WISCONSIN HOSPITAL ASSOCIATION

ADVOCATE. ADVANCE. LEAD.

5510 Research Park Drive
P.O. Box 259038
Madison, WI 53725-9038
608.274.1820 | FAX 608.274.8554 | www.wha.org

September 11, 2023

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-1786-P] RIN 0938-AV09 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

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 CY 2024 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's Proposed Payment Update is Inadequate Given Extreme Inflation and Other Cost Increases

In this rule, CMS proposes to update outpatient rates by 2.8% for calendar year (CY) 2024. This update is woefully inadequate and is not keeping up with the true level of inflation impacting health care and the country as a whole. It fails to account for the record-high inflation and persistent labor, supply and drug costs the hospital field has experienced in the last two years and continues to face. **Given the extreme levels of inflation our country is facing, the market basket is inadequate, particularly when taken together with the insufficient increases that greatly lagged true inflation in CY2022 and CY 2023.**

An April 2023 report released by the American Hospital Association highlights some of the cost increases hospitals are bearing right now:

- From 2019-2022 hospital expenses grew by 17.5% compared to IPPS increases of 7.5%.
- Meanwhile, hospitals have had little choice but to turn to contract labor to fill shifts, which led to an increase in contract labor costs by 258% over the same time period.
- Drug costs increased by 37% from 2019-2021, and by even more for 340B hospitals who are no longer receiving the full level of discounts for patients served by community contract pharmacies.

- The average Critical Access Hospital has seen drug costs increase by $500K annually while the average disproportionate share hospital has seen costs increase by $3M annually due to the contract pharmacy issue alone.

Despite numerous financial pressures, hospitals have worked hard in recent years to keep costs down. According to data from the Bureau of Labor Statistics, hospital prices have grown an average of 2.1% per year over the last decade, about half the average annual increase in health insurance premiums. However, with the combination of historic inflation, an unprecedented workforce shortage, and sustained underpayments by federal government health care programs, hospitals are facing significant fiscal pressures going forward.

Unfortunately, CMS's payment system does not reward Wisconsin hospitals for keeping costs down: Wisconsin ranks 16th lowest in terms of per-beneficiary spending according to the Kaiser Family Foundation, and yet, Wisconsin hospitals receive, on average, around 73% of what it costs them to provide Medicare services, well below the national average of about 84% of costs. At the same time, Wisconsin is also the 11th highest state in terms of the percent of its population on Medicare. As people move off private insurance and onto Medicare, it compounds the impact of insufficient Medicare reimbursements, as Wisconsin has seen annual Medicare underpayments for WI hospitals grow from $1.77B in 2016 to $2.53B in 2021 – a 42% increase. This trend is only projected to increase given that Wisconsin is an aging state.

What's more, hospitals are increasingly are not being reimbursed for long patient stays and post-acute care they are providing. The average length of a patient stay increased 9.9% by the end of 2021 compared to pre-pandemic levels in 2019, leading hospitals to have to devote more staff time and expenses per patient episode. On top of this, Wisconsin hospitals lost an estimated $465 million in uncompensated care from patients they have not been able to discharge due to the lack of available nursing home beds – patients hospitals are not receiving reimbursement for after their acute hospital care episode concludes. Yet, hospitals are still bearing the expense of their staff providing care for these patients.

These factors have created a perfect storm of circumstances where hospitals are being significantly underfunded by the nation's safety-net Medicare and Medicaid programs.

Unlike other industries, hospitals cannot simply raise prices to bring in additional revenue. Hospitals can only bring in additional revenue by renegotiating higher payments with employers and health insurers, something that is increasingly difficult in the current fiscal environment. Likewise, unlike other businesses, hospitals do not have the luxury of closing down the overnight shift when operating becomes unprofitable. If hospitals are unable to grow revenue from other sources, they must make cuts to important service lines just like any other business to remain financially viable, and indeed, many are already exploring this reality.

