September 9, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services, Department of Health and Human Services
Attention: CMS–9904–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Submitted via regulations.gov.

RE: "CY 2025 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1809)"

Dear Administrator Brooks-LaSure,

United States of Care (USofCare) is pleased to submit comments in support of the proposed rule by the Centers for Medicare & Medicaid Services (CMS) entitled "CY 2025 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1809)," also known as the 2025 OPPS proposed rule.

USofCare is a nonpartisan, nonprofit organization working to ensure everyone has access to quality, affordable health care regardless of health status, social need, or income. We drive change at the state and federal level in partnership with everyday people, business leaders, health care innovators, fellow advocates, and policymakers. Together, we advocate for new solutions to tackle our shared health care challenges — solutions that people of every demographic tell us will bring them peace of mind and make a positive impact on their lives. Through our work in states, we are able to identify unique perspectives from people on the ground to amplify on both the state and federal levels. We uplift voices of real people engaging with the health care system whose perspectives shape our advocacy work.

Our work listening to people demonstrates a desire for a high-quality, affordable health system that allows patients to spend more time with providers and for providers to communicate with each other to yield more personalized, holistic care. People crave a system where the patient is at the forefront of care and decision-making. We call this "patient-first care" (or value-based care) to underscore the importance of patients in care delivery, moving away from a system that incentivizes quality of care over quantity of care.

It is through this patient-first lens that we respond to the 2025 OPPS proposed rule, which focuses on the following areas:

I. **Implementing Price Transparency & Site-Neutral Payment Policies within the 2025 OPPS Final Rule**
II. **Expanding Access to Health Care Coverage & Promoting Health Equity**
III. **Obstetric Services Conditions of Participation (CoP)**

Including Price Transparency & Site-Neutral Payment Policies within the 2025 OPPS Final Rule

Our listening work demonstrates that people's top concern with the health care system is affordability. The United States spends considerably more on health care than peer nations despite no improvement in outcomes, saddling everyday people and families with the high cost of care. 75% of people, regardless of partisan affiliation, rate the cost of health care in the U.S. as "only fair" or "poor." What's more is that over half of Americans report skipping or delaying

care due to cost. Prices are rising in large part because of a decades-long movement toward consolidation led by corporate hospital and health care actors.

We ardently support fair health care billing practices and hospital price transparency policies at both the state and federal levels, including site-neutral payment reform. Last year, we applauded updates within the 2024 OPPS proposed rule requiring hospitals to provide the public with accessible standard charges data, as well as entrusting CMS with the appropriate enforcement capabilities to promote compliance. **USofCare is concerned that CMS did not pursue price transparency and site-neutral payment reform within the 2025 OPPS proposed rule. Because of this, we encourage the agency to adopt these policies in the final version.**

Adopting Greater Price Transparency Provisions

As we raised in our comments last year, **CMS should ensure that standard charges data is uniform and accessible in the 2025 OPPS final rule.** CMS should require hospitals to post their data in only one format (CSV or XLS) and convey all standard charges in dollars and cents, as opposed to in percentages or in algorithms, for their submission to be considered complete. We also encourage CMS to standardize Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes across hospitals. This increases dependability and minimizes the potential for error from the datasets, allowing people to more easily understand how they were billed for the care they received.

Previous policymaking from CMS, such as the Hospital Price Transparency (HPT) rule of 2019, outlines promising first steps to facilitate greater accountability from hospitals in this space. Similar to our recommendations from last year, **we encourage CMS to build on this progress by strengthening enforcement mechanisms and penalties to counter low compliance rates among hospitals.** For example, the HPT rule mandates that hospitals submit a statement of affirmation that the data they report is accurate and complete. In the final rule, CMS should require that statements of affirmation are corroborated by a senior-level hospital official to guarantee that the data for shoppable services is accessible in both a machine-readable and consumer-friendly format. Further, we urge CMS to increase the civil monetary penalty for noncompliance to $300 per bed per day for hospitals with 31 or more beds. Doing so will facilitate greater accountability, increasing the likelihood that hospitals will adhere to these critical protections for consumers.

Enacting Site-Neutral Payment Reform

We appreciate that the current proposed rule clarifies that OPPS payment for services furnished remotely by hospital staff to individuals in their homes are coordinated with those associated with Medicare telehealth and billed under the PFS. This applies to remotely-furnished outpatient therapy services, Diabetes Self-Management Training, Medical Nutrition Therapy Services, and mental health services. While this clarification allows for payment for certain services to be aligned across systems, **USofCare is disappointed in the lack of site-neutral payment proposals within the 2025 OPPS proposed rule and encourages CMS to include site-neutral payment reform within the finalized regulation.**

Outpatient health facilities, including hospital outpatient departments (HOPDs), are reimbursed by Medicare at higher rates for the same services that can be provided in a physician's office. This discrepancy incentivizes hospital systems to move patients into higher-cost settings to receive the higher reimbursement rate, leading patients to receive higher copays at HOPDs than at physician offices and encouraging corporate entities to acquire once independent physician

practices. As a result, hospitals amass market power, which leads to people experiencing higher insurance premiums and out-of-pocket costs without improvements in quality of care.

