

June 10, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

RE: CMS-1808-P: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Administrator Brooks-LaSure:

On behalf of our more than 200 hospitals and nearly 40 health systems, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to comment on the fiscal year (FY) 2025 Inpatient Prospective Payment System (IPPS) proposed rule. We support a number of the Centers for Medicare & Medicaid Services' (CMS') IPPS proposals, including moving additional Z-codes from non-complication and comorbidity status to complication and comorbidity status. CMS' continued focus on addressing health inequities aligns with IHA's vision to advance optimal health and healthcare for all Illinoisans.

To that end, we submit the following comments with the goal of working with CMS to ensure the FY 2025 IPPS adequately promotes the highest quality healthcare for all Medicare fee-for-service (FFS) beneficiaries.

FY 2025 IPPS Proposed Payment Update

We have serious concerns about CMS' proposed IPPS market basket update of 3.0% less a productivity adjustment of 0.4 percentage points. The resulting net 2.6% rate increase is simply too low to adequately support our nation's hospitals. **Consistent with our comments on the FY 2023 and 2024 IPPS proposed rules, we strongly urge CMS to reexamine the policies and methodologies utilized in updating hospital Medicare payment rates.** For the past several years, the current time-lagged approach has resulted in rate updates that are inadequate and inconsistent with the actual economic environment hospitals ultimately face.

In Illinois, we estimate CMS' proposed rule will actually only increase IPPS payments by 1.4% compared to FY 2024 IPPS payments. This proposed payment update follows CMS' trend to inadequately account for increased costs in labor and supplies from year-to-year. Specifically, because CMS' current market basket methodology forecasts

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expected economic conditions, it often misses unexpected trends that actually occur in the latter half of a given calendar year.

Since the COVID-19 pandemic, the economic environment has been anything but typical, making the current market basket methodology inadequate when it comes to estimating increased costs from year-to-year. This is perfectly illustrated by the FY 2022 market basket update versus actual economic environment. CMS finalized a 2.7% net market basket update for the FY 2022 IPPS, which is a full 3.0 percentage points lower than the actual FY 2022 market basket of 5.7%. This year's inadequate proposed rate update simply continues to dig a bigger financial hole that hospitals are constantly fighting to climb out of.

We urge CMS to use its "special exceptions and adjustments" authority to implement a retrospective adjustment for FY 2025 to account for the FY 2022 3.0 percentage point market basket difference. CMS has precedent for correcting forecasting errors, as it proposed to do for the FY 2025 skilled nursing facility prospective payment system. We ask that CMS not only make a similar correction to the IPPS, but also reevaluate its current method of projecting the IPPS market basket.

5% Cap on Wage Index Decreases

In the FY 2020 final rule, IHA supported CMS' adopted transition policy that placed a 5% cap on any decrease in a hospital's wage index due to the combined effects of policy changes in that fiscal year. Similarly, IHA supported CMS' decision to make the 5% cap policy permanent in FY 2023 and forward.

However, we continue to question CMS' decision to make this policy budget neutral. CMS clearly states that this policy is meant to increase predictability of hospital payments and mitigate instability and significant negative impacts to providers resulting from large wage index changes. Given the goal to stabilize the impact of wage index policies on hospitals, it does not make sense to essentially punish hospitals that do not experience wage index fluctuations by making this policy budget neutral. This is punctuated by the fact that the healthcare industry continues to face workforce uncertainty while costs, administrative burden and policy changes continue to stress the resources of hospitals and health systems. **Therefore, we continue to urge CMS to reconsider this policy, and make it non-budget neutral. Doing so would better align with the purpose of the 5% cap to increase predictability of hospital payments and mitigate instability and significant negative impacts to providers resulting from large wage index changes.**

That said, we thank CMS for applying the 5% cap policy on wage index decreases caused by proposed use of the July 21, 2023 OMB Bulletin No. 23-01 that reflects the 2020 Census. Using these CBSA delineations for the FY 2025 IPPS wage index affects the wage index classification for many hospitals, including moving some hospitals from rural to urban and vice versa. The 5% cap policy will mitigate the potential negative effects of these new market delineations, as well as any significant wage index fluctuations caused by future CBSA changes.

