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September 15, 2025

Administrator Mehmet Oz
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1834-P
P.O. Box 8010
Baltimore, MD 21244-1810

RE: CMS-1834-P – Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Star Ratings; and Hospital Price Transparency, published at Vol. 90, No. 135 Federal Register 33476-33865 on July 17, 2025.

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

Dear Administrator Oz,

UnityPoint Health appreciates this opportunity to provide comments on the proposed rule related to the Outpatient Prospective Payment System (OPPS) for Calendar Year (CY) 2026. UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 31,000 employees and our relationships with more than 400+ physician clinics, 36 hospitals in urban and rural communities, and 13 home care areas of service across our 8 regions, 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.

In addition, UnityPoint Health is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Accountable Care is the Accountable Care Organization (ACO) affiliated with UnityPoint Health and has value-based contracts with multiple payers, including Medicare. UnityPoint Accountable Care currently participates in the CMS Medicare Shared Savings Program (MSSP), and it contains providers that have participated in the Center for Medicare and Medicaid Innovation (CMMI) Global and Professional Direct Contracting Model, Next Generation ACO Model, and the Pioneer ACO Model.

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 2.4%. Additionally, CMS proposes 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 2.4% increase is insufficient and not sustainable. **This is particularly problematic should CMS choose to accelerate its 340B offset – equating to a +0.4% net increase for majority of hospitals after adjustments.** As costs in healthcare supply and labor continue to grow, we request that CMS continue to review rates to reflect the current healthcare financial landscape more accurately. UnityPoint Health supports the proposed adjustment for rural Sole Community Hospitals.

OPPS PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

Reporting Average Sales Price (ASP) for Diagnostic Radiopharmaceuticals

CMS proposes to pay separately for diagnostic radiopharmaceuticals with costs exceeding $655 per day.

Comment: UnityPoint Health supports separate payment for diagnostic radiopharmaceuticals above the $630 threshold. CMS 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.

Skin Substitutes

Consistent with its proposal in the Medicare Physician Fee Schedule (PFS), CMS proposes to unpackage skin substitutes and pay for them separately as incident-to supplies. The proposed per unit payment rate is $125.38, based on a volume-weighted ASP of products used in the hospital outpatient setting in Q4 2024.

Comment: CMS is reconsidering its payment policy for skin substitutes due to a nearly 40-fold rise in Part B spending over five years. **We wholeheartedly support the proposed change** in reimbursement of skin substitutes to address unsustainable spending growth and clinical inconsistency in the skin substitute product space. Current payment models incentivize the use of high-cost—rather than high-quality—solutions for patients. *UnityPoint Accountable Care has one patient that has received more than $4.6 million in skin substitutes over the course of 3.5 years.* While the patient is attributed to our ACO through primary care services, the specialist billing for these skin substitutes is not an ACO provider.

As a member of *Accountable for Health*, we echo their general recommendations:

- **Support treating skin substitute products that are not drugs and biologicals as incident-to supplies** in accordance with section 1861(s)(2)(A) of the Act.

- Agnostic on the proposal to subdivide the products into three different payment categories based on their FDA regulatory pathway – PMA, 510(k), 361 H/CTP. Instead, **CMS should consider greater aggregation within payment categories**, including CMS' recommended "synthetic" vs "non synthetic" option, given the lack of differences (i.e., clinical outcomes, supporting evidence, and resource costs) across products.
- **Support the development of a single payment rate across all non-biologic products** regardless of their classification.
- **Support the use of hospital outpatient utilization data** to inform the development of Physician Fee Schedule practice expense RVUs. While the CY 2026 proposal uses the highest volume weighted average to establish the initial payment rate of $125 per sq cm, we **recommend that CMS use the "pooled" payment rate that reflects an average across all products** and would establish a rate of $65 per sq cm. We believe a pooled payment rate will more accurately reflect resource costs and further discourage the "profiteering" and extreme growth in Medicare spending.

