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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: Comments on Proposed Rule CMS-1753-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Administrator Brooks-LaSure:

On behalf of our more than 150 member hospitals and integrated health systems, the Wisconsin Hospital Association (WHA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed 2022 rule related to the Medicare Program Hospital Outpatient Prospective Payment Systems.

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small Critical Access Hospitals, mid, and large-sized academic medical centers. We have hospitals in every part of the state—from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

# CMS should not increase Civil Monetary Penalties for its Price Transparency Rule

WHA and our members have long supported transparency. We have been voluntarily reporting hospital price information through a website called PricePoint since 2004. PricePoint provides complete, accurate and timely inpatient and outpatient data about charges and services provided by Wisconsin hospitals and ambulatory surgery centers. Every hospital in Wisconsin voluntarily participates in PricePoint, and it is licensed for use in ten additional states. In addition to PricePoint, Wisconsin hospitals have increasingly been developing consumer tools that help give consumers better information about their expected charges and out-of-pocket costs.

WHA has previously noted that the Price Transparency Rule is a one-size-fits-all mandate that fails to recognize the significant strides hospitals have made in providing consumers with useful information. We previously encouraged CMS to take a more cooperative rather than adversarial approach, given that the industry is already largely embracing transparency in response to consumer demand. We further noted that the type of information required by CMS in machine-readable files is unlikely to provide meaningful information to patients and that it is difficult for hospitals to compile the information requested since CMS has based everything around a chargemaster that is often not utilized when negotiating rates with insurers. The vast majority of consumers will not be able to meaningfully shop around with the information submitted by hospitals because, even if they can understand the machine-readable files, they are locked into the provider network negotiated by their insurance plan. For this reason, we have always advocated for the onus to be on the health insurance plans to provide consumers with the information that will allow them to understand both overall costs and their share of costs, since the insurer is the only entity with such information on hand. The Transparency in Coverage Rule issued by CMS seemed to recognize this in requiring this information to come from insurers.

However, while hospitals had only a year to set up complex machine-readable files or face civil monetary penalties (CMPs), CMS has chosen to be much more lenient on health insurers. In fact, in a recent <u>FAQ</u> <u>document</u>, CMS announced it would be delaying the effective date of enforcement for insurers to provide machine readable files containing information about drug pricing data and in and out-of-network billed charges to give insurers more time to prepare for implementation.

However, in this rule, CMS proposes to *increase* civil monetary penalties for hospital violations from \$300 per day (up to \$109,500 per year) to up to \$5,500 per day (or a maximum of more than \$2 million per year) for hospitals with up to 550 beds. This is an increase of over 1700 percent! It is very troubling that CMS would place this significant additional burden on hospitals and threaten to increase their fines for not adhering to strict compliance while at the same time delaying similar transparency provisions for insurers. While WHA and our members have worked diligently to comply, we remain even more convinced that the ultimate goal of this rule – providing consumers with meaningful information – is not being served. We oppose the proposal to arbitrarily increase penalties to hospitals, while at the same time delaying the effective date for insurers

#### Medicare Area Wage Index

The area wage index is designed to adjust payments based on local differences in labor costs. WHA has often noted concerns about manipulation of the Medicare Area Wage Index in the prospective payment system. CMS has echoed these concerns in recent proposed rules, noting that results of making the rural floor budget neutral on a national basis, as required by the Patient Protection and Affordable Care Act Section 3141, is that all hospitals in some states receive an artificial wage index that is higher than the what the single highest urban hospital wage index would otherwise be. WHA has previously joined with associations in other states to garner support from Congress to address this patently unfair payment manipulation, which has specifically benefited hospitals in states on the east and west coasts and has been commonly referred to as the "Bay State Boondoggle."

