, Premier believes that a one-time update to the market basket recognizes the extraordinary price increases that hospitals experienced during the pandemic compared to the inflation update they actually received for FY 2021-2024. ***At a minimum, CMS must address the gross underpayment that occurred in FY 2022 via a one-time adjustment of at least 3 percent.***

III. CHANGES TO THE HOSPITAL WAGE INDEX FOR ACUTE CARE HOSPITALS

Background

CMS adjusts a portion of hospital payments to account for area differences in the cost of hospital labor, known as the wage index. Statute requires CMS to update hospitals' wage indexes annually based on a survey of wages and wage-related costs (fringe benefits) of short-term, acute care hospitals, which is collected through the Medicare cost reports. As a result, there is generally a four-year lag in data. FY 2024

[5] CMS Market Basket history and forecasts, https://www.cms.gov/files/zip/market-basket-history-and-forecasts.zip

wage indexes will be updated based on data from the FY 2020 submitted cost reports. Statute requires any changes made to wage indexes to be done in a budget neutral manner.

As part of FY 2020 rulemaking, CMS adopted a low-wage index policy focused on increasing wage indexes for hospitals in the lowest quartile of wage indexes nationwide. The policy was originally intended to support hospitals in the lowest quartile in increasing wages and was adopted for four years to ensure sufficient time for this data to be reflected in hospitals' cost reports, and subsequently the updated annual wage index. Under this policy, CMS increases the wage indexes below the 25th percentile by one-half the difference between the hospital's wage index and the 25th percentile wage index. CMS applies a budget neutrality adjustment across all hospitals to account for the increase in wage indexes for hospitals in the lowest quartile.

The low-wage index policy has been subject to on ongoing litigation *(Bridgeport Hospital vs. Becerra*), with the D.C. District Court ruling last spring that the Secretary did not have the authority under statute to adopt the low-wage index policy and ordering additional briefing on the appropriate remedy. CMS subsequently appealed the court decision, and that appeal is still pending.

The low-wage index policy was intended to only be in place for four years to allow enough time for increased wages to be reflected in cost report data, and thus was set to expire after FY 2023. However, CMS extended the policy through FY 2024 to provide additional time to collect data and evaluate the policy.

Proposals and Premier's Recommendations

CMS proposes to extend the low-wage index policy for three more years to provide it additional time to evaluate the efficacy of the policy. In the rule, CMS notes that the COVID-19 Public Health Emergency (PHE) complicated its ability to evaluate the impact of the policy on compensation for low-wage hospitals, as hospitals were receiving additional funds during the PHE. For example, hospitals reported $31.1 billion in COVID-19 related funding on FY 2020 cost reports, according to CMS. Extending the policy an additional three years would provide a four-year lag between the end of the PHE and the time wage data would become available.

Premier appreciates CMS' recognition of a shortcoming in the wage index methodology, which has been detrimental to hospitals located in certain states and regions where wages tend to be depressed and especially affects rural hospitals. ***Premier is supportive of efforts to improve how the wage index system works to ensure all hospitals receive accurate and adequate payments to support their workforce. Premier strongly encourages CMS to actively solicit input from the hospital community on reforms to the wage index and efforts to improve the sustainability of workforce, especially in rural and underserved communities.***

IV. CHANGES TO SEVERITY LEVELS FOR Z-CODES DESCRIBING INADEQUATE HOUSING/ HOUSING INSECURITY

Background

IPPS payment is made based on the use of hospital resources in the treatment of a patient's severity of illness, complexity of service, and/or consumption of resources. Generally, a higher severity level designation of a diagnosis code results in a higher payment to reflect the increased hospital resource use associated with the diagnosis.

In prior rulemaking, CMS requested comments on how the reporting of diagnosis codes in categories Z55-Z65 (known as "Z-codes") that describe social determinants of health (SDOH) might improve its ability to recognize severity of illness, complexity of illness, and/or utilization of resources for these SDOHs. CMS also sought comment on which specific SDOH Z-codes were most likely to influence hospital resource utilization related to inpatient care. At the time, the agency noted that it believed a potential starting point was consideration of the SDOH Z-codes describing homelessness, as homelessness can be reasonably expected to have an impact on hospital utilization.

As part of FY 2024 rulemaking, CMS finalized changes to three ICD-10-CM diagnosis codes describing homelessness (Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness)) from non-complication or comorbidity (NonCC) to complication or comorbidity (CC) for FY 2024. CMS based this proposal on its analysis of claims for which these codes are listed as a secondary diagnosis, which resulted in a finding that the resources involved in caring for a patient experiencing homelessness are more aligned with a CC severity level than NonCC. Among the factors that may cause increased financial impact to hospitals, CMS noted that patients experiencing homelessness can require longer inpatient stays due to needing a higher level of care and/or difficulty finding discharge destinations to meet these patients' needs.

Proposals and Premier's Recommendations

Building on last year's policy, CMS proposes to change the severity designation of seven ICD-10-CM SDOH Z codes that describe inadequate housing/housing instability from NonCC to CC:

- Z59.10 (Inadequate housing, unspecified)
- Z59.11 (Inadequate housing environmental temperature)
- Z59.12 (Inadequate housing utilities)
- Z59.19 (Other inadequate housing)
- Z59.811 (Housing instability, housed, with risk of homelessness)
- Z59.812 (Housing instability, housed, homelessness in past 12 months)
- Z59.819 (Housing instability, housing unspecified)

Premier supports reclassification of the Z-codes representing inadequate housing and housing instability and urges CMS to finalize this policy.

Premier also encourages the agency to consider ways to address persistent issues that may limit how accurately these codes are capturing the significant resource use involved in providing care to this population. For these codes to adequately capture resources needs, hospitals must report corresponding Z-codes. However, only a small fraction of claims incorporate these Z-codes, mainly because these codes introduce complexity for coders, necessitating additional time and lacking incentivization. Based on a Premier analysis using the CMS Medicare Standard Analytical Files for 2021, out of 8.1 million Medicare claims from inpatient acute care and critical access hospitals (CAHs) nationwide, only 200,904 total SDOH codes were reported, with another 242,812 codes reported for homeless.

Coders will need additional guidance as they often see a listing of SDOH information in the patient's history, but nothing documented on how the SDOH is related to an associated problem or risk factor directly. Many times, this impact is inferred from the information in the record but not fully documented specifically by the provider, which complicates an already arduous process. Similarly, providers may not be accustomed to routinely capturing this information as part of their provision of care for a patient and may thus require

training and education. Additionally, expressing certain social risk factors, such as housing instability or inadequacy, can be uncomfortable for patients, which could result in underreporting. As a result, the Z-code may not accurately represent the entire population.

Finally, Premier encourages CMS to continue to explore additional Z-codes to apply this policy to. For example, researchers have found a strong association between food insecurity and chronic conditions and that individuals facing food insecurity often had higher healthcare utilization and costs[6,7]. As a result, we urge CMS to evaluate reclassifying Z59.41 (Food insecurity). As part of this, Premier urges CMS to issue guidance on how to document food insecurity, including how it is defined for purposes of the Z-code. Finally, we recommend that CMS work with stakeholders to evaluate if changes need to be made to the Z-code in the future to further distinguish types of food insecurity. For example, food insecurity could be an indicator of food deprivation, malnutrition or lack of access to healthy foods and diet, all of which could have differing impacts on a patient and may require different interventions.