Low-Volume and Medicare Dependent Hospitals

Our rural hospitals are the backbone of their communities, often serving as the economic engine for the families living in the towns in which they are located. There are currently 11 Illinois hospitals that receive a low-volume adjustment (LVA) and nine Illinois hospitals that are Medicare Dependent Hospitals (MDH).

As in years past, the expiration of the current LVA and MDH policies on Dec. 31, 2024 would be devastating for these hospitals and the communities they serve. **While we understand it takes Congressional action to extend these programs, we urge CMS to encourage members of Congress to ensure the LVA and MDH programs are extended or, ideally, made permanent.** The continual need to extend these programs creates uncertainty, and making them permanent would be a straight-forward way to provide more financial stability to hospitals that provide essential, life-saving services.

Distribution of Additional Residency Positions

The Consolidated Appropriations Act of 2023 (CAA 2023) requires an additional 200 residency positions be distributed by FY 2026, with at least 100 positions reserved for psychiatry or psychiatry subspecialty residency training programs. CMS proposed using the distribution methodology finalized in the FY 2022 IPPS rule, allocating at least 10% of the available residency spots to hospitals falling in each of the following four categories: (1) hospitals located in rural areas; (2) hospitals operating above their residency caps; (3) hospitals in states with new medical schools; and (4) hospitals that serve health professional shortage areas (HPSAs). CMS also proposed to once again prioritize providing additional residency slots to hospitals located in HPSAs.

IHA has concerns with CMS' interpretation of the residency slot distribution requirements under the CAA 2023. Specifically, prioritizing hospitals located *in* HPSAs deviates from the statute, which states slots are to be distributed to hospitals that *serve* HPSAs. **Limiting distribution priority to hospitals located in HPSAs may inadvertently disqualify hospitals that disproportionately serve large numbers of low-income and underserved individuals, particularly because HPSAs presumably do not have many access points for healthcare services.**

Additionally, the CAA 2023 did not prioritize hospitals serving HPSAs over the other three categories of hospitals for the 10% distribution requirement. **It would be more logical for CMS to consider the four categories equally, prioritizing hospitals that qualify in more than one of the four statutory categories and giving highest priority to hospitals that meet all four categories.** This is an approach CMS considered in 2022 but did not finalize. We urge CMS to reconsider that approach for the FY 2026 slot distribution, as it is more straightforward and aligned with statutory language.

Social Determinants of Health Diagnosis (SDOH) Codes

IHA strongly supports CMS moving additional SDOH diagnosis codes from a non-complication or comorbidity (NonCC) to a complication or comorbidity (CC). There is ample evidence that certain social needs are known drivers of health and health outcomes, requiring additional resources to provide the highest quality of care for patients facing certain significant barriers. Problems related to housing, economic circumstance and other social needs significantly impact one's health, and providers are moving beyond the preliminary step of screening to address these needs – often times providing care and facilitating access to solutions outside the four walls of the hospital.

While hospitals have made significant advancements on screening, data collection, reporting and ultimately addressing patient SDOH needs, we know there are limitations to utilizing claims data to understand the prevalence of SDOH and the impact on hospital resources. There are significant challenges for providers to include all relevant diagnosis information on claims within the finite space available, but we believe CMS' expansion of more SDOH diagnosis codes (Z codes) as a CC will increase the use of these codes on submitted claims going forward.

We believe CMS' increased focus and prioritization of addressing SDOH has already resulted in substantial increase in hospitals' use of these codes in recent years. In Illinois, data show a 99% uptick in the proportion of claims with Z codes and a 214% increase in proportion of claims with the SDOH Z59 codes since 2021. This increase was particularly driven by a 44% increase in claims with Z codes for homelessness during calendar year 2023 following CMS' decision to make these Z codes (Z59.0, Z59.00, Z59.01, and Z59.02) a CC in the FY 2024 IPPS final rule.