The Bipartisan Budget Act of 2015 required that HOPDs be paid the rate determined by the Physician Fee Schedule (PFS). However, this mandate is only applied to HOPDs established after November 2, 2015, meaning that all other HOPDs are "grandfathered" in and exempt from these requirements. Estimates from the Congressional Budget Office (CBO) indicate that eliminating the grandfathering requirement could save $13.9 billion between 2019 and 2028. **USofCare encourages CMS to close this loophole and collaborate with Congress to obtain the authority to do so if necessary.**

Additionally, MedPAC, the body of Medicare experts that evaluates and makes recommendations to Congress regarding the Medicare program, has reported that payment policy is misaligned when it comes to charges for care across dozens of services delivered at off-site locations. As such, **USofCare encourages CMS to utilize the 2025 OPPS final rule as a vehicle to align payments for the 66 services identified by MedPAC with the PFS.** People should be able to pay the same prices for the same services – regardless of where their care is administered.

Expanding Access to Coverage & Furthering Health Equity

While we are disappointed with the omission of hospital price transparency and site-neutral payment policies within this year's OPPS rule, USofCare does appreciate the efforts within the proposed rule to expand people's ability to receive coverage and promote health equity across the country. Namely, we are excited about the direly-needed proposed updates to ensure continuity of and access to coverage, especially among marginalized communities, through the 12-month continuous coverage Medicaid & CHIP requirement as well as the proposed exceptions to the Medicaid Clinic "Four Walls" requirements.

Shortened Timeframes for Prior Authorization Services

Although initially intended to protect patients, prior authorization processes can often serve as a barrier to accessing needed care. For example, a KFF survey revealed that consumers who reported problems with prior authorization were about 3 times more likely to report significant delays in receiving medical care or treatment as a direct result of their problems. USofCare supports the provisions in the proposed rule that aim to shorten the current review timeline for outpatient prior authorization from 10 business days to 7 calendar days for non-urgent medication. However, to ensure that people are able to get needed medication at a more timely manner, **we encourage CMS to narrow the window to 5 calendar days where possible, following in the footsteps of states like Illinois and Iowa.**

While we are supportive of measures to ensure that people receive their medication in a timely manner, USofCare urges CMS to further consider the role of artificial intelligence (AI) within PA approvals for both providers and plans to ensure the use is appropriate and not harmful to patients. For providers, the current PA approval process is incredibly time-consuming, who spend an average of 12 hours per week submitting PA requests. Not only is that time that they could be spending with their patients, it also means patients are delayed in getting medications their provider recommends. When used with appropriate safeguards in place, AI has immense potential to alleviate administrative burden among providers, with one analysis suggesting that AI could automate 50% to 75% of manual PA-associated tasks.

However, the use of AI in PA among plans thus far has led to rapid rates of claims being denied without those overseeing the claims ever actually reading them. Further, AI algorithms have

been demonstrated to perpetuate biases for marginalized communities – particularly for Black communities – which can be applied to coverage determinations. CMS should ensure patient protections are in place for AI use within PA determinations, including implementing transparency standards to ensure that patients know if the status of their request was determined by a doctor or an algorithm. According to USofCare polling, only 43% of American adults are aware of insurers using AI to process prior authorization requests and 75% want transparency into how AI is used within their health care.

> *"I'm extremely wary of transitioning to AI platforms for diagnostics and treatments primarily because I don't know if it would make any aspect of managing our care improved. Especially if we [women of color] struggle already to be seen and heard and for our pain and our symptoms and our concerns to be recognized. I'm not sure if I trust a machine to determine the gravity of my symptoms especially when I think it's going to be predicated and based on data and information that we know is already skewed or biased and doesn't fully reflect the breadth of our [collective] experiences."*
> *~ Black woman, Southeastern U.S.*

What's more, two-thirds of voters (66%) want policymakers to make the regulation of AI in health care a top or important priority, including over half of voters (63%) across party lines who support stronger regulation by policymakers. We appreciate CMS's prior efforts to streamline prior authorization and clarify the role of algorithms in decision-making within Medicare Advantage programs. In the absence of meaningful state and federal regulation of AI in health care, we encourage the agency to institute similar standards for its programs outside of the Medicare Advantage realm.