WHA applauds CMS for continuing policies designed to restore fairness to the wage index, such as bringing up those hospitals in the bottom quartile and excluding urban hospitals that reclassify as rural from the overall calculation of each state's rural floor. WHA opposed efforts by Congress to manipulate the rural floor by restoring the imputed rural floor for all-urban states. It was unfortunate that Congress included this blatant earmark in the American Rescue Plan Act of 2021, as it will unfairly manipulate the wage index to benefit only 3 states. We understand that they purposely did not apply budget neutrality to the restoration of this policy, in order to hold other states harmless. However, we still feel that this policy is unfair; with the Medicare Trust Fund facing more solvency concerns than ever, states should not be artificially steering a finite amount of Medicare taxpayer dollars by manipulating Medicare payment formulas.

More than ever, this shows the need for CMS to accelerate opportunities to pay Medicare services based on outcomes and the value of care provided. Wisconsin hospitals receive only 73% of costs from Medicare while the national average is closer to 87% of cost. While Medicare should be focusing on incentivizing and rewarding states like Wisconsin, payment policies such as this all too often create perverse disincentives to provide such care. Wisconsin hospitals and health systems continue to pursue high quality, high value health care and we continue to support CMS finding ways to correct past manipulations of the Medicare payment system in favor of incentivizing high-quality, high-value care.

# WHA Continues to Oppose "Site-Neutral" Payment Cuts

In the 2022 rule, CMS proposes to continue the prior policy of making payments for clinic visit services in grandfathered off-campus HOPDs at the physician fee schedule rate of 40% of the OPPS rate. WHA expressed its displeasure in prior OPPS rules and was joined by members of Wisconsin's Congressional Delegation in asking CMS to abandon this proposal that goes against the clear wishes of Congress. While CMS has cited unnecessary utilization, this contradicts past statements from CMS that recognized hospitals face a higher regulatory burden, serve sicker, more complex patients, must run 24/7 Emergency Departments, and thus face higher costs for which they are not adequately reimbursed.

WHA was relieved to see U.S. District Judge Rosemary M. Collyer rule in hospitals' favor initially in the lawsuit filed by the American Hospital Association, but troubled to see HHS successfully appeal the decision with the appeals court granting CMS wide deference based on past decisions rather than taking up the merits of the policy. We were further discouraged that the U.S. Supreme Court declined to review the appeals court decision.

We continue to have concerns that this policy will be detrimental to the lager picture of keeping care inside local communities. It is important to note that many of these HOPDs were purchased by hospitals to help keep access to care in their local communities when independent physician practices were at risk of closure due to poor payor mixes and low rates paid by the physician fee schedule. Requiring HOPDs to accept these lower rates will again jeopardize their ability to sustain access to care where it is needed most. Furthermore, given that many of these hospitals are dealing with additional losses due to COVID-19, we strongly believe HHS should reverse this unfair policy.

#### WHA Continues to Oppose 340B Reimbursement Cuts

HHS proposes to continue the cuts first proposed in the 2018 OPPS rule of minus 22.5% for 340B drugs. WHA continues to oppose these cuts, noting that the savings hospitals receive in discounts from drug companies participating in the 340B program were designed to help hospitals "stretch scarce federal resources as far as possible."

Furthermore, like the site-neutral policy, these cuts have been found to be unlawful by the courts, only to have such decisions overturned on appeal again based on judicial precedent giving agencies wide deference in interpreting statutes rather than taking up the merits of the case. Unlike the site-neutral decision, however, the U.S. Supreme Court has decided to take up this case in the fall of 2021. Given how controversial this policy by CMS has been and continues to be, WHA again calls on CMS to reverse these harmful payment cuts, or at least pause them until the Supreme Court has the opportunity to rule on the case in front of it.

# **Inpatient Only List**

CMS proposes to reverse the decision finalized in the 2021 OPPS rule to remove 298 services from the inpatient only list and further study this matter.

In WHA's comment letter regarding this proposed change in the 2021 rule, we urged CMS to take a more wholesale approach to understanding the impact of specific policies like this. It is important to recognize that hospitals care for the most vulnerable and most ill or medically complex patients even when certain care or procedures may be available in other settings. While WHA has consistently supported reducing regulations on hospitals and providers and allowing them to rely on clinical judgment to meet patient care needs, CMS has too often been unaware of the broader policy impacts of what might seem like narrow policy decisions.