We see similar trends for Z codes describing inadequate housing, with a 228% increase in the proportion of claims across Illinois hospitals with inadequate housing or housing instability Z codes (Z59.1, Z59.10, Z59.11, Z59.12, Z59.19, Z59.811, Z59.812, and Z59.819) in the past year alone. Moving these Z codes from NonCC to CC will further incentivize hospitals to append them to claims, increasing the reliability and validity of coded data and furthering the goals of the Biden-Harris Administration's initiative to tackle homelessness by recognizing housing stability as an essential component to the health and well-being of individuals and families.

We recommend that CMS continue moving more Z codes from NonCC to CC, as we know that problems related to other social drivers beyond housing affect access to care and health outcomes. In particular, we strongly encourage CMS to continue analyzing the impact of inadequate food (Z59.4, Z59.41, and Z59.48) and transportation insecurity (Z59.82) on hospital resource use and consider moving these Z codes from NonCC to CC as well.

Recognizing that only a portion of screened positivity is coded, we have already seen large upticks in both housing and transportation related codes on claims submitted by Illinois hospitals in 2023. Specifically, there was a 167% increase in proportion of claims with food insecurity codes in the past year, with the volume of claims with food insecurity Z codes reported went from 333 in 2021 to 6,443 claims in 2023. There have been similar increases in

the use of Z codes indicating transportation insecurity, with a 173% increase in proportion of claims with transportation insecurity codes in the past year.

Even ahead of potential CC Z code status, many hospitals have built robust programs to address food insecurity and transportation needs of inpatients at time of discharge. Hospital resources are required to not only screen patients for these needs, but to coordinate referrals for food assistance and transportation to safely return home and continue their recovery. Several hospitals have even begun to offer 'Food as Medicine' upon discharge, providing patients with fresh fruit, vegetables and other essential groceries to take home that very day without reimbursement. Additionally, hospitals have reported that patients with self-identified transportation needs have the largest impact on hospital utilization (i.e., increased length of stay). Beyond the impact on resources, food and transportation insecurity related codes would be valuable to account for patient factors in risk models and other claims-based analyses. Thus, **we encourage CMS to continue down this path, creating incentives for hospitals to continue screening patients for SDOH and report Z codes on claims so that we can continue to better address whole-person health in Illinois and across the country.**

Inpatient Quality Reporting (IQR) Program/Promoting Interoperability Program (PIP)

CMS proposed several changes to the measures collected under the IQR and PIP, particularly related to electronic clinical quality measures (eCQMs). Specifically, CMS proposed a stepwise increase in the number of eCQMs that hospitals must report, requiring hospitals to report nine eCQMs for the FY 2028 payment year and 11 eCQMs for the FY 2029 payment year. In each year, hospitals may only self-select three of the eCQMs reported, with the remaining six and eight eCQMs (respectively) specified. These changes double the amount of eCQMs reporting requirements hospitals currently face, and severely limit hospitals' flexibility in which eCQMs they choose to report.

Simultaneously, CMS proposed changes to the eCQM validation process. In the past, the validation process for eCQMs differed significantly from the validation process for chart-abstracted measures. Specifically, CMS validated eCQMs based on whether a hospital submitted 100% of requested eCQM medical record data. Chart-abstracted measures were validated based on CMS' ability to re-abstract the same measures submitted by a hospital and match them. In other words, eCQMs were considered valid if they were submitted and chart-abstracted measures were validated for accuracy.

Beginning with FY 2028 payments, CMS proposed aligning the eCQM validation process with the chart-abstracted validation process. Additionally, CMS proposed weighting validation scores for chart-abstracted measures and eCQMs equally, meaning hospitals would have to achieve the same agreement rate (75%) for both sets of measures to pass validation.

Further, CMS proposed increasing the meaningful use threshold under the PIP from the current 60-point minimum scoring threshold to an 80-point minimum threshold for the electronic health record reporting period in 2025. CMS stated just over 80% of hospitals currently meet

this threshold, and requiring it will encourage higher levels of performance and increased data exchange and interoperability.

Taken together, these proposed changes represent a significant shift in how hospitals meet the requirements of the IQR and the PIP. Implementing this volume of changes at the same time introduces a steep increase in administrative burden as hospitals, including Critical Access Hospitals, must dedicate additional resources and employees to meet these new requirements.

