UnityPoint Health

Government and External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

September 9, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1809-P
P.O. Box 8010
Baltimore, MD 21244-1810

RE: CMS-1809-P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities; published at Vol. 89, No. 140 Federal Register 59186-59581 on July 22, 2024.

Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure,

UnityPoint Health appreciates this opportunity to provide comments on the proposed rule related to the Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2025. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 29,000 employees and our relationships with more than 375+ physician clinics, 36 hospitals in urban and rural communities, and 13 home health areas of service throughout our 8 markets, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8 million patient visits.

UnityPoint Health appreciates the time and effort of CMS in developing this proposed rule. As a member of the American Hospital Association, UnityPoint Health supports their formal comment letter. Additionally, we respectfully offer the following input.

PAYMENT SYSTEM UPDATE

CMS proposes to update OPPS payment rates for hospitals that meet applicable quality reporting requirements by 2.6%. Additionally, CMS proposed to continue applying a 7.1% payment adjustment for rural Sole Community Hospitals.

Comment: While UnityPoint Health generally supports increases to the OPPS base rate, a 2.6% increase is not sustainable. As cost in health care supply and labor continues to grow, we request that CMS continue to review rates to reflect the current health care financial landscape more accurately. UnityPoint Health supports the proposed adjustment for rural Sole Community Hospitals.

INPATIENT ONLY (IPO) SERVICES

CMS proposes to add three new CPT codes to the IPO list on the basis they require a hospital admission or stay.

Comment: UnityPoint Health supports the IPO list additions.

TELEHEALTH AND REMOTE SERVICES

Telehealth and remote services have been transformative for health care delivery. In general, **UnityPoint Health urges coverage for comprehensive telehealth services on a permanent basis**, or care will continue to be inaccessible to beneficiaries who experience barriers to care. UnityPoint Health is committed to meeting patients at the right time, with the right care, and at the right place – and telehealth is vital to this commitment. **We appreciate CMS efforts to take definitive action and expand telehealth services and billing providers when authorized on a permanent basis**.

Outpatient Therapy, Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT)

During the PHE, outpatient therapy, DSMT, and MNT services were able to be furnished as remote services to beneficiaries in their homes. Congress has subsequently continued the virtual provision of these services for professionals via Medicare telehealth. CMS HOPD regulatory waivers are based on statutory waivers and, in the absence of Congressional action, will sunset after December 31, 2024.

Comment: Post-PHE waivers were extended by Congress to services when furnished by professionals via Medicare telehealth, including outpatient therapy, DSMT, and MNT services. CMS maintained consistent requirements for these policies across payment systems to enable these services to be furnished by hospital staff to beneficiaries in their homes. The ability for HOPD institutional professionals to furnish telehealth services is another workforce flexibility to promote patient access and well-being while allowing efficient use of scarce health care resources. **UnityPoint Health applauds and continues to support this interpretation**.

Periodic In-Person Visits for Mental Health

CAA 2021 waived certain in-person visits 6-months prior to administration of remote behavioral health services and annually thereafter. Congress has subsequently continued this waiver. CMS HOPD regulatory waivers are based on the statutory waivers and, in the absence of Congressional action, will sunset after December 31, 2024.

Comment: The requirement for periodic in-person visits triggering remote mental health services was actually limited to professionals billing via Medicare telehealth and RHCs/FQHCs furnishing remote mental health visits. CMS maintained consistent requirements for these policies across payment systems to enable these services to be furnished by hospital staff to beneficiaries in their homes. The ability for HOPD institutional professionals to furnish telehealth services is another workforce flexibility to promote patient access and well-being while allowing efficient use of scarce health care resources. **UnityPoint Health**

applauds and continues to support this interpretation.

VIRTUAL SUPERVISION FOR CERTAIN DIAGNOSTIC AND REHABILITATION SERVICES

CMS proposes to extend virtual supervision flexibilities through 2025 for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation as well as diagnostic services. This flexibility does not include audio-only technology.

Comment: Given workforce shortages, UnityPoint Health supports this proposal to provide health care access and efficient workflows. If "immediate availability" no longer includes a remote option, there may simply not be enough physicians for an onsite presence at each rural or underserved location. Presently, this flexibility enables a physician to virtually supervise multiple locations giving precedence to the convenience of beneficiaries. This also helps with provider recruitment and retention knowing that they are able to practice top of licensure more efficiently with less windshield time.

PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

CMS proposes to continue the cost threshold of $140 per day for threshold-packaged drugs. As proposed, drug pricing invoices may reflect invoice cost in the absence of available ASP, WAC, AWP, or mean unit cost information starting in CY 2026. CMS also proposes to pay separately for diagnostic radiopharmaceuticals with costs exceeding $630 per day and to establish a new $10 add-on payment for domestically produced radioisotopes derived from non-highly enriched uranium sources.

Comment: UnityPoint Health supports separate payment for diagnostic radiopharmaceuticals above the $630 threshold. In the preamble, CMS appropriately acknowledges the high costs of certain diagnostic radiopharmaceuticals and the potential access barriers that may result from packaged payment. We agree that a separate payment will help ensure continued patient access to diagnostic radiopharmaceuticals. While the payment threshold and proposed annual update methodology appear reasonable at this time, we encourage CMS to be proactive in maintaining adequate reimbursement and access. Specifically, we piggyback on Premier Inc's recommendations for CMS to (1) continue to evaluate its methodology for setting the threshold as additional radiopharmaceuticals enter the market; and (2) monitor for any unintended consequences, including manufacturers purposely pricing diagnostic radiopharmaceuticals just above the payment threshold to take advantage of the separate payment.

COVERAGE FOR COLORECTAL CANCER (CRC) SCREENING SERVICES

Consistent with CY 2025 Physician Fee Schedule proposals, CMS proposes to remove coverage for the barium enema procedure, add coverage for the computed tomography colonography (CTC) procedure, and expand the existing definition of a "complete colorectal cancer screening" to include a follow-up screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test.

Comment: Colorectal cancer is the fourth leading cause of cancer-related deaths in the United States, down from second in 2014. This progress is in large part due to early detection from CRC screenings. In 2014, UnityPoint Health – Meriter was part of this movement by being among the first group of health care providers to partner with Exact Sciences to offer Cologuard. In response to recommendations by the United States Preventive Services Task Force, CMS proposes to include coverage for CTC. As the science continues to advance, **UnityPoint Health supports the updates to CRC screening coverage**.

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

CMS proposes to adopt four new measures, remove two measures, and require that EHR technology be certified for all eCQMs. Beginning in 2025, Care Compare will publicly report Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure – Psychiatric/Mental Health Patients stratification. Additionally, CMS proposes to extend the voluntary reporting period until FY 2027 for both the Hospital-Wide All-Cause Readmission and Standardized Mortality measures.

Comment:

Health Equity and Social Drivers of Health (SDOH) Measures

CMS proposes three new health equity and SDOH measures.

(1) Hospital Commitment to Health Equity (HCHE) measure. This measure (Table 86) is identical to the HCHE measure (5 domains with 11 attestation elements) currently reported under the Hospital Inpatient Quality Reporting (IQR) Program. For hospitals with a common CCN that report under both OQR and IQR, the responses would be the same and result in unnecessary duplicative submissions, needless administrative burden, and added risk for data submission errors. **We recommend shared HDHE reporting for hospitals with a common CCN that report under both IQR and OQR programs**. We also seek clarity on how HCHE may be publicly reported for the OQR.

(2) Screening for SDOH measure. While OQR is the focus of this proposal, CMS seeks to require that all health care settings conduct SDOH screens for every patient and proposes the completion of these screens as a measure within each quality reporting program (impacting reimbursement). This Screening for SDOH process measure requires screening for social risk factors within five health-related social needs domains – food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Hospitals will self-select screening tools to capture and report this information. CMS states that "given the urgency of achieving health equity, it is important to implement this measure [without CBE endorsement] as soon as possible."

