Illinois Health and Hospital Association

September 17, 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: CY 2022 Outpatient PPS Proposed Rule (CMS-1753-P)

Dear Administrator 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 calendar year (CY) 2022 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) proposed rule. IHA thanks the Centers for Medicare & Medicaid Services (CMS) for its thorough analysis in the development of this rule, and we especially welcome the opportunity to comment on certain COVID-19 public health emergency (PHE) waivers that, if made permanent, will undoubtedly increase access to care, impacting certain health disparities that the Biden administration has promised to address.

Additionally, IHA and Illinois' hospitals welcome the opportunity to work with CMS toward a more equitable future. Suboptimal health is often the result of inadequate access to living wages, sufficient housing, good nutrition, quality education, and other social services. There is much we can do in the healthcare community to support the work our social services partners are doing, including through Medicare policies that directly affect access to items and services. With this in mind, we submit the following comments for CMS' consideration.

Hospital Price Transparency

Increased Civil Monetary Penalties (CMPs)

IHA understands that many hospitals have not achieved full compliance with CMS' hospital price transparency final rule. Illinois hospitals have invested significant resources, working diligently to comply with CMS requirements. Because we are still in the first year of required price transparency reporting, we believe that increased CMPs are premature. Before increasing fines, we urge CMS to work through its audit process to help hospitals achieve compliance. It is our understanding that hospitals that have received letters of noncompliance disclose required information thereafter, suggesting

that current CMPs are high enough to encourage compliance. Additionally, we appreciate recent price transparency education provided by CMS via webinar, as there are several sections in the hospital price transparency final rule that would benefit from additional clarification. For example, the final rule did not provide sufficient clarity around how hospitals should treat items and services offered by employed physicians and non-physician professionals that bill independently from the hospital chargemaster. As explained in past IHA comments, physicians are often employed through a separate affiliated corporation and not part of the licensed hospital. Therefore, such physicians would not be included in the various required price transparency files, and accurate comparisons across hospitals of the overall charge for a procedure would not be possible.[1] **IHA members have indicated that additional education opportunities would be helpful as they work toward full compliance. CMS can facilitate and help expedite the compliance process through the provision of education and technical assistance as opposed to coercive CMPs.**

Should CMS move forward with its proposal to increase CMPs, we request the finalized amounts be lower than proposed. Increasing the annual total CMP from a maximum of $109,500 to a range of $109,500 to $2,007,500 per hospital seems inappropriate given the ongoing pandemic and its relentless demand on hospitals' resources. Many hospitals in Illinois have dealt with several surges of COVID-19 over the past year. Furthermore, hospitals in our state are not immune to the hiring challenges felt by other industries. In addition to clinical personnel shortages, our hospitals have experienced administrative personnel shortages. Thus, **we urge CMS not to finalize its proposed increase in CMPs at a time when hospitals continue to stretch resources as they serve on the front lines of the COVID-19 pandemic.**

Alternatively, CMS should adopt factors that, if met, would allow a hospital to reduce the proposed CMPs. The automation and final product necessary for full compliance may require the establishment or restructuring of information technology systems and processes that were not previously in place, all while providing care to patients. The lack of full compliance may be easy to assess from a distance but the gap hospitals have to bridge to become fully compliant varies. While CMS has a legitimate interest in imposing penalties for willful non-compliance, it is our opinion that most hospitals are making good faith efforts and CMS should not punish them as if they have not. Furthermore, as previously stated, this time in history has made unexpected and extraordinary demands on hospital resources. CMS should take into consideration the availability of hospitals' resources to devote to full compliance. Finally, in recognition that the information technology focus of hospitals varies, progress toward compliance on a timeline tailored to a particular hospital is more appropriate than full compliance by a date disconnected from the reality of a hospital's infrastructure. Thus, **we urge CMS to adopt factors such as intent/good faith, availability of resources, and progress towards CMS and hospital's mutually agreeable milestones as factors that reduce the proposed CMPs**.

[1] https://www.team-iha.org/files/non-gated/finance/opps-price-transparency-comments.aspx

Deeming state forensic hospitals meeting certain requirements as complaint
IHA supports CMS' proposal to deem state forensic hospitals as compliant with transparency requirements if they meet certain requirements. We agree that such hospitals do not provide items and services to patients that would benefit from the ability to shop across providers. As CMS explains, state forensic hospitals have specialized patient populations, are not open to the general public, and do not negotiate their reimbursement rates. Therefore, we agree that it does not make sense to subject state forensic hospitals to the administrative burden necessary to comply with this rule.