In addition to the obvious concerns about patient safety which CMS now appears to be more concerned about, it is important to recognize what downstream impacts these changes have in regard to services hospitals can offer given disparities in payments. For instance, CMS must consider how changes such as this could lead to cherry picking of easier patients or more lucrative services in other settings, and how that might leave hospitals with worse patient-mixes that impact their ability to offer service lines they are not adequately reimbursed for (behavioral health being the most obvious example). As patient care evolves, CMS must also realign payment for hospitals so that losses from government programs like Medicare and Medicaid are not exacerbated by these changes and are not detrimental to the services hospitals can continue to offer their communities.

# WHA Supports Continued Regulatory Flexibility Past the End of the Public Health Emergency

WHA appreciates that CMS is raising the question of continuing regulatory flexibility beyond the expiration of the public health emergency. WHA has long supported flexibility for regulations that are detrimental to patient care and unnecessarily increases costs on hospitals. The COVID-19 pandemic was a proof-of-concept that these flexibilities can be effectively and safely utilized.

For instance, telehealth has been a lifeline to patients during the pandemic, and hospitals have been able to utilize telehealth services and capabilities to provide care in a variety of circumstances. Mental health services are one of the key areas that we continue to hear overwhelmingly positive feedback from our members and elected officials. Now that patients have been able to enjoy these services outside of the physical hospital setting, they do not want to have to go back to receiving them only in-person once the public-health emergency ends. Additionally, providers have reported fewer missed visits (leading to an increase in productivity) and better patient satisfaction scores.

Additionally, WHA has often highlighted the unnecessary requirements surrounding direct supervision and urged for greater flexibility by CMS. WHA supports continuing this flexibility beyond the expiration of the PHE. We have consistently viewed telehealth as simply another means of providing health care and believe continuing a direct supervision virtual option would be in line with such a philosophy. Furthermore, WHA continues to advocate at the federal level for a permanent end to Medicare's statutory geographic and site restrictions, and these proposals by CMS to continue utilizing flexibilities would harmonize CMS policies with where we hope Congress goes.

# Reporting of Health Care Personnel (HCP) COVID-19 Vaccination Should be Optional, not Mandatory

WHA and its members have gone to great lengths to both encourage and administer vaccinations for health care staff and the general public. However, it is premature for CMS to require the reporting of this measure for HCP, as it proposed in the 2021 IPPS rule. CMS relies heavily on its experience with influenza vaccinations as rationale for the reporting of COVID vaccination status. However, it is not yet known whether the COVID vaccines will follow the same path as the flu vaccines have. In fact, there are still many unknowns about the future course COVID-19 will take and how that will impact vaccines and their availability.

This measure is also not yet endorsed by the National Quality Forum. It is also important to note that only the Pfizer vaccine has been fully approved via the FDA, and others remain under the emergency use authorization. Additionally, more guidance will be required now that booster shots will be counted as a completion of a series.

CMS should keep the reporting of this measure optional for FY2022 while it continues to study these unresolved questions and evaluate ways to reduce duplicative reporting and align any requirements with other federal guidelines hospitals already comply with.

# WHA Does not Support Required Reporting of Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)

In this rule, CMS proposes to require reporting of five measures based on the OAS CAHPS survey beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period. If finalized, all locations (on or off-campus) of each eligible Medicare participating hospital that offers outpatient services or ASC would be required to participate in the OAS CAHPS survey unless they have fewer than 60 survey-eligible patients during the year preceding the data collection period.

WHA has concerns that this survey may overlap with other surveys sent to patients from providers and surgeons and will likely confuse patients. Patient experience results will then not be considered reliable and unfortunately costly to hospitals given such invalid data. This will ultimately not support the goal of datadriven decision making. While WHA believes moving to a web-based survey is a great step, we believe CMS needs to ensure that it is clear for patients what they are responding to.