First, UnityPoint Health recognizes that SDOH may affect health-related social needs, agrees that the timely identification of SDOH is important, and supports collecting SDOH information by means that are respectful, meaningful, and actionable. Second, we appreciate the ability to use existing screening tools to fulfill this requirement. However, **while we fundamentally agree with and support SDOH screening, we believe that CMS' sense of urgency has resulted in a reporting framework that is flawed**. Many patients receive care from multiple providers and settings whether due to chronic and/or complex conditions or to acute care episode that may require care transitions. There is great potential for repetitive screens on the same patient within short time intervals and "survey fatigue" that adversely impacts the patient experience. To address redundancies, CMS states that entities "could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period. In addition, if this information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, we propose that the HOPD, REH, and ASC could use that information for purposes of reporting the measure in lieu of screening the patient." This statement reveals CMS' lack of understanding of health care operations – how will entities know when SDOH screens conducted by other providers/settings are sufficient, particularly when

providers/settings may not share an EHR and screening tools vary. When CMS is hinging reimbursement on screen completion, these constructs make it easier for providers to conduct a repetitive screen rather than to track down and compare past screens. This also creates duplicative workstreams, when the healthcare industry is suffering from workforce shortages.

(3) Screen Positive Rate for SDOH measure. Like the underlying Screen for SDOH measure, CMS seeks to require that all health care settings track the Screen Positive Rate for every patient as a measure within each quality reporting program (impacting reimbursement). Again, UnityPoint Health supports timely identification of SDOH to ensure that patients are able to meet their needs; however, **this positive rate measure itself is not actionable and should not be tied to reimbursement.**

UnityPoint Health does applaud CMS for aligning data submission requirements for the proposed HCHE and SDOH measures between the IQR and OQR.

PRO–PM Measures

(1) Information Transfer PRO–PM measure. CMS proposes a fourth new measure, Patient Understanding of Key Information Related to Recovery After a Facility Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM). The purpose of this 9-question, 3-domain survey is to assess a patient's understanding of clear and personalized recovery information after a facility-based outpatient procedure or surgery. It is proposed to be administered in days 2 through 7 post-procedure.

UnityPoint Health recommends that the Information Transfer PRO-PM measure be incorporated into the OAS CAHPS survey. As proposed, it is duplicative and creates unnecessary administrative burden, including additional costs related to third-party vendor distribution. As CMS continues to push out patient surveys, this exacerbates "survey fatigue" that is commonplace within the patient experience. The Information Transfer PRO–PM is not just a separate survey, but as noted in the preamble, it overlaps the OAS CAHPS survey. For some patients like those with a total hip or knee arthroplasty (THA/TKA) procedure, this is a third survey. The duplication involves both content and timeframe. For content, the domains are covered in OAS CAHPS survey; and for timeframe, the post-procedure timeframe conflicts with the paper OAS CAHPS survey and a THA/TKA PRO-PM survey. While we appreciate that CMS delayed the administration timeframe so as not to conflict with the electronic survey timeframe, UnityPoint Health is actually reverting to a paper OAS CAHPS survey distribution to bolster response rates.

(2) THA/TKA PRO-PM measure. The Risk-Standardized Patient Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty is an existing measure within the OQR program. **Our concerns remain as this measure presents operational challenges when surveying patients pre- and post-surgical events and is overly burdensome**. HOPD challenges include:

- Multiple surveys: Patients are potentially surveyed multiple times during a year under the PRO-PM, which presents challenges for administering the survey pre- and post-procedure. Post-acute surveys often fall outside the purview of the HOPD. When surgeries are performed under the auspices of independent physicians with HOPD serving as the site of service, HOPDs become the

reporting agent for locums. HOPDs become the de facto reporter for pre- and post-surgical outcomes that are not centrally located within one EHR or even be available across platforms. The measure also requires a follow-up care survey after a 300-day window. This long window from the reference point may create confusion and inaccurate responses and may also conflict with the distribution of CAHPS surveys.

- Measure definition: The denominator includes four sources of data – PRO-PM, claims data, enrollment data, and Census Bureau survey data. Multiple data sources inherently create complexities and undue burdens to avoid potential mismatched patient information.

Other OQR Proposals

UnityPoint Health supports (1) policy modification to pause/suspend measures due to potential patient safety concerns pending a formal rulemaking process; (2) removal of the MRI Lumbar Spine for Low Back Pain and the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measures for CY 2025; (3) stratification of ED wait times for psychiatric/mental health patients on Care Compare; and (4) extension of the voluntary reporting period until FY 2027 for both the Hospital-Wide All-Cause Readmission and Standardized Mortality measures. Thank you!

RURAL EMERGENCY HOSPITALS (REHs)

Rural emergency hospitals are a Medicare provider type that furnishes emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week and may elect to furnish other medical and health services on an outpatient basis.