Clarifying output expectations for hospital online price estimator tools
IHA appreciates CMS' clarifications regarding the necessary output of a compliant online price estimator tool. Indeed, such tools appear much more useful to consumers than either a consumer-friendly database or the machine-readable file. However, we are concerned with CMS' expectation that "it is important for the hospital to select and offer a price estimator tool that provides a single dollar amount that is *tailored to the individual seeking the estimate, taking the individual's circumstances into consideration when developing the estimate*" (emphasis added).

This statement suggests CMS expects hospitals to connect their online price estimator with contracted payers and related plans. However, in the hospital price transparency final rule, CMS stated "we encourage, but will not require in this final rule, that hospitals provide appropriate disclaimers in their price estimator tools, including acknowledging the limitation of the estimation and advising the user to consult, as applicable, with his or her health insurer to confirm individual payment responsibilities and remaining deductible balances." Thus, the final rule appears to account for the lack of real-time communication between a hospital's price estimator tool and various payers. Establishing such a connection is costly, with industry leaders suggesting a real-time link with a payer requires not only the technological ability to query the patient's plan for cost-sharing and deductible information, but also comes with associated fees for each query made via the tool.

Given the disconnect between the CY 2022 OPPS proposed rule and the hospital price transparency final rule, we ask CMS to clarify what it envisions when it asks for "tailored" estimates. **If CMS does envision real-time communication between price estimator tools and payers, we strongly urge CMS to reconsider its position. Concerns over feasibility of provider-payer communications under the No Surprises Act led the U.S. Department of Health and Human Services to delay enforcement of requirements to provide insured patients with good faith estimates and advanced explanation of benefits.[2] Additionally, the cost associated with real-time communication will impede many hospitals from providing a web-based price estimator tool, and such hospitals will default to providing a consumer-friendly database to**

[2] https://www.hhs.gov/guidance/document/faqs-about-affordable-care-act-and-consolidated-appropriations-act-2021-implementation

achieve compliance. We believe consumers will find databases harder to use and understand compared with price estimator tools, and thus CMS will inadvertently be working against its own goals of making medical billing more transparent and easier to understand.

Payment for Drugs Acquired under the 340B Program

IHA is disappointed that CMS will continue paying for 340B drugs and biologicals at average sales price (ASP) minus 22.5%. As expressed in past comments on this topic, we believe this reimbursement policy is contrary to Congress' intent when it created the 340B program. Furthermore, this policy is inconsistent with OPPS statute requiring HHS to reimburse hospitals for covered outpatient drugs at ASP plus 6%.

Beyond these two arguments, we are surprised that CMS would continue this payment policy given the COVID-19 PHE and this administration's commitment to addressing health equity. In Illinois, 44% of 340B hospitals are critical access hospitals serving rural communities, and 15% are safety net hospitals serving primarily low-income patients. These hospitals serve communities that are not only disproportionately impacted by the COVID-19 PHE, but also have worse outcomes in general including lower life expectancy, higher rates of diabetes and heart disease, and increased risk of negative maternal health outcomes. In Illinois, 340B hospitals use program revenue to increase access to lifesaving medical care such as free mammograms, as well as other vital wellness services including school physicals, transportation to and from medical appointments, and oral health services via mobile dental clinics at low or no cost to patients. 340B hospitals also connect patients with other vital resources that contribute to health, including housing, nutrition services, and labor opportunities. With this reimbursement cut, CMS is exacerbating longstanding inequities in the communities 340B hospitals serve by decreasing available funding for these services.

We also suggest CMS reevaluate the budget neutrality factor used when CMS made this policy change. When CMS decreased 340B reimbursement, it did so in a budget neutral manner. Unfortunately, it appears CMS has not adjusted this budget neutrality factor over time to reflect changes in inflation or 340B drug utilization. Rather, it is our understanding that CMS continues to use the estimated dollar amount impact from when this policy was first enacted. Should CMS decline to pay for 340B drugs at ASP + 6%, it should update the 340B budget neutrality factor over time. We estimate the current net impact of the 340B budget neutrality factor at an estimated negative $558 million across the U.S., and a negative $1.7 million in Illinois.[3] Clearly, the long-term effect of the 340B reimbursement decrease is not budget neutral, resulting in a double hit for many of the hospitals serving our most vulnerable communities.

[3] Analysis based on 2019 Standard Analytic File OPPS claims.

CMS should immediately reverse its policy, restoring 340B reimbursement to ASP + 6%. Absent such action, CMS should reevaluate its budget neutrality factor annually to reflect updated utilization and inflation factors.