ACOs are a gatekeeper of total cost of care and are on the frontlines in identifying and reducing waste to deliver better care for beneficiaries. UnityPoint Accountable Care was one of the ACOs that identified fraudulent catheter claims and partnered with the Center for Medicare, the Center for Program Integrity and the Center for Medicare and Medicaid Innovation (CMMI) to seek resolution. As result, CMS acted to address the fraud and created a process to remove "suspect and anomalous" billing from the Medicare Shared Savings Program (MSSP) and ACO REACH. This was a win for beneficiaries, Medicare, and ACOs. Unlike the fraudulent catheter scam, skin substitutes more appropriately fall within a "dark grey" area of waste – e.g., services that are clinically inappropriate and incentivized as a result of payment policy and lax coverage policy. CMMI has stated that skin substitutes do not fit squarely within the significant anomalous and high suspect (SAHS) billing policy, and we agree but that does not excuse inaction. We encourage CMS to rethink how it could better leverage ACOs to identify potential fraud, waste, and abuse. CMS could streamline the process, build in transparency, and ensure that ACOs are not being held accountable for true fraud. **We reiterate the *Accountable for Health* recommendations for ACOs**:

- **Suspend potentially fraudulent providers** if the circumstance meets certain conditions and communicate this claims suspension to ACOs.
- **Permit REACH and MSSP ACOs to re-open their settlements** for two or three years prior if criminal proceedings are initiated against potentially fraudulent providers and those providers rendered services to ACO-aligned beneficiaries.
- **Create a new stop loss policy** that applies to skin substitutes claims.

Notice of Intent To Conduct Medicare OPPS Drugs Acquisition Cost Survey

CMS will be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including specified covered outpatient drugs (SCODs), and drugs and biologicals CMS historically treats as SCODs. CMS seeks comment broadly on how to approach payment to hospitals for drugs usually paid under the OPPS absent a hospital's response to the survey.

Comment: Cost acquisition surveys are resource intensive, are voluntary, and do not target relevant

stakeholders to accurately capture drug acquisition costs. Given the ongoing workforce and financial challenges facing hospitals, CMS' request should be withdrawn or at least postponed until CMS can revisit how to engage drug manufacturers, pharmacy benefit managers, and other direct stakeholders who influence acquisition costs. UnityPoint Health requests that CMS pursue a solution that:

- Minimizes burden to providers and hospitals. This survey requires significant detail placing "considerable burden for hospitals."1 CMS has grossly underestimated the time and effort to complete this survey at 73.5 hours and $4,000 per hospital.
- Engages drug manufacturers and other entities involved in the supply chain to incorporate data points, such as the cost of goods sold and any applicable discounts.

Foremost, hospital participation in the drug acquisition cost survey is not mandated in statute. Section 1833(t)(14)(D)(iii) sets forth survey requirements but not hospital participation. As stated, this voluntary exercise is resource intensive and will not yield accurate cost information. We are concerned that CMS is soliciting "comment on how we might propose to interpret non-responses to the survey." This is bizarre and does not substitute for the statutory requirement of "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." By requiring a large sample size, this reinforces the interpretation that survey participation is voluntary – otherwise this language would be nonsensical as all hospitals would be in the sample. Finally, it is also contrary to plain language that Congress would delegate to CMS the ability to substitute its opinion as to cost acquisition when survey participation does not reach levels dictated by statute.

340B DRUG PRICING PROGRAM

The 340B Drug Pricing Program allows safety-net providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The program requires pharmaceutical manufacturers to provide front-end discounts on covered outpatient drugs purchased by specified government-supported facilities that serve the nation's most vulnerable patient populations.

Comment: As a large nonprofit, integrated healthcare system in the Midwest, the UnityPoint Health network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals, and Rural Health Clinics provide vital access to healthcare services. The 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois, and Wisconsin. *Not including our affiliated 17 critical access hospitals, we have 12 hospitals that participate as covered entities under the 340B Drug Pricing Program*. Savings from this program help to provide affordable medications and support medication therapy management clinics, behavioral health outreach, preventive screenings, and other team-based and wellness initiatives.

340B Remedy Proposed Redistribution

The offset represents CMS' remedy to address budget neutrality for increased payment from CY 2018

[1] GAO, Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS (April 2006) accessed at https://www.gao.gov/assets/gao-06-372.pdf

through CY 2022 that CMS unlawfully redistributed. Effective January 1, 2026, CMS proposes to increase the annual reduction to the OPPS conversion factor for non-drug items and services from 0.5% to 2% and accelerate the period of reductions from 16 years to six years.

