

June 28, 2021

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue SW Washington, D.C. 20201

## Re: FFY 2022 Inpatient and Long-Term Care Hospital PPS Proposed Rule (CMS-1752-P)

Dear Ms. Brooks-LaSure:

On behalf of our more than 200 member hospitals and nearly 40 health systems, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to comment on the federal fiscal year (FFY) 2022 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) proposed rule. IHA commends the Centers for Medicare & Medicaid Services (CMS) for its thorough analysis in the development of this rule, particularly the attention paid to transitioning to a post-public health emergency (PHE) world that must still account for the presence of COVID-19.

Given all of the challenges and opportunities in front of the healthcare industry, we request that CMS consider the following recommendations:

- Work with stakeholders such as IHA to identify and validate actionable process and outcomes measures to support the Administration's commitment to health equity;
- Expand the per hospital per year cap on residency positions available under the Consolidated Appropriations Act, 2021 (CAA);
- Delay codification of proposed changes to Medicare organ transplantation payments and complete a comprehensive impact analysis on how proposed changes may affect organ availability, government spending, and hospital participation in the transplantation program;
- Continue analyzing the impact of LTCH site neutral policies on utilization, payments, and patient health outcomes;
- Reconsider the proposed structural maternal mortality measure for a measure that will provide more meaningful information on drivers of increased maternal mortality; and
- Provide specific goals for the public and private alignment CMS envisions around measure topics and specifications for future quality reporting changes and initiatives.

Details on these recommendations follow.

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### **Hospital Equity Score**

CMS proposed creating a Hospital Equity Score modeled after the Medicare Advantage Health Equity Summary Score (HESS). The HESS calculates standardized and combined performance scores using within-plan and across-plans methodologies, similar to the within-hospital and across-hospital methods used in analyzing hospital data. CMS envisions a Hospital Equity Score that synthesizes results for a range of measures and across multiple social risk factors including dual eligibility, race, and ethnicity. This new score would supplement the overall measure data already reported on Care Compare or a successor website, providing what CMS believes would be easy to interpret information regarding health equity measured within and across hospitals.

IHA applauds the initiative taken by CMS to tackle the issue of health equity within the Medicare program, and we welcome CMS' commitment to stratifying outcomes by different measures of socioeconomic status. Dual eligibility, race, and ethnicity are excellent starting points, and we urge CMS to continue identifying reliable and valid methods of analyzing data to more accurately identify areas where change is necessary.

We understand that the proposed Health Equity Score is a first step in discussing the data and transparency necessary to help patients access equitable and appropriate care. The appeal of a single summary score from the patient standpoint is undeniable; however, we are concerned that blending data into a summary score would not convey a true picture of a hospital's particular weaknesses or strengths. The effectiveness of a summary score depends on the measures that feed into it, the methodological construction of the summary, and the tangible action steps hospitals can take to improve their score. IHA suggests that before devising a summary score, CMS should work with organizations currently examining health equity to determine the process steps that might lead to equitable health outcomes across patient demographics. Identifying and validating process and outcomes measures, as well as actions that can improve performance on those measures, is a prerequisite to devising a meaningful summary score for both patients and providers.

Additionally, CMS may want to take this opportunity to ensure data collection and program measures are consistent and interoperable not only across CMS programs, but across other government agencies and programs as well. The COVID-19 pandemic proved what we already knew: health is one piece of the equity equation that connects with all other sectors of daily life from housing and food security, to educational and economic opportunities. A broad, de-identified data collection effort across federal agencies would allow us to address disparities holistically, rather than in silos. IHA and its members are committed to working toward equitable health outcomes, and we welcome the opportunity to collaborate with CMS on how best to measure equity within and across hospitals and the communities they serve.

# Indirect and Direct Graduate Medical Education (IME/GME)

IHA appreciates CMS utilizing the FFY 2022 IPPS rulemaking process to implement IME and GME provisions established under the CAA. The addition of 1,000 Medicare-funded full time equivalent (FTE) residency positions over the next several years is an important step toward

addressing the critical workforce shortage the U.S. healthcare system has dealt with for decades.

However, we question why CMS would limit each hospital to 1.0 FTE residency position each year. CMS makes clear in the proposed rule that it intends to release the maximum 200 FTEs per year until all 1,000 positions are distributed. It would take approximately five years to distribute these new positions, limiting any one hospital to five new residency FTEs. The CAA limits hospitals to 25 additional FTE positions, a ceiling that is much higher than the 5 FTE cap CMS is creating via this proposed rule.