V. MAINTAINING ACCESS TO ESSENTIAL MEDICINES

Background and Proposals

CMS indicates that over the last few years, shortages for critical medical products have persisted and continued to increase. CMS believes it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency to safeguard and improve the care hospitals are able to provide to beneficiaries. As a result, CMS had sought comment as part of last year's Outpatient Prospective Payment System (OPPS) proposed rule on separate payment under the IPPS for establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. CMS notes that majority of commenters did not support making a reasonable cost payment to maintain a buffer stock of essential medicines because of concerns about exacerbating existing drug shortages or causing demand-driven shortages.

Based on stakeholder input, CMS is proposing to establish a separate payment under the IPPS for certain hospitals to voluntarily establish a buffer stock of essential medicines.

- *Eligibility.* CMS proposes to limit the policy to small, independent hospitals, or hospitals that have 100 beds or fewer and are not part of a chain. CMS opted to limit the policy to these hospitals because it believes it will mitigate concerns raised by commenters regarding large demand driven shocks to the supply chain.
- *Proposed List of Essential Medicines.* CMS proposes to use a list of 86 essential medicines included on the Advanced Regenerative Manufacturing Institute's (ARMI) Next Foundry for American Biotechnology, as those medicines were considered by consensus to be most critically needed for typical acute patient care. CMS proposes that if the ARMI List is updated to add or remove any essential medicines, all medicines on the updated list would be eligible for separate payment as of the update date.
- *Addressing shortages.* CMS proposes that a hospital that newly establishes a buffer stock of a medicine while it is in shortage (as defined by the FDA Drug Shortage Database) would not be eligible for separate buffer stock payment for the duration of the shortage. However, hospitals that had already established and were maintaining a buffer stock prior the shortage would be eligible to

[6] Dean, E.B., French, M.T., & Mortensen, K. (2020a). Food insecurity, health care utilization, and health care expenditures. Health Services Research, 55(S2), 883–893. Available at: https:// doi.org/10.1111/1475-6773.13283.
[7] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: A longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

receive separate payment. Additionally, these hospitals would remain eligible for payment even if their buffer stock fell below a six-month supply.

- *Size of the Buffer Stock.* As part of the OPPS comment solicitation, CMS had sought comment on a three-month buffer stock under the payment policy. Some commenters had noted that drug shortages often persist for more than three months, making a three-month buffer stock inadequate for providing essential medicines in shortage. CMS agrees and proposes that eligible hospitals must maintain a six-month buffer stock of essential medicines in shortage but seeks comment on a transition to this policy over two years. Under the alternative proposal, eligible hospitals would be required to maintain a three-month buffer stock during the first year and would be required to maintain a six-month buffer stock by the second year.
- *Payment.* Under the policy, hospitals would be paid a separate IPPS payment for the Medicare inpatient share of the reasonable costs to establish and maintain access to a buffer stock. CMS proposes that policy would be non-budget neutral. The hospital would report these costs to CMS on a forthcoming supplemental cost reporting worksheet. These costs would not include the costs of the essential medicine itself, which would continue to be paid in the current manner. Payment could be provided as a lump sum at cost report settlement or biweekly as interim lump-sum payments to the hospital which would be reconciled at cost report settlement. CMS estimates that approximately 493 hospitals would be eligible under the policy and would receive on average $620 per year.

Premier's Recommendations

While Premier applauds CMS for thinking creatively about how it can leverage its authority to address drug shortages, Premier continues to have serious concerns that the policy as proposed will not be effective in establishing buffer stocks of essential medicines and may exacerbate drug shortages. As noted in our response to last summer's request for comment, ***Premier continues to be concerned that the proposed policy incentivizes individual stockpiling at the hospital level. This will create disparate stockpiles throughout the country as hospitals will compete with one another for inventory, further creating silos and fragmentation in our nation's emergency preparedness infrastructure.*** One major lesson learned during the COVID-19 pandemic is the need for cohesive, holistic and national strategies for preparedness, not strategies that create further fragmentation.

While CMS has revised its initial policy recommendation from last summer to now only be applicable to smaller and independent hospitals versus all hospitals, CMS fails to note that these hospitals are typically the most in financial strain and therefore unable to invest funds into new projects absent adequate reimbursement. For example, while the policy covers the costs of maintaining a stockpile, it does not cover the costs associated with acquiring the initial 90-day supply of the medications. Therefore, it is unlikely that smaller hospitals and those struggling financially will have the necessary capital to build a stockpile and benefit from the proposed policy, thereby disadvantaging providers who have the greatest resource limitations during shortages.

Furthermore, CMS estimates an average annual payment to each eligible hospital of $620 to maintain the stockpile. This dollar amount is woefully inadequate to properly cover the costs associated with proper storage and handling of these essential medications. The majority of these medications are sterile injectable medications that require stringent storage and handling requirements in order to ensure their stability, sterility and safety for patient use. In addition, many of these medications require refrigeration, and some may be required to be maintained at frozen temperatures. In order to maintain a stockpile of these medications, hospitals will need to invest in significant warehousing capabilities, sophisticated HVAC systems, inventory mechanisms to ensure product is properly rotated, and medical grade refrigerators and freezers. This level of investment, in addition to hiring the necessary expertise to properly maintain a

stockpile, would cost the hospital significantly more than $620 per year. In order for a policy of this nature to be successful, CMS must find a non-budget neutral manner to reimburse hospitals for the cost of purchasing the drugs as well as ensuring appropriate reimbursement to cover the cost of physically maintaining the stockpile.

CMS also proposes to increase the buffer inventory from an initial 90-day inventory in year one to a 180-day inventory in year two and beyond. Premier has significant concerns with a 180-day buffer inventory as it can result in widespread national shortages of these essential medications due to how the policy would skew the supply versus demand curve for these medications. In Premier's experience and in speaking with a multitude of suppliers of generic medications, a 90-day stockpile is an appropriate target and appropriately protects the supply chain while efficiently accounting for capacity, carrying costs and the need to reduce waste.

Another complicating factor that CMS fails to note is the ability of these smaller, independent hospitals to acquire the quantity of drugs necessary to stockpile. The distribution of drugs is primarily contingent upon wholesale distributors who often limit the ability of a hospital to purchase quantities of drugs above their historical purchasing threshold. This policy typically disadvantages small, independent hospitals in favor of providing available supply to larger health systems. In practice, this means that a hospital is unable to purchase more than they normally purchase and therefore may serve as a barrier to CMS' stockpiling proposal. Should CMS move forward with its proposal, it will need to work with wholesale distributors to ensure that distribution and business policies are adjusted to permit hospitals to purchase higher quantities of specific drug products to benefit from CMS' proposal.

Finally, should CMS move forward with its proposal, Premier urges CMS to instead leverage the Food and Drug Administration's (FDA) List of Essential Medicines, Medical Countermeasures, and Critical Inputs that are medically necessary to have available to serve patient needs as required by Executive Order 13944. The FDA's list of essential medications is the most recognized list amongst healthcare providers and would better serve CMS' policy interest than the ARMI. At the same time, Premier recognizes that the FDA List of Essential Medicines is expansive and therefore further recommends that CMS establish a public-private advisory committee to help refine which drugs are most subject to shortage and therefore should be stockpiled. The committee should also help dictate which drugs are most applicable to which hospitals to stockpile. For example, a hospital without a pediatrics unit should not be required to stockpile medications intended for pediatric populations. The committee should also help ensure that the list of drugs to stockpile remains dynamic and is adjusted to account for new drug shortage risks, drugs that are no longer at risk of shortage, and new drugs that come to market.