Comment: UnityPoint Health reiterates our position that a budget neutrality adjustment is not statutorily required and is in fact contrary to sound public policy.[2] Rather, CMS has both the legal obligation and legal flexibility, as well as the backing of sound public policy, to not seek a claw-back of funds that hospitals received as a result of CMS' own mistakes and that hospitals have long since spent on patient care. As CMS is now proposing to accelerate this illegal claw-back of funds under 42 § 419.32(b)(1)(iv)(B)(12), our position is the same, and **we again are opposed to the illegal claw-back regardless of its duration.**

If CMS insists on recoupment, the timeline should not be accelerated. Like any business, hospitals budgets for 2026 are set. Over the last two years, our hospitals have relied on this unlawful policy and have incorporated a 0.5 percent reduction into our budgets. Hospital reliance interests are not minimal. By potentially increasing the claw-back threefold on two-months' notice, this does create an unforeseen expense with operational implications. It bears repeating that the purpose of the 340B Drug Pricing Program as enacted in 1992 was to help eligible safety net providers "stretch scarce Federal resources as far as possible reaching more eligible patients and providing more comprehensive services." Any reductions in this program divert resources from providers that care for underserved and vulnerable populations. With thin operating margins, UnityPoint Health hospitals thoughtfully use 340B funds to maintain vulnerable service lines (such as behavioral health, maternal and child health, and/or emergency services), enable preventive/outreach services (such as financial assistance for medications, medication therapy management, meds-to-beds programs, and/or dental clinics), and simply keep doors open (such as salaries for nurses and other frontline care staff).

Ultimately, UnityPoint Health urges CMS to withdraw this proposal. If CMS continues to disagree with that legal analysis, it should maintain or extend the existing claw-back timeline.

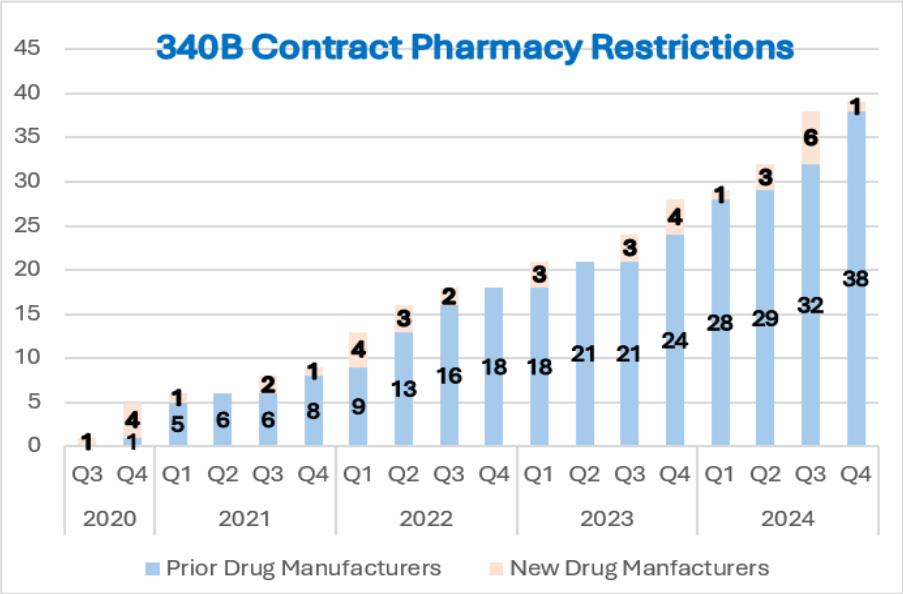
Manufacturer Restrictions on Contract Pharmacies

An important way covered entities are able to get 340B drugs to beneficiaries is through contract pharmacy arrangements. Under these arrangements, covered entities purchase drugs at 340B prices and contract with pharmacies in the community to dispense the drugs to covered entity patients on the covered entity's behalf. Since July 2020, 39 drug manufacturers have implemented policies refusing to provide or restricting 340B pricing to covered entities for drugs dispensed through contract pharmacies.