# WHA Does not Support the Adoption of Breast Screening Recall Rates Measure

In this rule, CMS proposes to adopt this claims-based process measure beginning with the CY 2023 reporting period. The measure calculates the percentage of Medicare fee-for-service beneficiaries who received a traditional mammography or digital breast tomosynthesis (DBT) screening study and then received a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging of the breast in an outpatient or office setting within 45 calendar days of the first image.

WHA is concerned that this measure is not beneficial to the public. Diagnostic breast screening typically takes place very quickly after an initial screening given that there is often a cause of potential alarm. Having this measure with a forty-five-day time period is not a quick turnaround time for the procedure. There is currently no evidence-based indicator of how many repeat screenings should be complete, yet CMS appears to have randomly selected a goal of a rate between 5-12%. Given that this is not supported by clinical evidence and not endorsed by the National Quality Forum, WHA does not support including this new measure.

# WHA Supports Adoption of ST-Segment Elevation Myocardial Infarction (STEMI) Electronic Clinical Quality Measure

CMS proposes to adopt this EHR-based measure in the place of OP-2 and OP-3 beginning with the CY 2023 reporting period. The measure calculates the percentage of ED patients with STEMI who received timely delivery of care, defined as:

- ED-based STEMI patients who received fibrinolytic therapy within 30 minutes of their arrival;
- Non-transfer ED-based STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival; or
- ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of their arrival at a non-PCI-capable hospital.

WHA agrees that chart-abstracted measures should be eliminated where possible with an electronic collection (eCQM) method preferred. This will reduce both provider burden and the chance for errors. The National Quality Forum is already in the process of endorsing this measure, and we believe their process will uncover any remaining questions regarding statistical issues.

# WHA Does Not Support Restarting ASC 1-4 Measures

In this rule, CMS proposes to resume data collection for ASC-1-4 beginning with the CY 2023 reporting period. Providers would submit data via the Hospital Quality Reporting (HQR) platform (the modernized version of the QualityNet Secure Portal).

WHA does not support restarting these measures because they were removed or suspended due to being topped out and performing inefficiently. We are unsure why CMS is now considering bringing them back. There does not appear to be an adequate explanation of the rationale for their resurrection and importance to patient safety. Given that they are not supported by the National Quality Forum, making them mandatory as the next step would be a mistake and would also unnecessarily add to hospitals already overtaxed reporting burden.

#### **Request for Information on Rural Emergency Hospitals**

WHA is pleased that CMS is asking for feedback regarding its implementation of the Rural Emergency Hospital (REH) designation created by the Consolidated Appropriations Act, 2021. This designation was created for hospitals that have seen dwindling inpatient volumes and financial challenges. It would allow a hospital with fewer than 50 beds to continue serving its community with an emergency department 24 hours a day and 7 days a week as well as certain hospital level outpatient services but no inpatient hospital services.

WHA believes CMS should be careful not to be overly prescriptive when creating this designation, but instead, allow for flexibility when implementing this statute. For instance, CMS should consider allowing hospitals that have fewer than 50 staffed beds to be eligible for this designation even if they have more than 50 licensed beds on paper. This would recognize that practical hospital operations must constantly adjust to the needs of the surrounding community even if state and local certifications and designations have not kept up with the changing landscape.

CMS, in its RFI, also asks for information about what services it should allow at REHs, what state licensure barriers may arise, and what special challenges rural hospitals routinely face. We are pleased CMS is considering all of these complex and interwoven factors when developing this designation. Rather than provide specific recommendations, WHA again cautions against being overly prescriptive when implementing this designation. CMS should see this designation as a tool that will help keep care in rural communities rather than a concern that must be strongly regulated. Rural hospitals routinely face challenges in finding adequate staff, adequate patient volumes, and inflexible licensure requirements that do not seem to contemplate a hospital's mission of providing life-saving care in the most efficient manner possible.

WHA appreciates the opportunity to provide comment on this proposed rule.

Sincerely,

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Eric Borgerding President & CEO