Instead, Premier urges CMS to consider alternative non-budget neutral policy solutions to address drug shortages within its authority such as paying a differential reimbursement for domestically manufactured essential medications, similar to CMS' recent policy of paying a differential reimbursement for domestically manufactured NIOSH-approved N95 surgical masks. In the FY 2023 IPPS and CY 2023 OPPS final rules, CMS finalized a policy for differential reimbursement where payments can occur as frequently as biweekly interim lump-sum payments reconciled as part of the cost reports. In order for the domestic NIOSH-approved surgical N95 respirators purchased during a cost reporting period to be reimbursable by Medicare, they must be wholly made in the U.S. based on the Berry Amendment (10 U.S.C. §4862), and the respirator and all of its components must be grown, reprocessed, reused or produced in the U.S. This policy is fully implemented now and several hospitals throughout the country are taking advantage of it to help offset the higher costs associated with purchasing domestic N95 masks versus globally sourced masks. The policy is also supporting domestic manufacturing, supply chain resiliency and preparedness for the next public health crisis.

Given the success of CMS' policy for differential reimbursement associated with N95 masks, ***Premier urges CMS to repurpose its proposal to institute a similar policy for differentially reimbursing domestically manufactured essential medications for all IPPS hospitals***. A policy of this nature would permit hospitals to support domestic manufacturing and supply chain resiliency while also helping to avert drug shortages by investing in locally made, high-quality products. However, given the differences between drugs and masks, Premier notes that few drugs would qualify as domestically manufactured under the Berry Amendment definition. Therefore, Premier urges CMS to adopt the Buy American Act of 1933 (41 U.S.C. §§8301–8303) definition of domestically manufactured, which requires that at least 60 percent of the costs of its components must be manufactured in the United States.

VI. NEW TECHNOLOGY ADD-ON PAYMENTS

Background

Over the last couple of years, CMS has finalized changes to its application process for New Technology Add-on Payments (NTAPs), including modifying the date that products must receive FDA marketing authorization in order to be considered for an NTAP. As part of this year's rule, CMS proposes additional policies in response to stakeholders' feedback on these recent modifications.

Premier's Recommendations

We appreciate CMS' ongoing efforts to improve the transparency of the NTAP application process. ***Premier also encourages CMS to consider ways to modify the process by which hospitals submit NTAPs as part of the claims process.*** Many hospitals have noted that the existing NTAP claims process is extremely cumbersome, which results in some hospitals choosing to forego submitting a NTAP because of the laborious process involved.

Premier encourages CMS to explore adopting clinical decision (CDS) technologies as a vehicle to help streamline and automate the NTAP claims submission process to ensure hospitals are receiving adequate reimbursement for the use of novel technologies and products when clinically appropriate. In particular, CMS should look to adopt CDS technologies that use artificial intelligence (AI) and are embedded directly in electronic health records (EHRs) to provide real-time, patient-specific best practices at the point of care. CDS provides clinical support best practices content for enhanced patient safety, including safe prescribing practices and antibiotic stewardship. CDS can also leverage and pull data from evidence-based practice guidelines to provide patient-specific recommendations to ensure patients are on the most clinically appropriate and cost-effective treatment regimen. In addition, CDS can also serve as a solution for electronic prior authorization (ePA) and minimize the time between prescribing and a coverage decision, thereby expediting patient access to necessary treatments.

VII. QUALITY REPORTING PROGRAMS

A. Hospital Inpatient Quality Reporting (IQR) Program

Background

The Hospital Inpatient Quality Reporting (IQR) Program is a pay-for-reporting quality program. Hospitals that do not submit specified quality data or fail to meet all program requirements are subject to a one-fourth reduction in their annual payment update.

Proposals and Premier's Recommendations

Measures proposed for adoption

CMS proposes to adopt several new measures into the Hospital IQR Program, including:

(1) Patient Safety Structural Measure

The Patient Safety Structural measure assesses how well hospitals have implemented strategies and practices that demonstrate a structure, culture and leadership commitment that prioritizes safety. CMS proposes to adopt this measure beginning with the CY 2025 reporting period / FY 2027 payment determination.

The measure includes five domains: (1) leadership commitment to eliminating preventable harms; (2) strategic planning and organization policy; (3) culture of safety and learning health systems; (4) accountability and transparency; and (5) patient and family engagement. A hospital could earn up to one point for affirmatively attesting to each of the statements that corresponds with each domain, for a total of five points. If a hospital includes more than one acute care hospital facility reporting under the same CMS Certification Number (CCN), all the facilities would need to satisfy these criteria for the hospital to affirmatively attest and receive points. Because the Hospital IQR Program is a pay-for-reporting program, hospitals would satisfy their reporting requirement for the measure so long as they attest "yes" or "no" to each statement in all five domains. CMS would begin public reporting the measure, including the hospital's measure performance score (0-5 points), on Care Compare beginning in fall 2026.

Premier supports adoption of measures that advance patient safety. However, Premier does not support adoption of this attestation-based measure which neither measures patient outcomes nor evaluates patient care. Premier strongly urges CMS to assess what (if any) gaps in quality measurement exist around patient safety in the current quality reporting programs and to work with stakeholders to develop meaningful outcome measures that provide hospitals with actionable quality data. As part of that, Premier urges CMS to work with stakeholders to advance the use of AI in its development of new digital quality measures. The use of AI has the potential to increase the availability of real-time, actionable quality data and to reduce provider burden and burnout. Finally, Premier recommends that the measure receive consensus-based endorsement prior to adoption into the IQR Program.

If CMS moves forward with this measure, Premier urges CMS to provide detailed and clear guidance on data collection and entry to help facilitate meaningful reporting, including how hospitals should document whether they are satisfying each domain.

(2) Age Friendly Hospital Measure

The Age Friendly Hospital measure assesses hospital commitment to improving care for patients aged 65 or older receiving services in the hospital, operating room or emergency department. CMS

proposes to adopt this measure beginning with the CY 2025 reporting period / FY 2027 payment determination.

The measure consists of five attestation domains (1) eliciting patient healthcare goals; (2) responsible medication management; (3) frailty screening and intervention; (4) social vulnerability; and (5) age-friendly care leadership. For each domain, hospitals would need to affirmatively attest to all of the statements within the domain for each hospital reported under their CCN to receive a point for the domain, for a total of five possible points. Similar to the proposed Patient Safety Structural Measure, hospitals would receive credit for reporting the measure regardless of their responses or points.

Premier supports the need to consider the aging population and improve geriatric care. However, Premier does not support adoption of this attestation-based measure which neither measures patient outcomes nor evaluates patient care. It is unclear what additional value this measure would bring to patients, caregivers, hospitals or other stakeholders. Premier strongly urges CMS to assess what (if any) gaps in quality measurement exist around geriatric care in the current quality reporting programs and to work with the stakeholder community to develop meaningful outcome measures around geriatric care if it is determined that gaps do exist. Finally, Premier recommends that the measure receive consensus-based endorsement prior to adoption into the IQR Program.