Comment: Hospital closures are still occurring, and the REH designation could serve as a solution to avert some closures and retain local health care services for rural residents. UnityPoint Health again requests that CMS continue dialogue with Congress to make recommendations related to REH program flexibility and financial viability. With oversight over REHs, Critical Access Hospitals, and small Prospective Payment System hospitals, CMS is well positioned to advise Congress on these facilities – successes and challenges. CMS holds data that could inform Congress on future REH revisions, including:

- 340B Drug Pricing Program eligibility – REHs do not qualify as covered entities for the 340B program. Many Critical Access Hospitals (CAHs) and other small rural hospitals have greatly benefited from the 340B program and would lose much needed funding with the conversion to a REH. **To inform Congressional decision-making, we encourage CMS to perform an analysis projecting the impact of 340B Drug Pricing Program eligibility for REHs.** Similar to CAHs, we would recommend that CMS model REH status with automatic eligibility per this designation and, due to low patient volume, not tie status to disproportionate share hospital percentages.

- Distinct Unit authorization – The statute prohibits REHs from furnishing any inpatient services, except that skilled nursing services may be furnished in a separate and distinct unit of the REH. **To inform Congressional decision-making, we encourage CMS to analyze the impact of furnishing inpatient psychiatric and inpatient rehabilitative services in a separate and distinct unit.** This would enable rural communities with these needs to offer such services, and in the absence of inpatient services, REHs may be able to make these accommodations more readily.

- Transport as a core REH service – As REHs are charged with a focus on emergency treatment, the availability of timely Emergency Medical Services (EMS) is crucial. EMS is not only vital to getting patients to the REH timely but is necessary for timely transfers. Due to large geographic service areas and low population density, rural EMS providers often travel longer distances per run. The availability of rural EMS is often scarce and patchwork funding does not encourage stability in service providers. To assure access to EMS and inform Congressional decision-making, **we encourage CMS to analyze the impact of furnishing EMS within the list of core REH services that receive enhanced reimbursement**.

OBSTETRICAL SERVICES CONDITIONS OF PARTICIPATION (CoPs)

CMS proposes to establish new CoPs for hospital and critical access hospital obstetrical services. These health and safety standards include organization and staffing standards, delivery of care standards, obstetrical staff training policies and procedures, quality assessment and performance improvement (QAPI) program requirements, emergency services readiness standards, and transfer protocols.

Comment: Obstetrical services are part and parcel to UnityPoint Health's identity. UnityPoint Health professionals and hospitals deliver the most babies in the State of Iowa, and UnityPoint Health-Meriter is Wisconsin's largest birthing center. Of our 17 regional hospitals, 12 house labor and delivery units and 9 offer NICU services. Of the 19 Critical Access Hospitals (CAHs) under management arrangements, 4 CAHs offer labor and delivery services.

While UnityPoint Health supports initiatives to improve maternal health care outcomes, we fear the proposed CoPs may create access barriers for obstetrics and may even jeopardize other hospital services, particularly in rural areas. **We request that CMS suspend this proposal until further stakeholder feedback can be gathered and alternatives to this detailed revision to CoPs can be considered**. We encourage CMS to review input provided by the American Hospital Association and Premier, Inc. and to engage these organizations and their resources moving forward. Additionally, CMS should also engage relevant practitioner organizations, including the American College of Obstetrics and Gynecology (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN).

PRIOR AUTHORIZATION TIMEFRAMES FOR HOSPITAL OUTPATIENT DEPARTMENTS

Earlier this year, the CMS Interoperability and Prior Authorization final rule was issued to create, improve, or shorten prior authorization timeframes for certain payers – namely managed care organizations and integrated plans. CMS proposes to align current review timeframes for provisionally affirmed or non-affirmed standard review requests from 10-business days to 7-calendar days. CMS is not proposing to revise the current expedited review decision timeframe from 2-business days to 72 hours (the latter instituted under the CMS Interoperability and Prior Authorization final rule).

Comment: The time and effort spent on prior authorizations has grown exponentially – diverting more health care system resources to this process and impacting the delivery of timely care to our patients. **UnityPoint Health applauds this change to standardized timeframes for standard prior authorization requests and supports maintaining the current expedited prior authorization timeframe.** In the latter case, the benefits of standardization should not increase patient wait times.