Comment: UnityPoint Health strongly encourages the enforcement of the 340B Program requirements to stop unilateral action by drug manufacturers to establish or alter conditions of participation. There are currently **39** drug manufacturers that have imposed contract pharmacy restrictions – AbbVie; Alkermes; Amgen; Astellas; AstraZeneca; Bausch & Lomb; Bausch Health; Bayer; Biogen; Boehringer Ingelheim; Bristol Myers Squibb; Eisai; Eli Lilly; EMD Serono; Exelixis; Genentech; Gilead; GlaxoSmithKline;

[2] UnityPoint Health comment letter to CMS-1793-P (Medicare Program: Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022) on September 11, 2023, accessed at Regulations.gov tracking # lmf-2d7j-f5ns

Incyte Corp.; Jazz Pharmaceuticals; Johnson & Johnson; Karyopharm Therapeutics; Liquidia; Mallinckroft Pharmaceuticals; Merck; Novartis; Novo Nordisk; Organon; Pfizer; Sandoz; Sanofi; Sobi; Sumitomo; Takeda; Teva; UCB; United Therapeutics; Vertex Pharmaceuticals; and Viatris. *This number keeps growing (see timeline at right – 340B Contract Pharmacy Restrictions) as there is no government reprisal.*



Meanwhile, the impact of these restrictions is devastating. First, as manufacturers step into the shoes of regulators and impose new rules, this increases administrative workload for hospitals just to access the drugs at 340B-acquired drug pricing. Each manufacturer has imposed different restrictions, such as mandating submission of claims data using 340B ESP (a specific vendor) to access 340B pricing for drugs dispensed at contract pharmacies, refusing 340B pricing for drugs dispensed at contract pharmacies unless a limited exception applies, or both claims reporting and limited exceptions. **Effectively, hospitals now have 40 340B drug pricing programs to administer, including the one authorized by Congress and administered by the Health Resources and Services Administration (HRSA).** The 39 drug manufacturer programs are subject to frequent change with little notice, if any, and the frequency of changes is increasing. Many drug manufacturers no longer provide advanced notification of policy changes and simply post changes to their websites with simultaneous effective dates. This results in compliance chasing activities that distract 340B safety-net providers with extra administrative burdens and divert resources away from the program's intent to administrative tasks. Second, **this assault on the 340B Program from manufacturers impacts beneficiaries and access to medications**. These medications are needed to treat and manage chronic conditions and are not luxury items. Contract pharmacies enable outreach to beneficiaries at convenient locations and often with more extended hours. These restrictions also impact the growing landscape of pharmacy deserts – an Iowa Pharmacy Association survey reported that upwards of 40% of independent pharmacies may shutter through 2025.[3] In an era when CMS is doubling down on telehealth to facilitate healthcare access and beneficiary convenience, the access to 340B-acquired drugs through community pharmacies seems similarly situated.

UnityPoint Health urges HHS and the Office of the Inspector General (OIG) to use current statutory authority in imposing civil monetary penalties against all drug manufacturers who have unlawfully

[3]C. Tevis, "Pharmacy deserts threaten Iowa's picture of health, Iowa Capital Dispatch, March 27, 2024, accessed at https://iowacapitaldispatch.com/2024/03/27/pharmacy-deserts-threaten-iowas-picture-of-health/

overcharged safety-net healthcare providers. These manufacturers' unlawful actions have undermined 340B hospitals' ability to serve vulnerable communities, particularly in rural areas, where contract pharmacies are vital to providing access to more affordable medications.

Manufacturer Rebate Reimbursement Actions

On August 1, 2025, HRSA announced a voluntary 340B Rebate Pilot to start January 1, 2026.

Comment: For over 30 years, the 340B Program has been administered by HRSA as a discount program with the exception of State AIDS Drug Assistance Programs. With the launch of the Rebate Pilot, HRSA indicated this would "fundamentally shift how the program has operated." This pilot is proceeding solely at the request of the pharmaceutical industry, and it basically forces 340B hospitals to float substantial funds to pharmaceutical manufacturers above 340B pricing. UnityPoint Health submitted comments to HHS Docket No. HRSA-2025-14998.[4] UnityPoint Health raised concerns related to the Rebate Pilot's absent rationale, its adverse, unintended impacts, and lack of guardrails.

PARTIAL HOSPITALIZATION AND INTENSIVE OUTPATIENT SERVICES

CMS proposes to maintain the current payment rate methodology for calculating PHP and IOP payment rates for hospital-based providers. For CMHCs, CMS proposes to multiply the CY 2026 rates for the hospital-based PHP and IOP APCs by 0.4 to calculate the payment rates for the CMHC PHP and IOP APCs.