Similar to the proposed Patient Safety Structural measure noted above, we urge CMS to provide detailed and clear guidance on data collection and entry if it finalizes adoption of this measure. The guidance should include how hospitals should document whether they are satisfying each domain.

(3) and (4) - Two Healthcare-Associated Infection (HAI) Measures:

(3) Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations (CAUTI-Onc)

(4) Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations (CLABSI-Onc)

CMS currently measures CAUTI and CLABSI in the Hospital Acquired Conditions (HAC) Reduction and Hospital VBP Programs. However, both measures do not currently measure care furnished in oncology wards. The CAUTI-Onc and CLABSI-Onc measures look to complement the existing CAUTI and CLABSI measures by measuring care furnished to populations not captured by the current measures --patients in oncology wards. CMS proposes adoption of the two measures beginning with 2026 reporting period / 2028 payment determination.

Under the proposal, hospitals would need to verify that all locations, including those with oncology patients, are mapped into the CDC's National Healthcare Safety Network (NHSN) to report the measures. The CDC defines an oncology ward as an area for the evaluation and treatment of patients with cancer.

Under the proposal, the NHSN would calculate the quarterly risk-adjusted standardized infection ratios (SIR) of CAUTIs and CLABSIs among inpatients at acute care hospitals who are in oncology wards. The CDC calculates the SIR using all four quarters of data from the reporting period year, which CMS then uses for performance calculation and public reporting. The SIR compares the actual number of CAUTIs and CLABSIs to the expected number. This is similar to the methodology used for the current CAUTI and CLABSI measures.

While Premier supports inclusion of these measures, we recommend that testing be conducted to determine if volume bias exists in the measure. It has been shown in the literature that risk adjustment of infrequently occurring outcomes can be biased due to the increased likelihood of zero events in low-volume facilities.[8] For example, consider Hospital A with an observed-to-expected (O/E) ratio of 0/3 compared to a larger Hospital B that has an O/E ratio of 0/20. Both hospitals would have an O/E value of 0, although the O/E for hospital B is arguably harder to obtain. For low-volume facilities, O/E ratios can remove important information contained within the denominator. As a result, Premier recommends measure testing for the presence of volume bias and making adjustments as necessary for fairness.

Finally, CMS should ensure facilities have sufficient time to operationalize the new requirement. Identification of oncology units/patient locations may be a resource intensive process that will increase administrative burden. For example, the NHSN/CDC location guide is 54 pages. Additionally, not all hospitals have a distinct oncology unit. For these hospitals it may be challenging to identify and map all locations where oncology patients are placed.

(5) Hospital Harm - Falls with Injury eCQM

The Hospital Harm – Falls with Injury measure is a risk-adjusted outcome eCQM that assesses the number of inpatient hospitalizations for which at least one fall with a major or moderate injury occurs among the total qualifying inpatient hospital days for patients aged 18 years and older. CMS proposes to adopt the measure beginning with the 2026 reporting period / FY 2028 payment determination. If finalized, the measure would be part of the eCQM measure set from which hospitals may self-select to meet the eCQM reporting requirement.

Premier generally supports adoption of this measure into the IQR program as an eCQM that hospitals can select to meet the eCQM reporting requirements. ***However, Premier encourages CMS to work with technical experts to improve risk standardization under the measure***. Fall risk varies considerably based on the patient's diagnoses, procedures and other aspects of care (e.g. medications). Specifically, this measure could be enhanced using indirect standardization (as the method of risk adjustment), whereby the expected value is conditioned on MS-DRG and potentially other patient- and visit-level factors. Such adjustment would control for non-homogenous case mix across facilities.

Finally, Premier also recommends that CMS work with stakeholders to evaluate whether the proposed Falls with Injury eCQM is duplicative of other quality measures, such as the PSI 08 In-Hospital Fall with Hip Fracture Rate measure which is part of the PSI 90 composite measure.

(6) Hospital Harm – Postoperative Respiratory Failure eCQM

The Hospital Harm – Postoperative Respiratory Failure measure is a risk-adjusted outcome eCQM that assesses the proportion of elective inpatient hospitalizations for patients aged 18 years and older without an obstetrical condition who have a procedure resulting in postoperative respiratory failure (PRF). CMS proposes to adopt the measure beginning with the 2026 reporting period / FY 2028 payment determination. If finalized, the measure would be part of the eCQM measure set from which hospitals may self-select to meet the eCQM reporting requirement.

[8] Armbrister AJ, Finke AM, Long AM, Korvink M, Gunn LH. Turning up the volume to address biases in predicted healthcare-associated infections and enhance U.S. hospital rankings: A data-driven approach. Am J Infect Control. 2022 Feb;50(2):166-175. doi: 10.1016/j.ajic.2021.08.014. Epub 2021 Aug 21. PMID: 34425178.

Premier generally supports adoption of this measure into the IQR program as an eCQM that hospitals can select to meet the eCQM reporting requirements. However, Premier recommends that CMS work with stakeholders to evaluate whether the proposed Postoperative Respiratory Failure eCQM is duplicative of other quality measures, such as the PSI 11 Postoperative Respiratory Failure Rate measure which is part of the PSI 90 composite measure. In the proposed rule, CMS notes that the Postoperative Respiratory Failure measure overlaps to an extent with the PSI 11 measure but captures a larger population and provides more timely information from electronic medical records. In working with stakeholders, CMS should assess whether there is any value to maintaining the PSI 11 measure and, if not, should swiftly remove the measure from the program.

(7) Thirty-Day Risk-Standardized Death Rate Among Surgical Inpatients with Complications (Failure-to-Rescue) Measure

The Failure-to-Rescue measure is a risk-standardized measure that assess the percentage of surgical inpatients who experienced a complication and then died within 30 days from the date of their first operating room procedure. CMS proposes to adopt the measure beginning with the July 1, 2023 through June 30, 2025 performance period affecting the FY 2027 payment determination.

As noted below, if adopted, CMS plans to replace the existing Patient Safety Indicator 04 (PSI 04) Death Rate among Surgical Inpatients with Serious Treatable Complications measure with the Failure-to-Rescue measure. While similar to the PSI 04 measure, the Failure-to-Rescue measure was respecified to address stakeholder concerns and captures all deaths of denominator-eligible patients within 30 days of the first qualifying operating room procedure, regardless of site and limits the denominator to patients in general surgical, vascular and orthopedic MS-DRGs. The measure also excludes patients with procedures that followed rather than preceded complications.

Similar to the PSI 04 measure, the Failure-to-Rescue measure is calculated using administrative claims data and is publicly reported on a rolling basis using rolling 24 months of prior data.

Premier supports adoption of the Failure-to-Rescue measure, which is an improvement over the PSI 04 measure that CMS is proposing for removal. However, we urge CMS to release full measure specifications as soon as feasible to ensure stakeholders have sufficient clinical documentation of coding. For example, it would be helpful to provide additional documentation regarding justification for each surgical complication used in the Failure-to-Resource measure along with their respective ICD-10 based definitions.