With these historic fiscal challenges facing hospitals, **we urge CMS to take action in the final rule to increase the market basket and other factors to be more in line with the true inflationary cost increases hospitals are facing. CMS must recognize the need for its payment policies to correspond to the actual inflationary environment hospitals are operating in in order to preserve the safety-net care it intends hospitals to provide.**

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, such as the blatant earmark in the American Rescue Plan Act of 2021, which unfairly manipulates the wage index to benefit only 3 states. We urge CMS to continue taking actions in line with the authority provided by Congress to restore fairness to the wage index.

CMS Should Not Recoup Payments from non-340B Hospitals to Correct its Own Error

WHA supports HHS's proposal for remedying its unlawful payment policy for 340B-acquired drugs for the period from CY 2018 through September 27 of CY 2022. The proposal to make one-time lump sum payments is undoubtedly the best remedial approach, minimizing burden for 340B hospitals and the agency.

At the same time, WHA continues to urge HHS to abandon its pursuit of "budget neutrality adjustments" to offset this legally-required remedy. As WHA has previously asserted in past comment letters, and as the American Hospital Association's (AHA) has stated in its own comment letter, the statutes that HHS relies on in its proposed rule do not give it the authority to make a "budget neutrality adjustment." Nor do they require budget neutrality as a matter of law. Contrary to suggestions in the proposed rule, HHS is not required to seek a clawback of funds that hospitals received as a result of HHS' own mistakes and that hospitals have long since spent on patient care—including during the COVID-19 pandemic. In fact, it has a legal obligation not to do so.

WHA strongly urges CMS to hold all hospitals harmless when correcting this error, both for this year and for prior years. Hospitals were not responsible for CMS's decision to make the prior unlawful payment cuts and they should not be penalized for CMS's decision. Furthermore, for the reasons previously mentioned earlier in this comment letter, hospitals cannot afford further unanticipated cuts from the Medicare program given the rising costs they are bearing for labor and from inflation.

Outpatient Quality Reporting Program

WHA offers the following comments on CMS updating its proposed outpatient quality measures.

Left Without Being Seen (LWBS) Measure

CMS proposes to remove the LWBS measure which assesses the percent of patients who leave the Emergency Department (ED) without being evaluated by a physician, advanced practice nurse or physician's assistant. This measure lost consensus-based entity (CBE) endorsement and lacks evidence linking its use to improved patient outcomes. WHA appreciates CMS's recognition of the fact that this measure does not accurately depict ED patient flow, access, or the patient reason for leaving the ED, and supports the removal of this measure.

COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Modification

The current measure assesses the number of HCP who have received a complete vaccination course against COVID-19; in this rule, CMS proposes to replace the definition of "complete vaccination course" with a definition of "up to date" in alignment with new guidance from the Centers for Disease Control and Prevention (CDC).

Given the confusion over the ever-evolving changes in this realm made by CMS, WHA encourages CMS to give hospitals maximum flexibility in this measure to account for the evolving COVID-19 landscape and to give hospitals the ability to best meet the needs of their communities. Hospitals are already dealing with a severe

workforce shortage, and CMS should not add to their burden with reporting requirements that are overly time consuming and may not reflect the current state of COVID-19.

Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery Measure Modification

This voluntarily reported measure assesses the percentage of patients who had cataract surgery and had improvement in visual function within 90 days of the procedure based on results from pre- and post-operative surveys. CMS proposes to limit the allowable survey instruments that an HOPD and ASC may use to inform this measure to the following 3 tools:

- The National Eye Institute Visual Function Questionnaire-25
- The Visual Functioning Patient Questionnaire
- The Visual Functioning Index Patient Questionnaire

WHA would support CMS more thoroughly analyzing the burden and validity that these tools bring upon providers. There is no requirement that the survey instrument be completed after a post-op follow-up visit, and therefore, the results could be very subjective if collected only after a completed survey. CMS has, to some degree, acknowledged the burden this measure would bring and should therefore identify a less burdensome and more valid methodology to collect before including it.

Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients Measure Modification

CMS proposes to amend this measure's denominator to include patients aged 45 to 75 based on recommended guidelines to begin screening at age 45 versus age 50. Given that this process is already in place and adds no extra burden moving the age range from 50 – 45, WHA supports this change and appreciates that CMS is working to keep measures in use in its quality reporting programs consistent with current standards.

Readoption of the HOPD Volume Data on Selected Outpatient Surgical Procedures Measure

WHA does not support the use of this measure in CMS quality reporting programs. The measure was already removed from the OQR and ASCQR in 2018 because it lacks value and evidence of a connection to improved outcomes; it has not been tested for validity or reliability; it was never reviewed let alone endorsed by a CBE because it predates the pre-rulemaking measure review process. In the time since the volume measures were removed from the OQR and ASCQR, no new information has emerged about the exact volumes of procedures at which patient outcomes will improve significantly. We also worry that if adopted into the OQR, it could be used in the calculation of Star Ratings performance or used in other patient safety programs, which would be wholly inappropriate considering the lack of evidence connecting use of the measure to improved patient outcomes.

Adoption of Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) as incorporated by IQR

Until this methodology is endorsed for use in the outpatient space, WHA does not recommend making this measure mandatory, especially given they are patient reported measures open to subjectivity. Testing of the measure for the HOPD and ASC settings has not been completed and the measure has not been endorsed by a CBE for use in those programs; we encourage CMS to wait until these processes have been completed before mandating reporting of the measure to ensure that the measure operates as intended and gleans information that is useful for providers performing and patients receiving THA and TKA procedures in these settings.

Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults Measure

Although we support the movement to electronic and digital clinical quality measures (and the Alara software is offered to hospitals for free), there is always additional burden for set up time for the data collection and staff training. Having only one year of reporting prior to pay-for-performance does not allow for hospitals to see their baseline data and solidify their processes. Because of these reasons, as well as the sheer complexity of the measure, WHA strongly urges CMS not to mandate its reporting until hospitals gain further implementation experience.

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

We are proud that Wisconsin hospitals have a long history of price transparency. Wisconsin hospitals are working diligently to maintain compliance with all CMS requirements, including the machine-readable file, the shoppable services/price estimator requirements, good faith estimates (GFEs) and the advanced explanation of benefits (AEOB) requirements under the No Surprises Act.

As CMS understands, health care price transparency goes well beyond the hospital to include insurers, self-funded employers, and entities in the middle such as employer benefit plan groups, re-pricers, and third-party administrators. Ultimately, what consumers need most is information about their specific services, insurance plan's provider network, out-of-pocket requirements, and benefit plans. Thus, we encourage CMS with their partners in the Department of Labor to continue to strengthen and enforce the transparency requirements for insurers and self-funded employers which are already required to provide such information, and to consider how it can advance transparency from other entities.

CMS proposes several changes to the requirements for hospitals to post their negotiated rates in a machine-readable file format. The proposal in many ways is responding to third party concerns about the data elements. While some third parties are indeed taking the information in the machine-readable files and creating new price comparison information, others simply appear to have a vendetta against hospitals. This latter group, as CMS rightly points out, erroneously claims hospitals are noncompliant, for example by misinterpreting blank cells or cells with "N/A". Wisconsin hospitals are concerned about the inaccurate and often vitriolic rhetoric of these organizations. These organizations appear more interested in falsely condemning hospitals, rather than furthering true price transparency for consumers. With that in mind, we support policies and changes that will truly provide meaningful price information for consumers and oppose those new requirements that appear more geared toward placating such organizations.