We urge CMS to consider a less aggressive approach to modifying the IQR and PIP, phasing changes in more slowly and systematically rather than all at once. For example, CMS might introduce the new eCQM requirements as proposed, but forgoing the changes to eCQM validation and the increased meaningful use threshold until hospitals have an opportunity to acclimate to the increased number of required eCQMs. Doing so would allow hospitals more time to acquire the resources necessary to meet new requirements, and likely result in better overall results for the patients hospitals serve.

Proposed Patient Safety Structural Measure “Accountability and Transparency” Domain 4

CMS also proposed a structural measure on patient safety, which includes several domains. Domain 4 of the proposed measure focuses on accountability and transparency, and would require hospitals to attest that they reported certain safety events, near misses and precursor events to a Patient Safety Organization (PSO) listed by the Agency for Healthcare Research and Quality (AHRQ) that participates in voluntary reporting to AHRQ’s Network of Patient Safety Databases (NPSD).

Under this proposal, a hospital receives a point toward their measure performance score which would be publically posted on an annual basis on Care Compare and on the Provider Data Catalog available at data.com.gov beginning the fall of 2026. In addition, a hospital would receive an incentive payment if it attests to all four activities in the Domain 4, including reporting these patient safety events to a PSO, beginning in 2027. IHA has several concerns with this proposal.

First, the proposed structural measure violates the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §299b-21, et seq. (PSQI Act) because the PSQI Act only allows for “voluntary” reporting of patient safety work product by hospitals to PSOs or by PSOs to the NPSD. By making a hospital’s publicly-available ratings contingent on the hospital’s attesting that it has reported certain information to PSOs (which, in turn, are reporting to the NPSD), CMS would, in effect, be compelling the reporting – making it mandatory, not voluntary. Furthermore, mandating reporting of hospital adverse events without protections will lead to a chilling effect on reporting, undermining the purpose of the patient safety structural measure. While the proposed attestation on reporting of safety events to a PSO is a well-meaning attempt to optimize patient safety, it cannot proceed because it would violate existing federal law.

Mandatory reporting aims to enhance transparency and accountability. Similar to any new requirement, this one must consider the potential unintended consequences, which in this case

could significantly undermine its purpose to improve patient safety by identifying and addressing preventable adverse events. Without legal protections, healthcare providers may become hesitant to report adverse events due to fear of repercussions, leading to underreporting.

Now known as The National Academy of Medicine, The Institute of Medicine's (IOM) follow-up 2004 report to its landmark 1999 report, *To Err is Human, Building a Safer Health System*, discusses Scherkenbach's "cycle of fear" as a model of how using performance data can instill fear and provoke defensive behavior on the part of providers.¹ This is not a new or unexpected concept as one of the 1999 IOM report's recommendations was to establish a nationwide mandatory reporting system about adverse events resulting in death or serious harm that was coupled with a call for legislation to extend peer review protection to data related to patient safety.

Hospitals are making efforts to create a reporting environment that encourages open communication without punitive measures against those who report adverse events. Transparency at the local level is essential. Hospitals and their staff must be assured that they can report events within a non-punitive, blame-free environment.

In discussing the need to foster innovation and improve the delivery of care, the IOM called for public accountability by emphasizing transparency as one of ten principles that should guide the redesign of the healthcare system. States have recognized the tension inherent in promoting transparency with regard to medical errors: although transparency can drive improvements, care must be taken to avoid penalizing institutions for honestly seeking opportunities for improvement. In response, states are beginning to encourage more transparency while providing strong protections for certain data (patient and provider identifiers).²

State systems do not punish facilities for events but do seek to hold them accountable for correcting system weaknesses. They do so by investigating events, providing expertise or information to help remedy problems, and insuring that appropriate changes are made and sustained to avoid similar problems in the future. The PSQI Act created PSOs, empowering them with providing privilege and confidentiality protections of submitted adverse events to strongly encourage reporting; however, it prohibits events from protection if they must be reported through federal and state mandate. In addition, as discussed above, CMS' proposal effectively compels reporting, which is contrary to the PSQI Act. **Thus, CMS' proposed attestation requirement under Domain 4 not only violates the PSQI Act but also contravenes the underlying purpose of the PSQI Act, which is to drive innovation in a non-punitive manner.**

¹ Institute of Medicine (US) Committee on Data Standards for Patient Safety; Aspden P, Corrigan JM, Wolcott J, et al., editors. Washington (DC): National Academies Press (US); 2004.