Finally, we are concerned that the measurement period began July 1, 2023, more than a year prior to finalization for inclusion in the Hospital IQR Program. Therefore, ***Premier recommends that CMS delay adoption of the measure for at least one year to allow hospitals time to familiarize and educate staff around the measure requirements.***

Measure proposed for refinement

CMS proposes to refine the Global Malnutrition Composite Score (GMCS) eCQM. CMS adopted the GMCS eCQM into the Hospital IQR Program as part of the FY 2023 rulemaking cycle. As currently specified, the measure assesses the percentage of hospitalizations for patients 65 and older with a length of stay of at least 24 hours who received optimal malnutrition care during the current inpatient hospitalization. CMS proposes to modify the measure to screen all patients 18 years or older, as it believes expanding the

population could improve clinical outcomes and reduce healthcare costs. If finalized, the modified GMCS eCQM would be included in the measure set from which hospitals can self-select beginning with the 2026 reporting period / FY 2028 payment determination. ***Premier supports expanding the population cohort to include all patients 18 years or older.***

Measure proposed for removal

CMS proposes to remove the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure pending adoption of the Failure-to-Rescue Measure. CMS notes in the rule that recent studies have indicated that the measure does not consistently recognize failure to rescue cases. The measure has also not been updated since 2017 and its endorsement has not been maintained. ***As noted above, Premier supports removal of the CMS PSI 04 measure.***

Increase number of mandatory eCQMs

Background

To meet the reporting requirements for both the Hospital IQR and Promoting Interoperability Programs, hospitals must currently report four calendar quarters of data for each of the three required eCQMs (Safe Use of Opioids, Cesarean Birth, and Severe Obstetric Complications), as well as three self-selected eCQMs.

Proposals and Premier's Recommendations

CMS proposes to progressively increase the number of mandatory eCQMs a hospital must report, beginning with the 2026 reporting period / FY 2028 payment determination. Under the proposal:

- Beginning with the 2026 reporting period / FY 2028 payment determination, hospitals would need to report six mandatory eCQMs and three self-selected. In addition to the current three mandatory eCQMs, hospitals would be required to report: (1) Hospital Harm - Severe Hypoglycemia eCQM; (2) Hospital Harm - Severe Hyperglycemia eCQM; and (3) Hospital Harm - Opioid-Related Adverse Events eCQM.
- Beginning with the 2027 reporting period / FY 2029 payment determination, hospitals would need to report on eight mandatory eCQMs and three self-selected. In addition to the current three mandatory eCQMs and the three mandatory eCQMs proposed for the 2026 reporting period, hospitals would be required to report: (1) Hospital Harm – Pressure Injury eCQM; and (2) Hospital Harm – Acute Kidney Injury eCQM.

Premier appreciates CMS' ongoing commitment to transition to digital quality measurement. We have long been committed to advancing providers' digital capabilities to analyze data from multiple sources and to manage the health of their populations. ***However, Premier does not support increasing the number of eCQMs at this time***. As we have noted previously, feedback to hospitals about their performances on eCQMs is infrequent and seldom helpful as a basis for performance improvement. Until regular, more frequent, and actionable eCQM performance feedback is provided, CMS should not increase the number of required eCQMs. We also strongly recommend that CMS address the eCQM reporting challenges before requiring additional eCQMs to be reported. Challenges include difficulties extracting data from "production-ready" eCQM products delivered by developers and insufficient time to complete testing, validation, staff education and rollout of eCQMs before their reporting is required. Costs to hospitals also remain a substantial obstacle to eCQM adoption.

Additionally, over the last several years, CMS has continued to articulate its goal of moving to fully digital measurement across its quality enterprise. As part of this goal, CMS aims to streamline the approach to data collection, calculation and reporting to fully leverage clinical and patient-centered information for measurement, improvement and learning. CMS has acknowledged the ongoing challenges of eCQM reporting and has noted it is considering how best to fit eCQMs will fit within a digital quality framework. ***Premier strongly recommends that in lieu of increasing eCQM reporting requirements that CMS work with stakeholders on fully building out its digital quality strategy and ensuring that any new requirements align with where CMS intends to focus its data collection approach, instead of requiring hospitals to invest the resources necessary to implement what is likely an intermediate step on the path to digital quality measurement.***

B. Hospital Star Ratings

Background

Medicare's Hospital Quality Star Rating (Overall Star Rating) program summarizes a number of measures across five quality areas into a single star rating for each hospital. CMS publishes the Overall Star Ratings annually using data reported on Hospital Compare from a quarter within the previous twelve months.

Premier's Recommendations

Premier strongly urges CMS to select one consistent quarter of data each year to improve transparency and predictability around the calculation of Star Ratings. In the past, CMS has indicated that it wishes to maintain flexibility in calculating the Overall Star Ratings in the event there are challenges with measure score calculations or data reporting disruptions, such as from a public health emergency. We understand the need to maintain some level of flexibility in the event there are methodological issues with a measure calculation or data collection. Under our recommendation, CMS could still maintain the ability to modify reporting periods as needed, so long as they notify hospitals in advance. For example, under our recommendation, CMS could use January Care Compare every year for the ratings which are generally released in July. If CMS were to discover issues with the measure calculations, it would notify hospitals when it sends out the April preview reports. This policy would still maintain the flexibility for CMS, while improving the predictability of measure calculations for stakeholders.

C. Medicare Promoting Interoperability Program

Changes to Antimicrobial Use and Resistance (AUR) Surveillance Measure

Background

One of the ways that hospitals have been required to demonstrate compliance with the Medicare Promoting Interoperability Program is through the submission of data on Antimicrobial Use and Resistance (AUR) derived from EHRs. As part of FY 2023 rulemaking, CMS finalized adoption of the AUR Surveillance measure, beginning with the 2024 EHR reporting period. This measure requires hospitals to report antimicrobial use (AU) data and antimicrobial resistance (AR) data to the CDC NHSN. To receive credit for reporting the measure, hospitals must report a "yes" response that they have submitted data for AU and AR, unless they claim an exclusion for which they are eligible. Additionally, hospitals must use technology certified for submitting the data.

Proposals and Premier's Recommendations

CMS proposes to separate the AUR Surveillance measure into two measures, beginning with the 2025 EHR reporting period: (1) AU surveillance measure; and (2) AR surveillance measure. Under the proposal, hospitals would need to report a "yes" response or claim an exclusion separately for each measure to receive credit. CMS notes that the separation into two measures is intended to clarify reporting requirements, incentivize data reporting and to more appropriately target potential exclusions since the AU and AR data rely on different data sources.

Premier supports CMS' proposal to separate reporting for AUR Surveillance into two discrete measures targeting AU and AR surveillance individually. As CMS notes, separating the measures will allow it to better target exclusion criteria. We have found that many CAHs and smaller acute care hospitals lack the infrastructure to report this level of data. CMS' policy will allow it to better tailor its exclusion criteria to ensure these facilities are not unduly penalized. Premier also continues to strongly urge CMS to continue to work with rural and small hospitals to ensure they have the resources and technical assistance needed to support interoperability.

VIII. CONDITION OF PARTICIPATION TO REPORT ACUTE RESPIRATORY ILLNESSES

Background

CoPs require that hospitals and CAHs have active facility-wide programs for the surveillance, prevention and control of healthcare-associated infections and other infectious diseases and for the optimization of antibiotic use through stewardship. During the COVID-19 public health emergency (PHE), CMS required hospitals to report specified information about COVID-19 in a format and frequency specified by the Secretary. CMS later modified this policy to require hospitals to electronically report information about COVID–19, seasonal influenza virus, influenza-like illness and severe acute respiratory infection in a standardized format following conclusion of the COVID-19 PHE through April 30, 2024.