PROVISIONS RELATED TO MEDICAID AND THE CHILDREN'S HEALTH INSURANCE PROGRAM

CMS proposes to align regulations with CAA, 2023, to make mandatory a previously optional continuous enrollment policy. CMS also proposes to remove the option to disenroll children from CHIP for failure to pay premiums.

Comment: UnityPoint Health supports both proposals. Ensuring the well-being of our children is of paramount concern as they are the future leaders and workforce of our nation and drivers of our future economic prosperity. Nearly half of all Iowa children rely on Medicaid and CHIP for their health insurance coverage. Medicaid continuous enrollment for children is a crucial step toward guaranteeing a stable, healthy future for the next generation. The policy represents our country's commitment to the health, stability, and future success of our youngest citizens. It ensures that children receive uninterrupted access to essential health care services, supports their educational and developmental progress, alleviates financial pressures on families, promotes equity, and enhances the overall cost-effectiveness of the health care system. By adopting the Medicaid continuous enrollment policy, we make a powerful investment in our children's well-being and the well-being of our nation as a whole by ensuring a healthier future for all.

Likewise, removing the state option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums ensures children will have access to the care they need, when they need it regardless of the financial hardships families may face from month to month. United Ways of Iowa 2023 Asset Limited Income Constrained Employed (ALICE) households have shown a statistically significant increase in the number of working Iowa households since 2021 who are unable to meet their basic needs each month, including housing, food security, and financial stability. This trend is true across the United States with worker pay not aligning with the cost of basic living expenses, but the impact is even greater in rural states like Iowa who have faced significant housing shortages and increased food production and transportation costs over the past three years.

REQUEST FOR INFORMATION: OVERALL HOSPITAL QUALITY STAR RATING MODIFICATION TO EMPHASIZE THE SAFETY OF CARE MEASURE GROUP

CMS seeks information aimed at gathering broad public input on increasing the Safety of Care measure group's contribution to the Overall Hospital Quality Star Rating. Options considered are (1) reweighting the Safety of Care measure group; (2) applying a policy-based adjustment that reduces the Star Rating of any hospital in the lowest quartile of Safety of Care by one star; and (3) reweighting the Safety of Care measure group combined with a policy-based 4-star rating maximum on Star Rating of any hospital in the lowest quartile of Safety of Care.

Comment: UnityPoint Health believes that quality is our best strategy, and we agree that the Safety domain within the Star Ratings is important. We are pleased that CMS is revisiting this domain as current Safety domain metrics may not be a true representation of patient safety and/or the safety culture within a hospital. The current Safety domain includes six hospital acquired infection (HAI) metrics, one THA / TKA complication metric, and one composite adverse event metric (PSI-90). **As we reviewed the three options, we were disappointed that CMS simply looked at methods to recalculate current efforts instead of evaluating whether Safety domains metrics capture a hospital's safety culture**. In that spirit, we encourage CMS to work with stakeholders and efforts could include aligning this domain over time with

performance on the new Inpatient Hospital patient safety structural measure.[1]

Among the options, we prefer Option 2 – reduce by one star, hospitals in the lowest quartile of the Safety domain – with the caveat that only hospitals with at least three metrics in the Safety domain would have the reduction applied. CMS should avoid disproportionate impact to small and rural hospitals from Star Rating changes that may be a function of the reporting mechanism and not the hospital's safety culture. For instance, without a threshold of at least three metrics in the Safety domain, small and/or rural hospitals may be overly penalized from a rare event that could cause a ratings drop into the bottom quartile.

Options 1 and 3 involved reweighting to emphasize the Safety domain at the expense of other domains. As other Star domains are also extremely important, such as Readmissions and Mortality domains, reweighting may be interpreted as CMS de-valuing or de-emphasizing other quality efforts. This also holds true for a combination approach, which could double penalize hospitals and potentially negatively impact other very important quality domains.

We are pleased to provide input on this proposed rule and its impact on our hospitals and health system, our beneficiaries, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

Cathy Simmons, MPP, JD
Executive Director, Government & External Affairs
UnityPoint Health

[1] See UnityPoint Health comment letter dated June 10, 2024, on CMS-1808-P – tracking number lx9-g166-pr90. In the comment letter, we stated our support for the intent of the Patient Safety Structural Measure but voiced concerns related to its prescriptive requirements and its redundancies.