We know that some of our hospitals located in geographic Health Professional Shortage Areas (HPSAs) are woefully understaffed and that residencies can serve as a pipeline to employment. For example, according to CMS' Market Saturation data, in 2019 there were 882 Medicare feefor-service beneficiaries using cardiac rehabilitation services in Sangamon County, Illinois (a primary care and mental health HPSA). During that same period, there were only two Sangamon County providers participating in Medicare Part A for cardiac rehabilitation services, resulting in a 441:1 ratio of beneficiaries to cardiac rehabilitation providers. Sangamon County had the worst beneficiary to cardiac rehabilitation provider ratio in the state, suggesting that teaching facilities in that HPSA would greatly benefit from additional FTE positions, more so than other HPSAs with relatively better beneficiary to provider ratios. Clearly, the needs for residency positions and full-time employees are not uniform across HPSAs, so hospitals should not be subject to a uniform cap. Instead, we ask CMS to rely on a detailed application process, and the demonstration of need hospitals must exhibit, in determining the total number of FTEs a hospital receives in any given application year. We recognize that the CAA's provisions will not allow CMS to provide every hospital with the resources needed to adequately address HPSAs, but imposing a seemingly random 1.0 FTE per hospital per year cap appears antithetical to the intentions of Congress.

### **Medicare Organ Transplantation Payments**

As CMS outlines in the proposed rule, Medicare financially supports organ transplantation, and has done so since the kidney acquisition policy implemented for kidney transplants following the Social Security Amendments of 1972 (Pub. L. 92-603). These amendments extended Medicare coverage to individuals with end-stage renal disease (ESRD) who required dialysis or transplantation. Payment policies covering kidney transplantation, organ procurement costs, and living donor expenses followed, including Medicare Part A and Part B benefits for the living donor. By design, the Medicare program provides what amounts to safety net compensation for the organ transplantation system by funding donor hospitals that excise organs for a variety of patients, including non-Medicare patients.

In the proposed rule, CMS aims to stop covering the cost of excising organs that do not go to Medicare beneficiaries, and to require donor community hospitals to track and verify insurance coverage for patients that receive the organs they excise. We understand why CMS wants to codify policies that limit Medicare organ transplantation costs to Medicare beneficiaries.

However, the proposed changes would dismantle an already under-resourced system that Americans rely on.

According to the United Network for Organ Sharing (UNOS), the shortage of suitable organs means only about 50% of people on the organ waiting list will receive an organ within five years.<sup>1</sup> Patients waiting for a deceased donor kidney wait an average 3.53 years while undergoing costly and life-threatening treatment to stay alive until a kidney is available. In fact, the lack of available organs prompted the previous administration to call for a doubling of kidneys available for transplant by 2030 under the 2019 Advancing America Kidney Health Executive Order.

The Advancing Organ Donation & Transplantation Alliance (The Alliance) estimates that CMS' payment changes would result in 1,771 (conservative) to 6,975 (significant) fewer donor organs per year, returning national volume of transplanted organs from deceased donors to 2016 numbers. Fewer donated organs will result in increased healthcare spending on services such as dialysis, with The Alliance estimating increased annual healthcare spending between \$85.6 million and \$337.6 million depending on a variety of factors that are impossible to predict. The estimated increase in healthcare spending could render the Medicare savings from this proposed rule moot in any given year, especially as The Alliance's analysis does not account for the increased costs in other sectors of the economy that postponed transplantation requires (e.g., reimbursement for home health aides, impact on workplace productivity, etc.).

Additionally, CMS' proposed changes will significantly increase administrative burden on donor community hospitals. The current payment process essentially assumes that recipients are Medicare beneficiaries. This was intentional, and incentivized hospitals with transplant centers to institute effective organ procurement programs. The proposed requirement to verify the insurance plan held by the organ recipient would increase administrative costs for the hospital excising the organ, many of which may not be able to afford to continue their organ transplant programs without Medicare wraparound funding. Further, it may be essentially impossible for providers to determine the insurance status of certain beneficiaries, as contrary to the assertions in the proposed rule, there is no established system for obtaining this information. Without a reliable system, obtaining evidence of Medicare liability will be time consuming and complex, especially when Medicare functions as a secondary payer.