Proposals and Premier's Recommendations

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, beginning October 1, 2024. Under this policy, hospitals would be required to report the following data elements:

- 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.

Hospitals would be required to report this data weekly – either in the form of weekly totals or snapshots of key indicators – through a CDC-owned or supported system.

CMS also proposes that if there is a future PHE declared for an infectious disease or the Secretary determines an event that is significantly likely to become a PHE for an infectious disease, CMS would have the authority to further expand on these requirements without undergoing notice-and-comment rulemaking.

This could include increasing the frequency of reporting (up to daily) or requiring additional or modified data elements that are relevant to the infectious disease PHE.

Given the five-month lag between the expiration of the earlier reporting requirement and the effective date of the one being proposed, CMS encourages hospitals and CAH to voluntarily continue reporting this information.

Finally, CMS is requesting feedback on ways it could advance syndromic surveillance. Currently, the CDC receives data from 78 percent of non-federal emergency departments across the country. CMS and CDC are seeking to close the remaining participation gap to ensure all communities are collaborating under the National Syndromic Surveillance Program (NSSP).

Premier recognizes the importance of collecting data on infectious diseases and supports ongoing efforts by CMS and CDC to streamline reporting as much as possible. However, we do not believe the CoPs are the appropriate vehicle for addressing many aspects of care. Using CoPs creates an extreme penalty (i.e. potential exclusion from Medicare) for aspects of care that can be assessed through other programs. ***Premier recommends that CMS avoid adding these reporting requirements through the hospital and CAH infection prevention and control and antibiotic stewardship programs CoPs. Instead, we encourage CMS to develop incentives for hospitals to report this information through quality (e.g. Hospital IQR Program) or payment programs (e.g., HVBP Program).***

Additionally, as noted above, CMS is proposing that the Secretary would have the authority to modify the reporting requirements if a future PHE related to infectious diseases is declared, including increasing frequency of reporting and modifying required elements. Premier continues to urge CMS to weigh the reporting burden on providers against any potential benefit gained from data collection, especially during any future PHE. The main priority for providers in a PHE is ensuring patients are getting the care that they need. For example, collecting and reporting patient-level data requires hospitals to invest significant human and monetary resources to ensure they have the processes in place to track this information. CMS should work with state governments, local health departments and the provider community to better identify how data could be shared across entities and the type of data that would be valuable in responding to PHEs. As part of this, CMS should work with stakeholders to align data requirements to ensure reporting is done in a consistent manner that reduces burden on providers.

If CMS finalizes this policy through the CoPs, Premier recommends that CMS use enforcement discretion and work with surveyors to ensure that there is ample time for hospitals to come into compliance. CMS must recognize that this type of reporting is resource intensive and will require hospitals to implement reporting processes and systems.

Finally, Premier urges CMS to engage with the CDC to enable national syndromic surveillance capabilities to better track and predict outbreaks – and quicken response times. Symptoms are the earliest and most reliable indicator of the emergence of infectious diseases that threaten our nation's public health. Identifying suspected cases early is the best signal of the need to take action. However, a recent Government Accountability Office (GAO) report notes how a lack of federal action to modernize the public health data infrastructure seriously undercut efforts to combat the COVID-19 virus. This is a situation that was unfortunately replayed with the Mpox public health emergency.

America needs an automated, near real-time means to collect symptoms and confirmed case information consistently and comprehensively so that it can be shared between and among multiple public and private stakeholders, including federal, state, local, Territorial and tribal public health authorities as well as on-the-ground providers. Such a system can pull in information on symptoms, comorbidities and other vital

information, allowing for targeted tracing and interventions to proactively prevent outbreaks. Earlier recognition of new hot spots speeds quarantining of potentially infected persons, reduces the spread of the virus and saves the nation money on contact tracing and testing. This reality is possible today as such a system was required by Congress for the CDC to implement under the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006 but is still not operational today. ***In lieu of placing additional burden on hospitals and health systems to report this data, or jeopardize their CoPs, CMS should collaborate with CDC to implement the system it was instructed to create almost 20 years ago to combat this phenomenon and better protect public health.***

IX. OBSTETRICAL SERVICES CONDITION OF PARTICIPATION REQUEST FOR INFORMATION

Background

There are no baseline care requirements for hospitals, CAHs and rural emergency hospitals (REHs) that are specific to labor and delivery, prenatal and post-partum care and care for newborn infants. Given the ongoing concerns about the delivery of maternity care in Medicare and Medicaid certified hospitals, CAHs and REHs, CMS plans to propose baseline health and safety standards for obstetrical services in the CY 2025 OPPS proposed rule.

Proposals and Premier's Recommendations

CMS is soliciting comments on what should be the overarching requirement, scope, and structure for an obstetrical services CoP. Potential options that CMS is exploring include:

- Creating an optional services CoP specific to obstetrical services, similar to the current Optional Services CoPs for Surgical services (42 CFR 482.51), Anesthesia services (42 CFR 482.52).
- Modeling an OB services CoP after infection prevention and control stewardship program CoPs (42 CFR 482.42).
- Requiring hospitals to develop standard processes for managing pregnant, birthing, and postpartum patients with or at risk for:
    - Obstetric hemorrhage (a leading cause of maternal mortality); and
    - Severe hypertension (a common pregnancy complication).

CMS also includes several specific questions in relation to creation of a CoP specific to obstetrical services which we have answered below.

Premier appreciates the opportunity to provide input on this important topic as the maternal mortality rates in the United States continue to be of grave concern. Premier's research, data analytics and on the ground member efforts are all working together to understand what elements are leading to these concerning outcomes and what we can do to address them.

To address this problem head-on, the Department of Health and Human Services (HHS) Office of Women's Health (OWH) through the Maternal Morbidity and Mortality Data and Analysis Initiative has tapped into Premier's extensive data to understand why disparate maternal outcomes occur. The HHS Perinatal Improvement Collaborative, a multi-year collaborative comprised of more than 220 hospitals from all 50 states and the District of Columbia, leverages standardized data and proven performance improvement methodology to scientifically identify root causes of maternal-infant mortality and morbidity. With these resources, the collaborative is implementing and analyzing evidence-based interventions to drive clinical quality improvement, advance health equity and help make America the safest place to have a baby.

Premier supports the standardization of data collection and measurement as it relates to obstetrical services. Through our intensive maternal work, Premier recognizes that reliable, comparable, and comprehensive data is needed to achieve real improvement in maternal morbidity and mortality. Premier agrees with CMS that obstetrical care delivery standards can help address the maternal morbidity, mortality, and maternity care access issues in the United States, and we reference several existing consensus documents throughout our comments in response to the questions outline in the RFI. However, ***Premier believes that any policy change to improve maternal health care outcomes must ensure that it does not exacerbate access to care issues. An obstetric services CoP would carry far too harsh a penalty, in that failure to comply with the new CoP would result in the loss of Medicare certification. This result would further limit access to obstetrical care and could potentially exacerbate rates of maternal morbidity/mortality***. In trying to address the maternal crisis, the last thing we want to do is intensify disparities in obstetrical care.