Standardization of Machine-Readable Files

CMS proposes several changes requiring hospitals to conform to a standardized format for the machine-readable files. The proposed changes appear to be in part a result of feedback the agency has received from hospitals and other stakeholders on the initial guidance for implementing the machine-readable files. WHA appreciates CMS's willingness to address issues raised by hospitals.

Hospitals, often in partnership with vendors, have developed their machine-readable files based on their understanding of CMS guidance and to accommodate the different types of contracts insurers and providers have. Hospitals have shared CMS's concern about how to assign a single rate for a service when the contract with the payer does not include a simple fee schedule but is rather based on multiple factors. In response to this concern, CMS is now proposing that hospitals include far more information in their machine-readable files that would detail both the methodology used to derive a negotiated rate, as well as the amount the hospital expects to be paid based on that methodology. The additional fields detailing the methodology (e.g., percentage, algorithm) would be incredibly burdensome to produce while potentially creating more confusion for anyone attempting to use the files to create apples-to-apples comparisons across hospitals. Moreover, it would introduce new access issues to the files based on their expanded size.

As CMS points out, the consumer-friendly expected allowed amount is likely to represent reimbursement for an *average patient*. Unless this is noted and clearly identified by any third party attempting to use the machine-readable files to create a comparison across hospitals, this fundamental distinction will likely cause more confusion and frustration for users of the data.

CMS is also proposing additional modifier and drug data fields that are superfluous and burdensome to produce. CMS proposes that hospitals specify in a new field any relevant modifiers that would change the negotiated rate. Many items and services can be billed with multiple modifiers that impact the calculated payment creating an almost endless number of permutations that would need to be included in the machine-readable file if CMS finalizes this requirement. For drugs, CMS proposes that hospitals indicate the drug unit and type of measurement as separate data elements, which is information already captured in the item description. The inclusion of these new data fields would significantly increase the cost to comply with the new requirements while not providing additional insights to the data users beyond what is already available in other fields. They also would vastly increase the size of the machine-readable files, making them more cumbersome to utilize. We note that CMS has postponed the requirement that insurers include prescription drug information in their machine-readable files and encourage CMS to work toward implementing that provision for insurers.

Should CMS move forward with modifying the data elements and standards, we request that CMS allow hospitals up to 18 months to adopt the new standards following the release of final technical guidance. Hospitals have already dedicated significant resources toward complying with the machine-readable file requirements with hospitals reporting spending thousands of dollars and significant labor resources to implement these requirements. Given the complexity of these files, detailed guidance is going to be required to properly ensure that the new standard format is implemented consistently across hospitals and to avoid excessive updates to the guidance in the future. This will require collaboration between CMS and hospital technical experts and is unlikely to be completed by the time the final requirements are released. The implementation period for the standard files should not begin until this guidance is complete as attempting to meet the requirements before the guidance is released would be inefficient.

Monitoring, Assessment and Enforcement

We share CMS's concern that some external groups are attempting to determine a hospital's compliance and support that CMS is in fact the only agency that has the authority and ability to do so.

CMS proposes several changes to their monitoring and enforcement practices, including requiring a hospital official to certify the accuracy and completeness of the hospital's machine-readable file. CMS is also proposing an accuracy and completeness affirmation within the standardized file, which would serve the same purpose but would be completed during the development of the file. A second, duplicative certification after the file has been developed would be administratively burdensome with no additional utility. Therefore, should CMS finalize the affirmation within the standard format, they should not require a separate attestation during the monitoring process.

CMS proposes the addition of § 180.70(a)(2)(v) which would require hospitals and health systems to submit "additional documentation as may be necessary to make a determination of hospital compliance." While WHA understands CMS's interest in assessing hospital compliance, we are concerned that the language is overly broad, and encourage CMS to finalize the rule with greater specificity and clarity.