Continuous Eligibility for Medicaid & CHIP Coverage

USofCare applauds the provisions within the proposed rule that codify requirements established in the Consolidated Appropriations Act of 2023 (CAA). Children's enrollment in Medicaid is projected to decrease from 37 million in 2023 to 31 million in 2025, largely due to the "unwinding" process as a result of the end of the COVID-19 public health emergency. Compared to their adult counterparts, children – especially Black and Hispanic children – are more likely to "churn" in and out of coverage depending on fluctuations in their family's income that determine their eligibility for public health insurance programs like Medicaid and CHIP. Children without access to health insurance are less likely to visit or be seen by a physician and receive less adequate preventive services, among other harmful impacts to their health.

Before the passage of the 2023 CAA, states had the option to offer 12 months of continuous eligibility (CE) for Medicaid and CHIP beneficiaries under the age of 19. There is a robust body of evidence demonstrating the benefits of establishing a 12-month CE period for Medicaid and CHIP beneficiaries, including links to improved health coverage and better health outcomes. Oregon is a leader in this space, utilizing a Section 1115 waiver to become the first state in the country to establish CE for children from birth through age 6 and 24 months of CE for children six years or older. **USofCare commends the provisions of the proposed rule that upgrade this 12-month CE option to a requirement for all states to follow, especially considering the variations across different states in the Medicaid and CHIP unwinding process.** In fact, recent projections indicate that over 17 million children nationwide stand to benefit from this policy, with Medicaid and CHIP eligibility for children in states with no or limited CE policies beforehand increasing by 3.5%.

We are also appreciative of the additional proposed updates to Medicaid and CHIP regulations that codify the 2023 CAA. This includes the removal of previous options to apply CE to a subgroup of enrollees, as well as limiting CE to a time period of less than 12 months. Our listening work indicates that affordability is people's top concern with the health care system. Health care costs – even as low as a dollar or two – have continued to be shown to be significant barriers to care for patients, especially for low-income people. As such, **we support the removal of failure to pay premiums as an optional exception to continuous eligibility in CHIP.**

Individuals Formerly in the Custody of Penal Authorities

USofCare applauds the efforts within the proposed rule to expand access to Medicare coverage for formerly incarcerated individuals by narrowing the definition of "custody" in Medicare's no legal obligation to pay payment exclusion. The current definition of "custody" in Medicare differs from that of Medicaid and Affordable Care Act (ACA) plans. While the Medicaid and ACA coverage allows anyone not currently serving time in prison – including people living in halfway houses – to sign up for coverage, Medicare does not. Overall, the updates included within the proposed rule will bolster alignment across programs and ensure that individuals who have recently been released from incarceration; are on parole, probation, or home detention; and are residing in halfway houses are able to sign up for Medicare coverage.

Updating the definition of whether someone is in "custody" will increase access to Medicare coverage for disabled people and older individuals who are re-entering their communities, who often cite difficulty obtaining health coverage following their release and we urge CMS to finalize this proposal. This is especially troubling considering that formerly incarcerated patients are at a higher risk of visiting the emergency room for conditions that can be managed in outpatient settings. Formerly incarcerated patients also face difficulty navigating the health care system and may encounter providers who do not understand incarceration, which can contribute to fear of retraumatization and further stigma. The benefits of increasing formerly incarcerated people's access to health care are evident. Studies examining the effects of the similar Medicaid program on recidivism have demonstrated that post-carceral access to public health insurance coverage options is associated with higher employment rates, higher earnings, and improved recidivism.

Similarly, USofCare supports the proposed revision of the Medicare special enrollment period (SEP) for formerly incarcerated individuals so it aligns more closely with the Social Security Administration's criteria. People who have recently been released from incarceration or are on parole, probation, or home detention will no longer need to wait for the general enrollment period to sign up for Medicare and can instead enroll during a SEP following release. This will ensure access needed coverage and maintain continuity of care for this population. To further prevent lapses in coverage, CMS should consider pathways to pre-enroll people leaving incarceration in Medicaid before release, similar to options to do so in Medicaid using a Section 1115 waiver.