In lieu of proposing a new CoP, Premier recommends that CMS work with stakeholders to create a less onerous policy that balances these concerns and allows for sufficient time for hospitals to come into compliance with any policy once it is finalized. As part of this, CMS must recognize that any type of data reporting is resource intensive and will require hospitals to implement reporting processes and systems.

Below, Premier provides detailed responses to the questions outlined in the RFI and asks CMS to carefully consider the responses below when developing policies to advance maternal health. ***Premier's responses are not in support of a creation of a new CoP, but are instead intended to help inform CMS' thinking of how it can improve data collection, standards and other elements of obstetrical care in the United States.***

i. What are existing acceptable standards of practice, organization, and staffing for obstetrical services (including staff qualifications and scope of practice considerations) in hospital obstetrical wards, emergency departments, CAHs, and REHs?

Existing acceptable standards of practice, organization and staffing for obstetrical services across various healthcare settings, including hospital obstetrical wards, emergency departments, CAHs and REHs, are grounded in ensuring patient safety, quality care and positive outcomes for pregnant and postpartum individuals. These standards encompass a range of considerations, such as staff qualifications, scope of practice, clinical protocols and facility resources. Qualified obstetricians, certified nurse midwives and skilled nursing staff are integral to providing comprehensive care throughout the perinatal period. Additionally, adequate staffing levels and appropriate skill mix are essential to meet the dynamic needs of obstetrical patients, particularly in emergency situations.

A consensus document defining the levels of maternal care was released in August of 2019 with the goal to reduce maternal morbidity and mortality, and disparities, by standardizing and defining risk-appropriate care.[9] However, there remains considerable variation in the adoption of these maternal levels of care across the United States.[10] The Association of Women's Health, Obstetrical and Neonatal Nurses (AWHONN), published standards for registered nurse staffing for perinatal units in 2022[11] and implementation of these standards is still variable across the United States. Unfortunately, significant workforce challenges have severely impacted the ability to adopt these standards.

Prior to proposing any staffing ratios or mixes for obstetrical services, Premier urges CMS to study and understand barriers to implementation of existing recommendations related to staffing standards for perinatal units. Furthermore, CMS should study and evaluate the ability of the healthcare workforce to meet the needs of any future staffing mandates that may

[9]Obstetric Care Consensus: levels of Maternal Care, Number 9, Vol 134, No.2, August 2019. Obstetrics and Gynecology
[10]State Implementation | ACOG
[11] AWHONN *Standards for Professional Registered Nurse Staffing for Perinatal Units,* 2022.

inadvertently force additional hospitals to close their maternity services and create further maternal deserts.

ii. What are existing regulatory barriers to quality care for pregnant and postpartum patients in hospital obstetrical wards, hospitals and CAHs that do not operate obstetrical wards, emergency departments, and in REHs?

Regulatory barriers to quality care for pregnant and postpartum patients exist within hospital obstetrical wards, hospitals without obstetrical services, emergency departments, CAHs, and REHs. These barriers may include inconsistent regulatory requirements (state versus federal), inadequate staffing levels, limited access to specialized obstetrical care and challenges in care coordination between facilities. Addressing these barriers requires a multifaceted approach that emphasizes regulatory clarity, resource allocation, workforce development and integrated care delivery models.

iii. How could CMS better understand patients' experience of maternity care? What tools or instruments exist to understand individuals' experience of maternity care? How might CMS incorporate these tools or instruments into an obstetrical CoP?

To better understand patients' experience of maternity care, CMS can leverage various tools and instruments designed to capture individuals' perspectives and feedback. These tools include patient satisfaction surveys, such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), which assesses patients' experiences with their hospital stay, including aspects specific to maternity care.

Specifically, Premier recently responded to an RFI from the Agency for Healthcare Research and Quality (AHRQ) regarding the potential implementation of a CAHPS survey to assess patients' prenatal care and childbirth care experiences in ambulatory and inpatient care settings. Currently, no CAHPS instrument is available that is specifically designed to measure prenatal and childbirth care from the patient's perspective in these settings. In its comments, Premier supported a dedicated survey tool designed to measure prenatal and childbirth care from the patient's perspective and recommended methodologically sound approaches to capture this data in healthcare settings, including:

- Creating survey questions that include communication with providers, access to services and patients' perceptions of bias in receiving care.
- Developing different delivery mechanisms for the survey tool, as well as various language versions and survey questions posed in a manner that is suitable for individuals with varying health literacy levels to reflect the diverse birthing population.
- Creating a unique survey for maternity care, but if AHRQ does not pursue the creation of a unique survey, Premier urges that a path be explored for integrating questions into the existing inpatient CAHPS surveys that explicitly address prenatal and childbirth care experiences.

Premier urges CMS to work with AHRQ to expeditiously develop, test and implement a CAHPS survey instrument that is specifically designed to measure prenatal and childbirth care from the patient's perspective.

Additionally, CMS can utilize patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) tailored to maternity care. PROMs focus on assessing patients' health status and functional outcomes following childbirth, while PREMs capture patients' perceptions of the care they received during pregnancy, labor, delivery and postpartum care.

Furthermore, qualitative research methods, such as focus groups and interviews, can provide valuable insights into patients' experiences, preferences and unmet needs in maternity care.

CMS can also encourage healthcare organizations to implement real-time feedback mechanisms, such as patient portals or mobile applications, to solicit ongoing input from maternity patients throughout their care journey.

iv. What policy options would help alleviate any potential unintended consequences of an obstetrical services CoP and the impact on maternity care access and workforce? How should these policy options account for variation in hospital size, volume, and complexity of services?

The Maternal Levels of Care Consensus Document already represents a professional expert consensus of what is necessary to address these concerns. In addition, the effectiveness of prenatal and postnatal care using telehealth[12] and remote patient monitoring is emerging in the published literature. A study published in 2023 concluded that at the state level telehealth use increased during the pandemic without variation in practice type with implications for learning and designing innovative solutions for providers and patients[13]. One current example is the Maven Clinic[14] virtual care model which has improved outcomes and lowered costs.

v. What should minimum oversight requirements be for an obstetrical unit?

Premier supports the oversight requirements published in the Guidelines for Perinatal Care, 8th Edition which was created with input from multiple professional societies. Standardization across states would benefit the interpretation of data for consistency in delivery and implementation and address the gap in measurement and accountability.

vi. What should be required with respect to credentialling of health professionals to provide obstetrical services within a specific facility?

Premier supports the credentialing published in the Guidelines for Perinatal Care, 8th Edition, which was created with input from multiple professional societies, noting that registered nursing staffing for perinatal units has been updated. Standardization across states would benefit the interpretation of data for consistency in delivery and implementation.

vii. Should obstetrical units be required to maintain a minimum set of obstetrical care equipment and supplies?

Premier supports the requirements published in the Guidelines for Perinatal Care, 8th Edition, in addition to the capabilities and equipment recommendations defined in the Levels of Maternal Care Consensus statement.

viii. Beyond what is already required for emergency department (ED) patients under EMTALA, should a hospital obstetrical services CoP include a requirement for transfer protocols for when a non-ED patient needs care that exceed the capability of the hospital (that is, inpatient to inpatient transfers)? Should a similar requirement apply to hospitals and CAHs without emergency services and/or obstetrical services?