CMS proposes several other changes to the enforcement process. First, CMS proposes to allow notifications to health system leadership of any compliance activity within their system, as well as notifications to leadership of specific hospitals, to better accommodate health systems with a central office responsible for compliance. CMS also proposes requiring hospitals to confirm receipt of warning notices to accelerate hospital attention to the issue identified and streamline further communication with CMS. We appreciate CMS's desire to

streamline this process and avoid unintentional delays due to communication issues. We support these proposals.

Publication of Compliance Actions and Outcomes.

CMS proposes several changes to the public disclosure of information regarding the agency's oversight of hospital compliance with the rule. Specifically, CMS proposes to give itself authority to make public additional information related to which hospitals are being reviewed for compliance (either as part of routine oversight or in response to a public question or complaint), any compliance actions taken against a specific hospital, the status of the compliance action(s), and the outcome of the action(s).

While we respect CMS's role as the sole arbiter of compliance and some stakeholders' desire for additional transparency regarding the agency's compliance actions, we are concerned that some of the information that could be released as a result of this proposal could be misconstrued. Specifically, we would expect that some stakeholders may misinterpret CMS guidance and believe that hospitals under a routine compliance review are noncompliant and use that information to confuse the public and policymakers about the true state of compliance. Wisconsin hospitals have already experienced this kind of mischaracterization by third-party groups who purport themselves as judges of compliance yet, as previously noted, have been wrong on many occasions about Wisconsin hospital compliance.

Similarly, we know there will be situations where CMS may have questions about a hospitals' compliance and engage in follow-up with the hospital only to ultimately conclude that the hospital is indeed compliant. We based this on our understanding that there have been many productive collaborations between hospitals and CMS during review processes to date that have involved education on both sides around what information is and should be displayed in the machine-readable files.

Should CMS finalize this proposal and eventually release this information, we urge the agency to make it clear that hospitals are <u>not</u> deemed non-compliant when under review. Alternatively, we recommend CMS set up a regular cadence under which they will review hospitals' machine-readable files and publicize that information, making it clear that all hospitals are reviewed on a set schedule and further taking stigma away from the review process.

Price Transparency Alignment

WHA appreciates CMS's recognition of the several overlapping federal price transparency policies and interest in how changes to the hospital price transparency requirements could help achieve alignment.

Hospitals and health systems are dedicated to improving price transparency for patients. We are concerned, however, that the numerous and sometimes conflicting requirements at both the state and federal levels create an overwhelming landscape of pricing information that not only is challenging for patients to navigate but also adds excessive costs and workforce burden to the health care system. As we enter the next phase of price transparency regulation implementation, with most of the federal requirements already executed or on the horizon, we strongly recommend CMS focus on streamlining current policies to remove complexity from the patient experience by narrowing the options for patient estimates and other pricing information and ensuring those estimates are as accurate as possible. This will allow the policies to achieve their intended purpose — to help patients understand and compare their expected costs prior to care — while also minimizing duplication and excess burden on the health care system.

Our specific recommendations for aligning the policies are as follows.

- We recommend CMS require GFEs and AEOBs for scheduled services only, while relying on the shoppable service/price estimator requirements of the Hospital Price Transparency and Transparency

in Coverage rules to provide pre-service information to shopping patients. GFEs and AEOBs should provide individualized, and therefore highly accurate, pricing information for scheduled services where patient characteristics and the course of care are known. However, generating them is labor and time intensive and their usability is often dependent on clinical information and other personal information that is not known for nonscheduled patients. Therefore, we recommend the agency be thoughtful in applying these requirements where they will provide the most value and rely on the more scalable shoppable service/price estimator tool requirements to meet the needs of patients who are evaluating different options (i.e., shopping). In addition, we recommend CMS engage with Congress to preserve hospitals' ability to meet the shoppable service requirement with a price estimator tool. These tools are currently the best mechanism for patients to access price estimates. Changing this policy would move the field in the wrong direction, requiring patients to navigate machine-readable files that can be confusing.