² <https://psnet.ahrq.gov/perspective/advancing-patient-safety-through-state-reporting-systems>

Further, the timeline for attestation of the proposed patient safety structural measure related to reporting to PSOs that report to the NPSD will be difficult to meet. As organizations that are committed to fostering safety culture, systems improvement, and high reliability in healthcare, federally listed PSOs and hospitals have a significant interest in this proposed measure. According to AHRQ, the work of federally listed PSOs and healthcare providers to reduce medical errors and increase patient safety in various clinical settings and specialties is highly valued, successful, and thriving.³

The Patient Safety and Quality Improvement Act of 2005 is a federal statute designed to promote activities to improve the quality and safety of healthcare on a national scale. Through this Act and the implementing regulations, Congress and the U.S. Dept. of Health and Human Services (HHS) intentionally declined to define the term “patient safety event” by statute or regulation, encouraging innovation by PSOs that decided to collect patient safety events.

PSOs for all provider types are able to create their own definition of patient safety events to complement their specific quality improvement program. If PSOs are forced to drop their innovative programs to be CMS’ reporting agent, there will be a breakdown in innovative healthcare programs and patients will be harmed. This flexibility was intended by Congress, which encouraged PSOs to be innovative and did not require PSOs to collect patient safety event reports in a standardized manner with a common taxonomy. As such, PSOs created taxonomies tailored to their provider members’ specialties in order to develop meaningful improvement strategies. As a result, very few PSOs that collect event reports are using the AHRQ common formats, the taxonomy needed to report events to the NPSD.

Due to economic and data mapping difficulties, even fewer PSOs are presently reporting to the NPSD. Additional time and resources will be needed in order for existing PSOs to convert their data submission and reporting platforms to conform to that of the NPSD.

PSOs are doing exceptional work to optimize patient safety. This attestation measure and the associated 2025 reporting timeline will force hospitals to leave their current PSOs and join one of the few that is reporting to the NPSD, impeding innovative approaches to improving the quality of patient care delivery and driving many PSOs out of business.

Additionally, under the Patient Safety and Quality Improvement Act of 2005, not all hospitals are eligible to report patient safety events to a PSO because of their legal structure. For example, Accountable Care Organizations and health systems with health insurance issuers that conduct their risk management and quality analysis cannot participate in a PSO program. Hospitals under this structure cannot confidentially report to a PSO because the information is reported by a health insurer, not a healthcare provider. Hospitals that are structured to work with a health insurance issuer for quality purposes will be rated as lower quality under the measure performance score compared with hospitals that do not work with health insurance

³ “Strategies to Improve Patient Safety: Final Report to Congress Required by the Patient Safety Act of 2005,” AHRQ, December 2021.

issuers because of the statutory prohibition on these hospitals participating in a PSO under the Patient Safety and Quality Improvement Act of 2005.

Finally, of those hospitals eligible to participate in a PSO, many do not have compatible risk management systems to report to a PSO. Rather, many hospitals have homegrown or closed-system risk management systems that cannot electronically report to a PSO. These hospitals are not reporting to a PSO and will not be able to participate in event reporting without making expensive capital investments, including purchasing new risk management systems, resulting in an inaccurate downgrade on their quality performance driven by their inability to report to a PSO.

Thus, we strongly urge CMS to strike the PSO attestation piece of Domain 4 from the proposed patient safety measure. Not only do we believe this attestation requirement to be in violate of the PSQI Act, but we believe implementing this part of the measure will create a fearful environment across hospitals and provider types, unintentionally hindering patient safety and innovation.