Comment: UnityPoint Health is the largest provider of behavioral health services in Iowa. In addition, we operate 5 CMHCs in Iowa and 1 CMHC in Illinois. **We support continued federal payments for behavioral health services across the care continuum.**

INPATIENT ONLY (IPO) SERVICES

CMS proposes to eliminate the IPO list with a transitional period of three years. For CY 2026, CMS proposes to remove predominantly musculoskeletal procedures from the IPO list and assign them to clinical ambulatory payment classifications (APCs), including a proposed level 7 musculoskeletal procedures APC. These services will typically be treated as a single episode of care with one co-payment and be exempt from the two-midnight rule medical review.

Comment: We do not support this proposal. The IPO list contains mostly surgical procedures that are majorly invasive, complicated, and require the care and coordinated services provided in the inpatient setting of a hospital. With high-quality beneficiary outcome being paramount, we are concerned that IPO list elimination will result in more adverse safety and quality issues for beneficiaries outside an inpatient setting.

Should CMS elect to continue with the proposed phased-in approach, we urge CMS to monitor beneficiary outcomes for procedures removed from the IPO list across settings, including quality measures (readmissions, avoidable ED visits, adverse events, etc.), beneficiary characteristics (age, comorbidities, etc.), and post-acute service utilization. To further support quality outcomes for all beneficiaries, we request CMS to continually evaluate baseline Fee-For-Service payments for potential readjustment to reflect heightened patient acuity and assure access to inpatient services. As an early adopter of value-based arrangements, including ACO contracts, UnityPoint Health understands and

[4] 340B Rebate Pilot_UnityPointHealth_9.8 – Regulations.gov comment tracking # mfb-cy0k-6jxz

supports transitioning care to lower acuity settings as dictated by each patient's status and population health principles. From a policy perspective, this highlights issues related to inequities perpetuated within the Fee-for-Service structure. Currently, lesser costs from "healthier" patients balance greater costs from more complex patients. As procedures are removed from the IPO list, "healthier" patients are transitioned to outpatient settings leaving more complex, costly patients within inpatient settings. These policies perpetuate a for-profit mentality and encourage more infrastructure builds to cater to younger, healthier, and less costly patients, divert resources from existing inpatient settings, and lead to greater healthcare costs overall. In the Midwest where access is determined by geography, this approach significantly impacts the sustainability of inpatient services, particularly in the nonprofit arena, and ultimately undermines access to care.

SITE NEUTRAL PAYMENTS FOR SERVICES FURNISHED AT OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

CMS proposes to expand site neutral payments to drug administration services furnished by excepted off-campus provider-based outpatient departments, with an exemption for rural sole community hospitals (SCHs). Payment for these services would be reduced to the "PFS-equivalent" rate of 40% of the OPPS rate.

Comment: UnityPoint Health is strongly opposed to the proposed expansion of site-neutral payment policies for drug administration services in grandfathered off-campus hospital outpatient departments (HOPDs). These departments are held to significantly higher regulatory and safety standards than freestanding physician offices, and the beneficiaries served are more vulnerable and medically complex in comparison .

The *American Society of Health-System Pharmacists* graphic to the right lists the heightened safety and care coordination standards that are embedded in HOPDs. This is a differentiator, especially for medically complex patients. Hospitals must maintain sterile environments, including clean rooms with positive air pressure, and conduct environmental sampling to prevent microbial contamination. Drug preparation is supervised by licensed pharmacists, and hospitals implement strict protocols to protect staff from exposure to hazardous drugs. Moreover, hospitals are equipped to make real-time clinical adjustments and respond to adverse drug reactions with on-site physicians and emergency infrastructure. These standards are mandated by the Food and Drug Administration, U.S. Pharmacopeia, DNV (Det Norske Veritas), and state boards of pharmacy. Site-neutral principles disregard these variations and create a false equivalence between fundamentally different care environments.