- Rely on the No Surprises Act AEOB process by requiring insurers to collect and collate estimates from providers to generate the AEOB. This will provide patients with the most meaningful estimates for their course of care. We believe that once fully implemented, the No Surprises Act, AEOB policies will have the greatest impact on insured patients. These estimates will be tailored to the patients' unique characteristics and expected care pathways and, in the case of insured patients, take into account their health care coverage, including where they are in their deductible. In addition, patients will automatically receive these estimates as part of their pre-care paperwork without additional effort on their part.

  Hospitals are engaged with CMS and other stakeholders in workgroups to ensure that the insured AEOBs will be implemented in a way that will create meaningful estimates in an efficient manner. However, there are still several issues that are slowing down the process, including determining which entity is responsible for collecting and collating estimates from various providers involved in a patient's episode of care. There are two general approaches this process could take: 1) each provider would submits its own pre-service estimate to the insurer who would collate them and apply its coverage rules to generate the AEOB, consistent with how the explanation of benefit (EOB) process works today or 2) where a single "convening" provider would assume responsibility for collecting estimates from different providers and transmitting the bundle of estimates to the insurer. To accelerate the process and avoid unnecessary costs and duplication of effort, we recommend CMS clarify that it is the insurer's responsibility to collect and collate all the estimates from the various providers to generate the patient's estimate.

  The AEOB process is intended to provide patients an EOB in advance of care. AEOBs, like EOBs, are not simply a compilation of claims from unique providers. They are the result of the insurer processing the individual claims and applying its coverage rules, including considering where the individual is within their deductible and maximum out-of-pocket cost limits. These coverage rules — such as whether the insurer bundles some set of services into a single reimbursement or even covers certain items in a given circumstance — are all elements that must be known to generate the AEOB. Insurance companies already have the workflows and technology to not only collect and collate claims from different providers but also to apply their coverage rules and adjustments.

  Requiring a single convening provider for AEOBs would create enormous administrative burdens for providers. It would utilize a process that diverges from the claims process used to create patient bills and could potentially lead to delays in care. To ensure that the estimates are most reflective of a patient's final bill and do not create unnecessary burdens on the care delivery process, WHA urges CMS not to require a single provider to compile preservice estimates before they are sent to the insurer.

Telehealth

WHA supports HHS's proposal to delay the requirements for an in-person visit within six months prior to the first remote mental health service and within 12 months after each remote mental health service. As WHA wrote in March 2023 in its comment to the Drug Enforcement Administration's telehealth proposed rule, transportation is a significant access barrier for patients in rural areas and patients with mental health needs. Widespread adoption of telehealth during the public health emergency has significantly improved access to care for these patients. WHA's members are concerned that a return to in-person care requirements when not medically indicated will reverse those gains for many patient populations.

HHS's proposed delay to establish in-person visit requirements for remote mental health services will give HHS time to develop a more complete, evidence-based assessment of perceived risks and benefits at a patient and population level of providing mental health services via a telehealth encounter compared to an in-person patient encounter.

Mental Health and Addiction Care Updates

WHA is broadly supportive of HHS's various proposals to expand behavioral health benefits available to Medicare beneficiaries. However, WHA offers several technical comments regarding these proposals.

Consistent with Parity Principles and to Improve Access, HHS Should Further Reduce Paperwork and Regulatory Burden in Providing Mental Health and Addiction Care Services

Regulatory and paperwork burden has an outsized impact on the provision of mental health and addiction care services compared to physical health services. Workforce challenges in mental and addiction care services are well documented, thus regulatory and paperwork burden that takes time away from an already limited mental health and addiction care workforce has significant impact on access to care. To maximize our nation's limited mental health and addiction care workforce to care for a population with increasing needs, we urge HHS to re-examine both existing and proposed regulatory and paperwork requirements on mental health and addiction care providers.