Comment Solicitation on Temporary Policies for the COVID-19 PHE

IHA urges CMS to make permanent certain policies enacted during the COVID-19 PHE. These policies expand access to care for Illinoisans, particularly in communities that are historically underserved and continue to be disproportionately impacted by COVID-19. We respond to CMS' specific requests for information (RFI) below.

RFI: The extent to which hospitals have billed for mental health services provided to beneficiaries in their homes through communications technology during the PHE, and whether hospitals anticipate continuing demand for this model of care following the conclusion of the PHE.

IHA supports continuing to allow beneficiaries to utilize mental health services from their homes via communications technology or telehealth. One of Illinois' health systems, AMITA Health, is now providing two-thirds of its partial hospitalization program for behavioral health via virtual appointments. Additionally, in recent surveys more than 71% of Illinois hospital provider respondents and 78% of community-based behavioral healthcare professional respondents reported that telehealth has helped drive a reduction in the rates at which patients missed appointments. **We urge CMS to make permanent the use of telecommunications technology, including audio-only telehealth as determined appropriate by healthcare professionals, to increase access to vital mental health services.** Telehealth facilitates high quality, clinically appropriate mental healthcare, and CMS should not only extend this allowance beyond the PHE but also expand modalities it will reimburse under the Medicare program.

RFI: The extent to which hospitals used virtual presence through audio/video real-time communications technology to fulfill direct supervision requirements for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, and whether CMS should continue to allow the provision of direct supervision for these services using audio/video real-time communications.

IHA supports CMS making permanent the PHE waiver allowing direct supervision for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services via audio/video real-time communications technology. We supported this same proposal in our comments on the CY 2021 OPPS proposed rule.[4] This policy allows better access to cardiac rehabilitation services for beneficiaries in underserved areas of Illinois, particularly low-income and rural communities.

[4] https://www.team-iha.org/files/non-gated/advocacy/cy-2021-opps-comments.aspx?ext=.pdf

RFI: Whether CMS should keep HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and associated OPPS payments active beyond the conclusion of the COVID-19 PHE.

IHA encourages CMS to keep HCPCS code C9803 and associated OPPS payments active beyond the conclusion of the COVID-19 PHE. There is no reason to believe SARS-CoV-2 and COVID-19 will cease to be a significant part of hospitals' caseloads in the near future, and given the unpredictable nature of this virus, it is likely we will experience localized surges for several years. Keeping current coding and payment policies will minimize future administrative burden by maintaining billing consistency.

Site-neutral Payment Policies for Off-campus Provider-Based Departments (PBDs)

IHA appreciates CMS' recent announcement rescinding prior audit denials for hospitals that failed to qualify for the "mid-build" exception, allowing the agency to review previous determinations. That said, we continue to be concerned that this decreased reimbursement rate may ultimately lead to reduced access to care. We do not yet have the data to examine the impact of CMS' decreased reimbursement rate for hospital outpatient clinic visits furnished at excepted off-campus PBDs, but **we implore the agency to carefully examine the effect of reimbursing such providers at 40% of the OPPS rate over the coming years.** Many Illinois off-campus PBDs serve underserved communities, providing access to services that would otherwise not exist. We know that low reimbursement can lead to provider or service line closures, particularly in areas where patients predominantly rely on Medicare or Medicaid for insurance. Currently underserved communities, which the Biden administration is appropriately focused on, suffer the most from continued reimbursement cuts. Thus, we urge the administration to be diligent in its examination of potential unintended consequences of reimbursement changes such as this.

Changes to the Inpatient-Only List (IPO)

IHA supports CMS' proposal to halt the elimination of the IPO list, and to return codes removed from the IPO list in CY 2021 to the list beginning CY 2022. We also support CMS' proposal to codify its five criteria for assessing the removal of codes from the IPO list.

IHA agrees with comments opposed to removing the IPO list. Consistent with our CY 2021 comments, there are certain services that clearly require inpatient care for Medicare beneficiaries, despite advances in medical knowledge and technology. As CMS states, the IPO list plays an important role in protecting Medicare beneficiaries, over half of whom are medically fragile with two or more comorbidities.[5]

[5] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf

Codifying CMS' criteria for assessing the removal of codes from the IPO list ensures that future administrations will be unable to erase decades of policy without due diligence. We agree it is important to regularly revisit policies to ensure they reflect progress and remain efficient. CMS' criteria allow for that reflection while ensuring outpatient departments and ASCs are equipped to provide safe and appropriate medical care.