Premier supports the requirements published in the Guidelines for Perinatal Care, 8th Edition, in addition to the capabilities and equipment recommendations defined in the Levels of Maternal Care Consensus statement.

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[12] Shmerling, A., Hoss, M., Malam, N., Staton, E. W., & Lyon, C. (2022). Prenatal Care via Telehealth. *Primary care*, *49*(4), 609–619. https://doi.org/10.1016/j.pop.2022.05.002

[13] Mallampati, D. P., Talati, A. N., Fitzhugh, C., Enayet, N., Vladutiu, C. J., & Menard, M. K. (2023). Statewide assessment of telehealth use for obstetrical care during the COVID-19 pandemic. *American journal of obstetrics & gynecology MFM*, *5*(6), 100941. https://doi.org/10.1016/j.ajogmf.2023.100941

[14] Maven Clinic – The next generation of care for women and families

ix. How could CMS help improve data collection related to maternal morbidity and mortality across all demographics?

Premier has experience collecting and standardizing data, as is done in the PINC AI Healthcare Database (PHD). It is one of the most comprehensive electronic healthcare data repositories in the country. More than 1,300 hospitals/healthcare systems contribute data to the PHD. It provides a unique source of real-world data to conduct evidence-based and population-based analyses of drugs, devices, other treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes. The PHD comprises United States service-level, all payer information on inpatient discharges and outpatient encounters, primarily from geographically diverse non-profit, non-governmental, and community and teaching hospitals and health systems from rural and urban areas.

Premier also utilizes QualityAdvisor™ (QA), which is a clinical benchmarking solution that enables users to identify opportunity for improvement, analyze resource utilization at the item level and mitigate unjustified variation through self-service analytics and executive-ready dashboards. Through Premier's robust QA database and Perinatal Quality Dashboard, Premier supports over 1,350 hospitals with capability to report on birthing populations including through customizable benchmarks and ability to drill down to many features, including the following, and more. This same standardized database has been used to support multiple perinatal collaboratives.

CMS plays a crucial role in improving data collection related to maternal morbidity and mortality across all demographics. By working closely with healthcare providers and organizations, CMS can implement policies and standards that ensure comprehensive and accurate data collection.

In addition, CMS can work with various stakeholders who have already created comprehensive data processes, such as Premier, to effectively design collection practices. Furthermore, CMS can help align data collection standards across state Medicaid programs.

x. Should hospitals be required to directly report to MMRCs when available?

Hospitals should be required to report to Maternal Mortality Review Committees (MMRCs) whenever available. This collaboration between hospitals and MMRCs facilitates thorough investigation and analysis of maternal mortality cases, leading to targeted interventions and improvements in maternal healthcare. However, Premier recommends that this be part of the Death Certificate reporting and be automated. If "pregnant in the last year" is checked, it would automatically go to the relevant agency or MMRC, and not be dependent on any one person submitting data.

xi. Could such a data collection requirement be incorporated into an obstetrical services CoP, or would it be more appropriately incorporated into another existing hospital CoP, such as QAPI?

Regarding the incorporation of data collection requirements into existing hospital CoPs, it may be most appropriate to integrate them into existing data and reporting mechanisms, integration into other existing CoPs, such as Quality Assessment and Performance Improvement (QAPI), could also be considered. Regardless, structures that are already in place to manage data reporting should be utilized since cost and skills may impact building this out separately. Premier does not support the implementation of an obstetrical services CoP.

xii. Are there common critical data elements that would be most important and appropriate to collect through a CoP aimed at improving maternal health data? Are there data standards currently available or under development that can support standardized reporting? How do we ensure data collection encompasses all demographics?

Identifying common critical data elements is essential for improving maternal health data. CMS should work with relevant stakeholders to determine these elements, ensuring that they encompass a wide

range of factors affecting maternal health outcomes. A report in 2021 by the Commonwealth Fund[15] describes several of the opportunities available to improve measurement of maternal morbidity crisis across the United States.

To ensure data collection encompasses all demographics, CMS must prioritize equity and inclusivity in data collection efforts. This may involve implementing strategies to reach underserved populations, addressing language and cultural barriers, and incorporating demographic variables in data collection tools and processes.

Examples of such strategies to support comprehensive demographic data collection include:

- Collection or urbanicity and location/distance traveled for care from primary zip code.
    - Women in rural areas have had a consistently higher predicted probability of Severe Maternal Morbidity (SMM), such as sepsis, pulmonary edema and acute renal failure, as well as mortality, even after accounting for sociodemographic factors and clinical conditions. Rural and urban health disparities have continued to widen over time.
- Standardization of data collection with an equity lens for outcomes by location/distance travelled for care from primary zip code.
    - Exploring resource allocation by location may confirm and allow for close monitoring of outcome inequities by local of care provision.
- Additional guidance to support accurate coding of SDOH Z-codes.
    - As noted above, for these codes to adequately capture resources needs, hospitals must report corresponding Z-codes. However, only a small fraction of claims incorporate SDOH Z-code. Additional guidance and education is needed on how to accurately document SDOH and capture Z-codes in claims.
- Gender identity data collection
    - Not all patients who give birth identify as female. Data should be collected for gender identity to allow reporting across genders and investigation of inequities.
- Age
    - Data should be collected for the age of the patient to allow for a greater understanding of the relationship between age and outcomes, and to determine the impact of interventions on outcomes related to patient age. Data collection and research should allow for expanded age groupings as the overall population ages. Many national measures exclude patients falling outside of a standard age grouping, which limits the ability to analyze patients outside of the specified range.

xiii. How can any associated burden of possible future data collection and reporting requirements for providers be mitigated?

Finally, mitigating the burden of future data collection and reporting requirements for providers is essential. CMS can support providers by offering resources, guidance and technological solutions to streamline data collection processes. Additionally, ensuring that data collection requirements align with existing workflows and minimizing duplicative reporting efforts can help alleviate the burden on healthcare providers while still ensuring comprehensive data collection for improving maternal health outcomes.

For example, Premier's data processes require technology team support but there is minimal to no effort needed from front line clinicians, which gives them the opportunity to focus on patient care instead of data collection.

[15] Severe Maternal Morbidity in the United States: A Primer | Commonwealth Fund

X. ENSURING APPROPRIATE PAYMENT FOR AI TECHNOLOGIES

As CMS considers future Medicare payment updates in light of ever-evolving costs and new technologies, ***Premier urges CMS to proactively address how to incorporate incentives and appropriate reimbursement models for AI technology into Medicare payment systems***. While it has been thoroughly established that AI tools can provide life-saving insights to physicians, optimize workflow and reduce time spent on administrative tasks away from patients, these technologies have a prohibitively high up-front cost and current payment schemes do not adequately capture the value AI provides. ***Premier urges CMS to issue a formal request for information to learn from healthcare stakeholders how AI can be used to optimize the delivery of healthcare for Medicare beneficiaries and how CMS can properly incentivize the adoption of new AI technology in future rulemaking.***

XI. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments on the FY 2025 IPPS proposed rule. If you have any questions regarding our comments or need more information, please contact Melissa Medeiros, Senior Director of Policy, at melissa_medeiros@premierinc.com or (202) 879-4107.

Sincerely,

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Premier Inc.