Finally, as the U.S. healthcare sector continues educating itself and moving toward equity, these proposed changes may make hospitals more reliant on patients with private insurance. Unfortunately, by limiting Medicare funding, CMS is creating competition for resources between commercially insured living patients and potential donor patient payments. While we know our providers constantly strive to provide the highest quality care to patients regardless of payer, the proposed changes will create situations where patients and providers ultimately lose. Providers will be forced to make cost-driven choices that were not necessary in the past, such as forgoing excising organs altogether because the hospital is unable to cover costs based on payer mix of donors and receiving patients.

<sup>&</sup>lt;sup>1</sup> <u>https://transplantliving.org/before-the-transplant/waiting-for-your-transplant/</u>

IHA strongly urges CMS to study the potential impact of its proposed changes to the Medicare transplantation program. We ask that CMS refrain from implementing any of these changes pending the completion of a more thorough study of the potential ramifications of these policies. Should CMS ultimately move forward with these changes, we ask that CMS implement additional policies ensuring necessary funding for hospitals participating in organ transplantation in an effort to improve the organ transplantation system, support donor community hospitals, and minimize time spent on organ wait lists.

## Long-Term Care Hospital Site-Neutral Cases

IHA remains concerned about the impact of CMS' LTCH site-neutral payment policy on LTCH patients and providers. While Illinois is fortunate that no LTCH facilities closed since the implementation of the site-neutral policy, we echo 2020 comments from the American Hospital Association (AHA) that CMS' belief that LTCH site-neutral cases would eventually mirror the clinical and cost profiles of similar inpatient PPS cases has not materialized.

Since the implementation of the LTCH site-neutral payment policy in 2015, the overall number of Illinois LTCH cases decreased by 34.8% with significant drops occurring in 2019 when the blended payment rate was introduced (18% decrease between FFYs 2018 and 2019) and in 2020 (15% decrease between FFYs 2019 and 2020). The number of site neutral cases also decreased by 20.8%, with a significant 42.7% decrease in site-neutral cases in 2019. Additionally, Medicare payments to Illinois LTCHs decreased by 41.5% since FFY 2016. It is clear that the scale of the site-neutral cuts reduced overall LTCH case volume, which in turn is having a significant negative fiscal impact on Illinois LTCHs.

LTCHs play a critical role in providing care to some of our most critically ill patients. This is even more evident in the era of COVID-19. We are very concerned that the unintended consequences of CMS' site-neutral payment policy will significantly affect access to much needed services as the healthcare industry continues to treat COVID-19 long-haulers on top of the more traditional long-term care needs of the U.S. population. IHA urges CMS to continue tracking LTCH utilization, payment, and patient outcomes and reevaluate this policy should patient access and outcomes prove stifled.

# Inpatient Quality Reporting (IQR) and LTCH Quality Reporting Programs (QRPs)

# Public Reporting of IQR, Hospital Acquired Condition (HAC), Readmissions Reduction Program (RRP) and Value-Based Purchasing (VBP) Measures Impacted by COVID-19 Exemptions

On behalf of Illinois hospitals and health systems, IHA thanks CMS for the temporary quality reporting exemptions granted to providers for Q4 2019, Q1 2020 and Q2 2020. We agree with CMS' decision to freeze the data displayed on Care Compare with the December 2020 refresh values until the agency determines a way to adjust public data for the Public Health Emergency (PHE) and exempted reporting quarters in publicly displayed data. IHA supports and applauds CMS' thoughtfulness in creating its measure suppression policy. We urge CMS to consider making its measure suppression policy permanent as the U.S. healthcare system will likely face additional PHEs in the not-so-distant future. Having a plan in place that builds off lessons

learned during the COVID-19 PHE will allow both CMS and the hospital community to expend more resources on treating patients, rather than diverting attention toward creating policies that could already be in place.

To that end, we support CMS' proposals to suppress certain measures across the IQR, HAC, RRP and VBP programs. This includes support for the suppression of the RRP Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure for the FFY 2023 program year. However, we urge CMS to consider suppressing this measure for FFYs 2024 and 2025 as well because calendar year (CY) 2020 data would be included in those payment years.

## Changes to IQR Measures

IHA supports CMS' proposed removal of five IQR measures, including Death among Surgical Inpatients with Serious Treatable Conditions (CMS PSI-40); Exclusive Breast Milk Feeding (PC-05); Admit Decision Time to ED Departure Time for Admitted Patients (ED-2); Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK-03); and Discharged on Statin Medication (STK-06).