Further, consistent with the mental health parity principles articulated on July 25, 2025, in HHS's proposed rules implementing the Mental Health Parity and Addiction Equity Act, HHS should re-exam and remove existing and proposed CMS regulatory and payment provisions that include regulatory burdens that apply only to mental health and addiction care providers but not physical health care providers.

For example, the proposed rule appears to establish payments for IOP services provided in Rural Health Clinics that are tied to PPS hospital payment rates rather than the typical cost-based rate provided for physical health services. Other examples include physician certification requirements for outpatient addiction care services that do not exist for outpatient physical health services.

Having regulatory requirements that apply only to mental health and addiction care services but not similar physical health services is not only contrary to mental health parity goals we share with HHS, but also creates disincentives to providers to enter or expand into service areas that could create additional access for those with mental health and substance use disorder needs.

Expanding the Types of Professionals Who May Enroll as Medicare Providers is Welcome.

WHA supports HHS's inclusion of marriage and family therapists and mental health counselors – including addiction counselors who meet the requirements to be a mental health counselor – as providers who may now bill Medicare for their services. The inability for these types of mental health professionals to bill Medicare for their services has limited our members' ability to utilize these types of professionals in their communities and further strained the resources of members that do utilize these professionals but cannot receive reimbursement for services they provide.

Re-examine the Proposed Rule to Ensure that Nurse Practitioners and Physician Assistants May Perform Newly Proposed Physician Certifications or Requirements.

Over the past decade, HHS has incrementally, but positively, updated its rules to recognize the existing scope of practice of individual nurse practitioners and physician assistants to perform regulatory requirements that previously specified an action by a physician. Given workforce shortages in behavioral health services, it is particularly urgent that CMS rules allow nurse practitioners and physician assistants to perform regulatory tasks if the task is within their scope of practice.

It appears that the proposed rule creates a new specification for opioid treatment programs that wish to provide IOP services which would require a "physician" to certify that a higher level of care intensity is needed. Consistent with other CMS rules recognizing the modern scope of practice of nurse practitioners and physician assistants, with strongly encourage HHS to amend its proposed rule to allow those providers to also perform that certification if retained in the final rule.

Removal of Supervision Barriers in RHCs.

WHA supports HHS's behavioral health services change to allow general supervision, rather than direct supervision, for "incident to" services provided in Rural Health Clinics. We agree with HHS that this could help expand access to behavioral health services in rural communities.

Substance Use Disorder and Psychotherapy Services Payment Rates

WHA supports HHS's proposal to increase the payment rate for psychotherapy services and substance use disorder treatment. Without sustainable reimbursement to care for the populations needing these services, access cannot be sustained for those populations.

Additional Care Complexity Payments for Primary Care Providers.

WHA supports HHS's effort to better account for the complexity of primary and other longitudinal care provided by primary care providers, particularly for behavioral health care services. With mental health and substance use disorder treatment increasingly treated alongside physical health services within a primary care setting, recognizing the additional complexity and time that adds to a primary care visit is imperative to sustain primary care services generally and the continuation of including behavioral health services within primary care.

Crisis services increase

WHA supports HHS's proposal to increase the value of psychotherapy for crisis services to pay 150% of the usual Physician Fee Schedule rate when the crisis care is provided outside of traditional health care settings. We agree with the rationale that this increase better reflects the costs incurred to provide these services.

Potential Payment Under IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines

While WHA appreciates CMS's recognition that a more reliable and resilient drug supply chain is needed so that hospitals can better care for their patients and communities, we have several concerns with the potential payment proposal to aid in establishment of a 3-month buffer supply of essential medicines.

The payments would take into account the reasonable costs of a hospital to establish and maintain access to its buffer stock, such as the costs to hold essential medicines directly at the hospital or through contractual arrangements with a distributor or wholesaler, but not the costs of the essential medicine itself. Especially for safety net hospitals, paying for this stockpile of medications may create a financial burden that puts other services at risk. WHA encourages CMS to include a methodology for hospitals confronted by this barrier to receive up-front payment for the initial creation of the buffer supply.