Medicaid Clinic Services Four Walls Exceptions

Under current law, Medicaid clinic services must be furnished within the "four walls" of the clinic, with a lone exception for services furnished to unhoused patients. The 2025 OPPS proposed rule establishes mandatory exceptions to the "four walls" requirement for Indian Health Service (IHS) and Tribal clinics. As noted within the proposed rule, this exception was requested by the Tribes, the CMS Tribal Technical Advisory Group (TTAG), and the HHS Secretary's Tribal Advisory Committee (STAC) in order to reduce barriers to care. IHS and Tribal clinics often look for ways to better serve their communities by meeting people where

they are, but current reimbursement policies make it difficult for them to continue to do so. **As Indigenous communities already face significant health disparities rooted in systemic racism and chronic underinvestment in the IHS, it is imperative that CMS implement these exceptions – in addition to further investment in and listening to Indigenous communities – to improve Native American health outcomes.**

Additionally, rural communities often face barriers to receiving needed health care services, which include inconsistent access to health care coverage, long distances and limited transportation options, workforce shortages, and insufficient broadband access. Initiatives that meet people where they are, such as mobile health clinics, have proven to be cost-effective and successful at improving health outcomes for people in rural areas. Similar initiatives that don't require the means, time, and ability to travel to seek care in a physical location with "four walls," such as expanded access to telehealth, have allowed more people to access necessary mental and behavioral health care services. This is especially critical amidst a national mental health crisis and chronic underinvestment in behavioral health infrastructure. **Because of this, USofCare supports exceptions to the "four walls" requirement within the proposed rule for clinics located in rural areas and for clinics providing mental and behavioral health care services.**

Updates to Quality Reporting Programs

USofCare applauds the proposed implementation of quality reporting measures focused on the Social Determinants of Health (SDoH) into the Outpatient Quality Reporting Program (OQR), the Ambulatory Surgical Center Quality Reporting Program (ASCQR), and the Rural Emergency Hospital Quality Reporting (REHQR) Program. **We specifically commend the addition of the Hospital Commitment to Health Equity (HCHE) measure, the Screening for SDOH measure, and the Screen Positive Rate for SDOH measure into these metrics.**

The HCHE measure evaluates the degree to which hospital leadership are committed to providing equitable health care, which is assessed in accordance with the following criteria: equity as a strategic priority, data collection, data analysis, quality improvement, and leadership engagement. Earlier in our comments, we discussed the importance of buy-in and compliance from hospital leadership in regards to to accountability measures surrounding price transparency, which we also believe extends to accountability measures surrounding health equity. Similarly, as a majority of this data is self-reported by hospitals, we encourage CMS to strengthen data attestation processes, including third-party verification and follow-up.

Health-related social needs (HRSNs) – such as food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety – are estimated to account for 80% of health outcomes. Failure to screen and address these needs further breeds health inequities, particularly for communities of color. The Screening for SDOH measure examines the extent that hospitals screen for these HRSNs, while the Screen Positive Rate for SDOH measure determines the percentage of patients who have at least one HRSN out of the patients who were screened for HRSNs. USofCare applauds the inclusion of these measures within the reporting programs and encourages CMS to require disaggregated collection of these measures at the individual level. Doing so will allow providers to assess the factors impacting an individual patient's health in order to better meet their needs. Although the proposed rule offers hospitals the choice of which screening tool they use to screen for both measures, USofCare also encourages CMS to adopt one data collection method in order to ensure that data is standardized at both the patient and population level.

Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments

Pre-Exposure Prophylaxis (PrEP) is a treatment that has demonstrated to be highly effective at preventing HIV. In fact, when taken as prescribed, PrEP reduces the risk of acquiring HIV from sexual activity by about 99% and from injection drug use by at least 74%. Despite these high levels of efficacy, the high costs of and associated with PrEP medication often serve as barriers to accessing it, especially in Black and Hispanic communities.

Over 150 million Americans' access to preventive services at no-cost is at risk due to the *Braidwood v. Becerra* lawsuit, which targets no-cost coverage of PrEP in particular. It is estimated that if cost-sharing for PrEP returns, as many as 2,000 additional HIV infections could occur per year. **Because of this, USofCare applauds the proposal to pay for HIV PrEP drugs and related services covered as additional preventive services under the OPPS, if covered by CMS through a National Coverage Determination (NCD).** We particularly appreciate the detail that PrEP will be administered under the OPPS in a site-neutral manner. As the proposal will only cover PrEP as an additional preventive service if it is covered by a NCD, we urge CMS to formally adopt the NCD proposed in July 2023 that would cover PrEP and related services, including counseling and HIV/Hepatitis B Screenings.