CMS also proposed adding five measures to the IQR, including a Maternal Morbidity Structural Measure; Hybrid Hospital-Wide All-Cause Risk Standardized Mortality with Claims and Electronic Health Record Data (NQF #3502); COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP); Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e); and Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e). We appreciate the three proposed NQF endorsed measures. Below we discuss our concerns about the proposed Maternal Morbidity and COVID-19 Vaccination measures.

<u>Maternal Morbidity Structural Measure</u>: IHA supports CMS' commitment to addressing rising maternal morbidity and mortality rates. The latest data from the Centers for Disease Control and Prevention (CDC) show that America's mothers continue to face significant challenges in every phase of childbirth. The 2019 maternal mortality rate was 20.1 deaths per 100,000 live births, a rate that is significantly higher than 2018's 17.4 deaths per 100,000 live births. Non-Hispanic Black mothers and mothers aged 40 and older face even higher mortality rates, at 44.0 and 75.5 deaths per 100,000 respectively (166.5 deaths per 100,000 for Non-Hispanic Black mothers aged 40 and older).<sup>2</sup> In Illinois, the pregnancy-associated mortality ratio is even more dire with 58 deaths per 100,000 live births. Again, the mortality rate is worse for Black mothers (142 deaths per 100,000 live births) and mothers aged 40 and older (89 deaths per 100,000 live births).<sup>3</sup>

The data show that the most dangerous periods for mothers are during pregnancy and 43 to 365 days postpartum.<sup>4</sup> That is why IHA is pleased and supportive of Illinois' decision to be the first state to extend continuous eligibility for full Medicaid benefits from 60 days to 12 months postpartum. Illinois also has a Perinatal Quality Collaborative that is planning a Birth Equity

<sup>&</sup>lt;sup>2</sup> www.cdc.gov/nchs/data/hestat/maternal-mortality-2021/E-Stat-Maternal-Mortality-Rates-H.pdf

<sup>&</sup>lt;sup>3</sup> www.dph.illinois.gov/sites/default/files/maternalmorbiditymortalityreport0421.pdf

<sup>&</sup>lt;sup>4</sup> <u>www.cdc.gov/reproductivehealth/maternal-mortality-erase-mm/mmr-data-brief.html</u>

Initiative for birthing hospitals to address bias, racism, and social factors influencing maternal health. To date, approximately 75% of Illinois' birthing hospitals plan to participate in this initiative.

We appreciate that CMS wants to ensure hospitals are engaging in quality improvement (QI) collaborative programs like those in Illinois. However, a structural measure simply requiring hospital attestation to participating in a QI initiative and implementing safety practices does not seem to add much value to this conversation. Unfortunately, the measure put forth by CMS does not measure the effectiveness of the policies and procedures hospitals are utilizing to address maternal morbidity and mortality, which may result in resources invested in programs and initiatives that do not address the root causes of these issues.

Instead of implementing this particular measure, IHA urges CMS to invest resources in the development of outcomes measures. It is likely that such measures will require more resources and action from hospitals than the measure proposed in this rule. However, our hospitals want meaningful measures that provide real insights and lead to improved health outcomes and health equity, even if they require more work to report. CMS has been moving away from process and structural measures toward outcomes measures, and IHA urges CMS to continue down that path when it comes to maternal mortality. The stakes are simply too high to rely on measures that yield little value in improving outcomes for America's mothers.

<u>COVID-19 Vaccination among HCP Measure</u>: IHA appreciates the process CMS went through to assure the validity of the proposed COVID-19 Vaccination among HCP measure. Illinois hospitals look forward to full U.S. Food & Drug Administration (FDA) approval of the various COVID-19 vaccinations on the market, and IHA urges CMS to continue pursuing full National Quality Forum (NQF) endorsement of the COVID-19 Vaccination among HCP measure in the coming months. While CMS has the authority to include measures in the IRF QRP that are not NQF-endorsed, securing NQF endorsement is typically required when creating and implementing measures for the Medicare QRPs. We believe NQF endorsement of this measure is especially important because we agree with CMS that patients, particularly those most vulnerable to COVID-19, will consider the vaccination rate among HCP when deciding where to pursue medical services in the future. Providing such information through an NQF-endorsed measure affords patients greater certainty that the information they rely on is fully vetted and reliable.

### Transfer of Health (TOH) Information to the Patient Post-Acute Care (TOH-Patient)

IHA supports CMS' proposal to remove patients discharged to the home under the care of a home health agency or hospice from the TOH-Patient measure utilized in the LTCH QRP. We appreciate CMS' continued review of measures used in its various Medicare QRPs to make changes that mitigate unnecessary provider burden.