Proposed Payment for a Buffer Stock of Essential Medicines

IHA appreciates CMS' efforts to support a more reliable and resilient drug supply chain so that hospitals may better care for their patients during drug shortages. We also appreciate that CMS proposed to make the creation of a buffer stock of essential medicines voluntary, limiting the proposal to small (100 bed or less), independent hospitals, and that such payments would not be budget neutral.

However, we continue to have concerns about potential unintended consequences associated with this proposed policy, particularly given the lack of payment for the cost of the medicines themselves. Maintaining a 6-month supply of an essential medicine will undoubtedly be difficult for small, independent hospitals. Such hospitals have fewer resources to invest in creating and maintaining a buffer stock. Without up-front payments to small, independent hospitals to support the acquisition of essential medicines, many such hospitals may forgo creating a buffer stock.

Further, many small, independent hospitals serve more Medicaid or Medicare Advantage patients than Medicare FFS patients. This is particularly true for small, independent Safety Net Hospitals that serve patients and communities that have historically experienced health inequities and are more likely to experience difficulty obtaining essential medicines during a shortage or time of crisis. Thus, the proposed policy that only covers costs attributable to Medicare FFS patients has the potential to exacerbate the inequities that were highlighted by the COVID-19 pandemic during future public health emergencies.

We are also concerned that the proposed reporting requirements would deter several small, independent hospitals from participating. Separating out the costs attributable only to Medicare FFS patients will undoubtedly be administratively burdensome. Small, independent

hospitals in Illinois have not recovered from the workforce shortages exacerbated by the COVID-19 pandemic. Additional resources are often devoted to bolstering their frontline workforce, including ensuring an adequate number of registered nurses and filling specialist positions. The costs of procuring and maintaining a 6-month supply of essential medicines that are not covered by CMS will be infeasible for many small, independent hospitals, again potentially leading to disparities in access to essential medicines during the times of scarcity that this policy is meant to address.

We also request that CMS provide clearer guidance on what it considers to be a domestically manufactured medicine. While a medication may be finished and shipped from a U.S. location, the process of arriving at the final product may not be straightforward or limited to domestic outlets. According to the Food and Drug Administration (FDA), only 28% of manufacturing facilities making active pharmaceutical ingredients supplying the U.S. market were located in the U.S.⁴ Thus, we question how realistic and meaningful this policy is overall.

Relatedly, should CMS finalize this policy, we strongly urge them to continue making participation voluntary rather than moving toward making this a Condition of Participation (CoP) as suggested in the calendar year 2024 Outpatient Prospective Payment System (OPPS) proposed rule. Given uncertainty around the definition of a domestically produced medicine, and the potential financial barriers to participation, making this policy a CoP would be extremely problematic for many hospitals across the U.S. Doing so would likely result in curtailed access to not only these medications, but healthcare services in general as many hospitals would be unable to meet this CoP.

Finally, Illinois hospitals are concerned about the potential waste this policy may create. While there is data available to predict the quantity of certain medicines a hospital will use in a given period of time, utilization of such medications can fluctuate, creating potential for certain medicines to go unused altogether before their expiration date. This issue is further complicated for hospitals by the fact that, again, CMS will not be making payments for the cost of purchasing the actual medicines under this policy, leaving hospitals solely responsible for covering the cost of unused medicines.

Overall, we continue to believe that focusing essential medicine resiliency policies on hospitals is a misstep. Instead, we suggest CMS work with drug manufacturers and the drug supply chain to ensure ample supply of essential medicines. Working with the upstream stakeholders in the country's drug supply chain will better identify issues that lead to shortages of essential medicines, and more quickly address them. Further, pharmaceutical manufacturers and distributors are better positioned to facilitate a robust essential medicine supply from a financial perspective, particularly compared with small, independent hospitals.

⁴ U.S. Food and Drug Administration (October 2019). Safeguarding Pharmaceutical Supply Chains in a Global Economy. <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

June 10, 2024

Page 11

Administrator Brooks-LaSure, thank you again for the opportunity to comment on this proposed rule.

Sincerely,

A.J. Wilhelmi
President & CEO
Illinois Health and Hospital Association