Obstetric Services Conditions of Participation (CoP)

The U.S. is facing a dire maternal and child health crisis, which disproportionately impacts Black women and pregnant people, who experience significantly higher maternal mortality rates compared to their white counterparts, in addition to poor birthing experiences and racial discrimination. Within the 2025 OPPS proposed rule, CMS seeks to establish baseline health and safety standards for hospital and maternity care through new Conditions of Participation (CoP), to which USofCare offers the following feedback:

Organization & Staffing

USofCare recommends adding an explicit recognition of doulas as a member of the interdisciplinary care team within the proposed CoP framework, which is currently absent within the proposed rule. Doulas provide continuous physical, emotional, and informational support to pregnant women and people throughout their pregnancy journeys. Research shows that doula guidance in perinatal care was associated with positive delivery outcomes including reduced cesarean sections, premature deliveries, and length of labor, and other outcomes including reduced anxiety and stress. There is currently a lack of standardization surrounding the use of doulas in hospital policies. Doulas report challenges when working within the American health care framework, including issues related to communication, respect, and integration into birth teams. CoPs can be a lever to ensure that hospitals incorporate evidence-based interventions such as doulas into maternity care and minimize barriers to accessing doula care.

> *"I felt maybe if there had been a doula [during the childbirth experience], I would probably have been a lot more calm, not so anxious, and less annoyed. I would expect a doula to help throughout the process with those small things."*
> *~ Black woman, Midwest U.S.*

Staff Training

USofCare supports the provisions of the proposed rule that require OB staff to be trained on evidence-based best practices aimed at improving the delivery of maternal care, encouraging hospitals and critical access hospitals (CAHs) to look beyond just the clinical requirements necessary. Our listening research reveals that unsurprisingly, many women of color, especially

Black women, have poor birthing experiences. They feel unheard and experience differential treatment, stereotyping, and racism during labor and delivery.

> *"As an African American woman, they [health care providers] look at you and feel like your pain is less than [someone] outside of my race."*
> *~ Black woman, Northeast U.S.*

We encourage CMS to specifically incorporate training on implicit bias and racism so staff mitigate unconscious biases, ensure high quality maternity care, and foster an equitable and supportive environment for women and pregnant people. For example, one study found that white medical students have false beliefs about biological differences between races which predict racial bias in pain perception and treatment recommendations, leading to Black Americans being systematically undertreated for pain compared to white Americans. In our listening work, Black women reported being routinely subjected to the "strong Black woman" trope and having their pain minimized by providers. As a result, **we encourage CMS to ensure that these training modules address and rebuke medical misinformation that promotes health inequities.**

Quality Assessment & Performance Improvement (QAPI) Program
It is well known that there are racial disparities in maternal health, with Black and American Indian and Alaska Native (AIAN) people experiencing higher rates of poor outcomes. People of color are more likely to be uninsured and face other barriers to care. In particular, they may face barriers including limited access to providers and hospitals and lack access to culturally and linguistically appropriate care. Collecting data is crucial for identifying disparities and understanding the specific needs faced by different communities, enabling targeted, data-driven interventions to address these barriers and improve outcomes.

With this in mind, **USofCare supports initiatives within the proposed rule requiring hospitals and CAHs with OB services to use their Quality Assessment and Performance Improvement (QAPI) programs to assess and improve health outcomes and disparities among patients on an ongoing basis.** The California Maternal Quality Care Collaborative (CMQCC) is one example of this idea already being practiced. The CMQCC was created to end preventable morbidity, mortality, and racial disparities in California's maternity care. CMQCC has data-driven collaboratives with state hospitals (and a growing number of hospitals in other states) to generate near-real-time data and performance metrics to generate quality metrics and compare hospital performance to statewide, regional, and system benchmarks. Program partners are then able to use the data to implement evidence-based quality improvement initiatives, including techniques that target obstetric complications that disproportionately affect Black pregnant women, and drive better perinatal outcomes. CMS can follow in the footsteps of these state successes by adopting similar initiatives into the CoP.

The proposal also includes a requirement that each OB facility's leadership are involved with their facility's QAPI activities. One real-world example of this comes from the Penn Medicine Department of Obstetrics and Gynecology in Philadelphia, Pennsylvania. The department adopted the goal of reducing maternal morbidity and mortality among Black women across the system's five maternity units across the city. It then created a quality metric based on major factors contributing to maternal morbidity, and also tied a portion of senior leaders' compensation to the metric. Subsequently, severe complications in Black women declined by

29% in one year. **Like with other accountability measures, USofCare believes that QAPI activities will be more successful with greater buy-in from facility leadership.**

Conclusion

Thank you for the opportunity to respond to this proposed rule, which builds towards USofCare's mission to ensure that everyone has high-quality, affordable, personalizable, and understandable access to care. Please reach out to Orla Levens, Federal Policy & Government Affairs Coordinator, at olevens@usofcare.org with any questions.

Sincerely,

Lisa Hunter (she/her)
Senior Director for Policy & External Affairs
United States of Care