Medical Review of Certain Inpatient Hospital Admissions (2-Midnight Policy Change)

In addition to supporting CMS' proposal to reinstate the IPO list, **IHA supports CMS' proposal to preserve the two-year exemption from 2-midnight medical review activities for services removed from the IPO list on or after Jan. 1, 2021.** This reversal in CMS policy aligns with the reinstatement of the IPO list. Additionally, we feel it is important for CMS and Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) to provide education to providers as services are removed from the IPO list. Such education ensures provider understanding, increases compliance, and ultimately protects Medicare beneficiaries.

Proposed Changes to ASC-Covered Procedures List (CPL)

IHA supports CMS' proposal to restore ASC CPL provisions and exclusionary criteria. Similar to our comment above regarding the IPO list, we believe that the previous administration's changes to both the IPO list and the ASC CPL were ultimately detrimental to patient safety. While it may be appropriate to remove some services from the IPO list and add them to the ASC CPL, CMS' ASC CPL provisions and exclusionary criteria do not preclude that from happening. In fact, CMS' ASC CPL provisions and exclusionary criteria maximize patient access in a safe and appropriate manner for Medicare beneficiaries. **The reinstatement of the 2-midnight medical review policy and CMS' reversal of CY 2021 IPO and ASC CPL decisions put the safety of Medicare beneficiaries first by ensuring procedures are performed at sites that are equipped to provide the highest quality care.**

Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Tests

IHA supports CMS' use of this proposed rule to implement colorectal cancer screening coinsurance provisions established in the Consolidated Appropriations Act, 2021 (CAA). Waiving patient coinsurance beginning Jan. 1, 2022 for screening flexible sigmoidoscopies and screening colonoscopies is an important beneficiary protection and consistent with current surprise billing initiatives under this administration. According to the Centers for Disease Control and Prevention, the rate of new colon and rectum cancer cases in Illinois is higher than the U.S. average at 40.6 per 100,000 people compared to 37 per 100,000 people nationally. This fact together with recent recommendations from the U.S. Preventive Services Taskforce for expanded screening[6] highlights the importance of increased patient access, and Illinois hospitals support Congress' decision to waive patient cost sharing for colorectal cancer screenings.

[6] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening

Low Volume Policy for Clinical, Brachytherapy, and New Technology APCs

IHA supports CMS' proposal to designate clinical, brachytherapy and New Technology APCs with fewer than 100 single claims in the year used for rate-setting as low volume APCs. We agree that the use of up to four years of claims data to establish payment rates for low volume items and services will minimize unpredictability in payment. IHA also appreciates CMS' proposal to reimburse the higher of either the median, arithmetic mean, or geometric mean based on pooled claims data. **We urge CMS to finalize its proposed low volume policy for clinical, brachytherapy, and new technology APCs.**

Request for Information on Rural Emergency Hospitals

IHA appreciates CMS' engagement with stakeholders on creating conditions of participation (CoPs) to govern rural emergency hospitals (REHs). However, we cannot provide meaningful comments on potential CoPs until Medicaid payment methodologies are established. Illinois' small and rural hospitals rely more on government payers than other hospitals in our state, with Medicare and Medicaid serving as the primary payer for 58% of outpatients. In fact, almost a quarter of patients utilizing services at small and rural hospitals have Medicaid as their primary insurance.[7] Thus, payment methodologies from government payers is paramount for Illinois providers considering the REH model. We urge CMS to work with states to establish comprehensive payment methodologies, and address the outstanding questions on payment in this proposed rule, before establishing CoPs or other operational details.

COVID-19 Vaccination among HCP Measure

IHA appreciates the process CMS went through to assure the validity of the proposed COVID-19 Vaccination among HCP measure. Now that the U.S. Food & Drug Administration (FDA) has granted full approval to certain COVID-19 vaccinations on the market, **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 collect quality data for measures that are not NQF-endorsed, we believe securing NQF endorsement is an important standard lending credibility to CMS' Medicare quality programs. 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.

Health Equity

IHA appreciates CMS' and the Biden administration's focus on health equity, as demonstrated by many of our comments above. Regarding CMS' request for comments on expanding the agency's efforts to address disparities through data collection and outcomes measurement, we

[7] Illinois Health and Hospital Association. Advancing Rural Health in Communities Across Illinois. 2018. Available from: www.team-iha.org.

welcome the opportunity to work with CMS and other organizations currently examining health equity to determine the optimal methods and processes to collect and utilize data leading to more equitable health outcomes. Specifically, we urge CMS to first consider determining the process steps providers might take to 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 necessary preliminary step to real change.

CMS may also 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 to 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.

Administrator 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 cyarbrough@team-iha.org.

Sincerely,

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