WHA appreciates the IPPS payment proposal is not budget-neutral, recognizing the investment necessary to create this safety buffer, and is concerned that CMS noted that the OPPS payment to be considered in the future would be budget neutral. WHA cautions that redistributing payments to make the OPPS payment budget neutral would not be of benefit to patients or providers. If CMS moves forward in future years to adopt this policy under the OPPS, we urge it to seek Congressional authority to make any additional payments non-budget neutral.

WHA would like to offer the following comments on the specific questions posed by CMS regarding the 3-month buffer supply of essential medicines:

Are these 86 essential medicines prioritized in the ASPR report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* the appropriate initial list of essential medicines for this potential payment policy and how often should HHS consider updating the respective list used for establishing these potential additional payments?

WHA appreciates and respects the expert input of pharmacists and physicians from a cross-section of health care providers and other experts and supports the existing list as appropriate to use for this proposal.

Should HHS consider expanding the list of essential medicines used in establishing these potential additional payments to include essential medicines used in the treatment of cancer?

Given current cancer drug shortages and the likely future shortages of other drugs not included in ASPR's list, we believe that additional drugs could be prioritized, but given that most cancer chemotherapy is provided in outpatient settings and the agency's current proposal only applies to drugs used in inpatient care, CMS may wish to work with ASPR and FDA to create another list of essential drugs for the outpatient setting, including for outpatient cancer care, for a possible future CMS proposal for OPPS.

How effective would this potential payment policy be at improving the resiliency of the supply chain for essential medicines and the care delivery system? How could it be improved, either initially or through future rulemaking? Are there suggested alternative pathways for establishing similar separate payments?

Holding a 3-month supply at hospitals may not be the most efficient or advantageous model. In addition to financial barriers, some hospitals would simply not have the physical space to safely store this amount of medication inventory, especially for medications requiring cold storage. These barriers could even create unintended inequity for small rural facilities and safety net hospitals. Distributors and wholesalers are far better equipped than individual hospitals to determine what a three-month supply would represent or, given that most drug shortages last more than three months, whether holding a longer period of buffer supply is appropriate. Furthermore, such an approach would avoid the increased reporting burden on hospitals and the potential unintended consequences related to equity, as discussed above. We recognize that additional congressional authority would be necessary to carry out this alternative pathway.

What type of additional hospital resource costs are involved in establishing and maintaining access to domestically manufactured essential medicines compared to non-domestically manufactured ones? Are there alternative approaches that might better recognize the increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines? How might any suggested alternatives be better at improving the resiliency of the supply chain for essential medicines and the care delivery system?

As noted above, it is unlikely that many hospitals would be able to independently establish and maintain access to a three-month supply of essential medicines within their facilities, regardless of whether they were domestically or non-domestically manufactured. But for hospitals that do have the space and funds to do so, these costs would include purchasing more freezers, refrigerators, and racking, leasing additional space,

administrative costs related to contracting and record-keeping, additional security to adequately protect the buffer supply and hiring additional staff to manage the extra inventory to ensure it does not out-date.

In regards to domestic sourcing, even if it were not proprietary information, it would still be challenging for a hospital to calculate this cost, as the cost for different generic versions of the same drug is affected by multiple factors and likely varies by purchaser. WHA believes that determining these incremental costs is better suited to drug supply chain organizations upstream of the hospital. As noted above, there would be substantial efficiencies in inventory allocation by storing the buffer stock in these upstream locations where it could be shipped as needed and hospitals would not face the risk and potential cost of expired inventory that they don't have the patient demand for to use in a timely manner. Such a model also creates procurement opportunities for hospitals that help foster a more resilient supply chain for essential drugs and having sufficient inventory that can be leveraged in the event of a supply disruption or demand increase — as opposed to "just-in-time" inventory.

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

Sincerely,

Eric Borgerding
President & CEO