# Definition of Digital Quality Measures (dQMs) and Request for Information on Fast Healthcare Interoperability Resource (FHIR)

IHA appreciates CMS' tireless work to improve its quality programs and move toward more meaningful quality measurement. In this proposed rule, CMS requested feedback on the following definition of dQMs:

dQMs are quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. A dQM includes a calculation that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patientgenerated health data), health information exchanges (HIEs) or registries, and other sources.

This proposed definition includes a long list of potential sources of digital data, and does not appear tailored to any particular healthcare service, provider type, patient type, or environment. While we appreciate that the Meaningful Measures 2.0 initiative is meant to innovate and modernize quality measurement across a wide variety of settings, we question whether such a broad definition allows CMS to utilize only the most valuable and impactful quality measures. We also question how this definition improves upon today's quality reporting program, beyond the fact that measures will be digital. We believe a more specific definition would provide CMS and healthcare providers greater direction in the quality space, allowing for more effective measures and meaningful insights. We respectfully ask CMS to revisit this definition of dQMs and create a more focused path forward.

With regard to use of FHIR-based standards, IHA generally agrees that electronic exchange of clinical information may lead to improved health and quality outcomes. However, fully moving to dQMs by 2025 is an ambitious goal, particularly because the adoption of health information technology is not uniform across provider settings. For example, many PAC providers lagged behind their acute care hospital counterparts on the path toward digitization even before the COVID-19 pandemic, primarily because PAC providers could not participate in the Electronic Health Record (EHR) incentive program established under the HITECH Act. As healthcare providers build back from the COVID-19 PHE, they will need increased time and resources to move toward CMS' goal of a fully digital electronic health information system. To that end, we ask CMS to reconsider its timeline, and the monetary and technical assistance available, for providers to adopt the technologies necessary to realize the goals of the Meaningful Measures 2.0 initiative, including FHIR-based standards.

Finally, Illinois hospitals and health systems have expressed difficulties with the myriad standards and formats used by various stakeholders to electronically capture and exchange information. IHA is pleased to see that CMS intends to foster greater public and private alignment around measure topics and specifications. To that end, we encourage CMS to be more specific about their vision and goals for this alignment. Providing a roadmap to ensure consistency in formatting and process across providers, vendors and payers will set industry

expectations, lessen provider burden, and better equip the healthcare industry to realize improved communications and health outcomes.

# New Technology Add-On Payments (NTAPs)

IHA supports CMS' proposed one-year extension of NTAPs for the 14 technologies that are set to expire in FFY 2022 (Azedra<sup>®</sup>, Cablivi<sup>®</sup>, Elzonris<sup>™</sup>, AndexXa<sup>™</sup>, Spravato<sup>®</sup>, Zemdri<sup>®</sup>, T2 Bacteria<sup>®</sup> Panel, ContaCT, Eluvia<sup>™</sup> Drug-Eluting Vascular Stent System, Hemospray<sup>®</sup>, IMFINZI<sup>®</sup>/TECENTRIQ<sup>®</sup>, NUZYRA<sup>®</sup>, SpineJack<sup>®</sup> System and Xospata<sup>®</sup>). We agree that using FFY 2019 data to develop FFY 2022 relative weights makes it illogical to discontinue NTAPs for these products at this time.

Similarly, IHA supports CMS' proposal to extend the New COVID-19 Treatments Add-on Payment (NCTAP) for eligible products through the end of the FFY in which the COVID-19 PHE ends. We agree that NCTAPs should end once a product receives NTAP approval.

# Use of 2018 S-10 Data

Consistent with our FFY 2021 IPPS comments, we respectfully suggest that CMS work to expand the number of hospitals included in Medicare Cost Report Worksheet S-10 audits. Several of our audited hospitals experienced significant changes to their worksheet S-10 data, and we are unsure how CMS extrapolates the results of a limited number of audits to the universe of Medicare DSH-eligible hospitals. Expanding the pool of audits would yield results that are more representative of all Medicare DSH-eligible hospitals and provide more consistency year over year ensuring that hospitals do not face dramatic swings in payment year to year.

Ms. Brooks-LaSure, thank you again for the opportunity to comment on this proposed rule. Please direct questions or comments to Cassie Yarbrough, Senior Director, Medicare Policy, at 630-276-5516 or <u>cyarbrough@team-iha.org</u>.

Sincerely,

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