	REQUIREMENTS	HOSPITAL	PHYSICIAN OFFICE	FREE-STANDING SITE
SAFE PREPARATION	Clean room with positive air pressure to prevent microbial contamination	✓	✗	✗
	Environmental sampling to ensure sterile conditions	✓	✗	✗
	Drug preparation supervised by a licensed pharmacist	✓	✗	✗
	Employee protections from exposure to hazardous drugs	✓	✗	✗
	Drug Supply Chain Security Act rules prevent use of counterfeit or mishandled drugs	✓	✗	✗
SAFE ADMINISTRATION	Drug barcoding and EHR integration reduce administration errors	✓	✗	✗
	Hospital pharmacist confirms safe dosing and checks for drug-drug interactions	✓	✗	✗
	On-site physician for prompt response to adverse reactions	✓	✓	✗
CARE COORDINATION	On-site pharmacy prevents delays accessing medication	✓	✗	✗
	On-site pharmacy can modify dosing on day of infusion based on therapeutic needs	✓	✗	✗
	Provides care for the most complex patients	✓	✗	✗
	Provides access to care 24 hours per day	✓	✗	✗
	Provides care to uninsured and underinsured patients	✓	✗	✗
SAFETY OVERSIGHT	Food and Drug Administration, state boards of pharmacy, U.S. Pharmacopeia, and The Joint Commission	✓	✗	✗

The proposed regulation disregards that HOPDs serve a sicker, more clinically complex, and more economically vulnerable Medicare population. Our experience mirrors data collected for the American Hospital Association[5] that finds Medicare beneficiaries primarily treated in HOPDs as compared to independent physician offices are:

- 54% more likely to be under age 65 with Medicare eligibility based on disability, end-stage renal disease or amyotrophic lateral sclerosis.
- 61% more likely to be dual eligible.
- 60% more likely to reside in rural counties.

HOPD Medicare beneficiaries are also more likely to be living with more severe chronic conditions and have a recent history of hospital inpatient and emergency department services.

In general, patients with higher complexity likely require a heightened level of care and the additional safety and care coordination standards demanded of HOPDs. When payment is eroded to support the continuum of care options, increased wait times and reduced access to higher acuity levels of care for all patients is the certain outcome.

TELEHEALTH AND REMOTE SERVICES

Telehealth and remote services have been transformative for healthcare 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**.

Virtual Supervision for Certain Diagnostic and Rehabilitation Services

CMS proposes to make virtual supervision flexibilities permanent for coronary rehabilitation, intensive coronary rehabilitation, and pulmonary rehabilitation as well as certain diagnostic services. This flexibility does not include audio-only technology.

Comment: UnityPoint Health supports this proposal to provide healthcare 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.

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

[5] Prepared for AHA by KNG Health Consulting LLC, Comparison of Care in Hospital Outpatient Departments and Independent Physicians Offices: Updated Findings for 2019-2024 (September 2025)

for professionals via Medicare telehealth. CMS HOPD regulatory waivers are based on statutory waivers and, in the absence of Congressional action, will sunset after September 30, 2025.

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 healthcare 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 September 30, 2025.

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 healthcare resources. **UnityPoint Health applauds and continues to support this interpretation.**

REQUEST FOR INFORMATION: MEASURE CONCEPTS UNDER CONSIDERATION FOR FUTURE YEARS IN THE HOSPITAL OUTPATIENT, ASC, AND REH QUALITY REPORTING PROGRAMS

CMS seeks information on well-being and nutrition measures for consideration in future rulemaking.

Comment: UnityPoint Health appreciates the Administration's interest in preventive care and encouraging healthy lifestyles. These upstream supports are welcome to avoid healthcare interventions when possible. Currently hospitals collect, track, and report numerous quality measures, and similar to our input on all new measures, **we encourage CMS to thoughtfully design measures / tools that are meaningful, actionable, and avoid duplication**. From the patient perspective, CMS should also consider reducing survey fatigue by avoiding lengthy screening tools with repeated and duplicative administration across settings of care. Until we understand CMS definitions, goals, and objectives in these areas, it is difficult to opine as to how to appropriately identify these concepts in constructs that are meaningful and capture improvement / outcomes. We look forward to partnering with CMS as details are released and are happy to participate in stakeholder groups that develop and review such measures / tools.

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

CMS proposes the following updates: (1) Adopting the emergency care access and timeliness eCQM; (2) removing the COVID-19 vaccination coverage among healthcare personnel (HCP) measure, the health equity commitment measure, two social drivers of health screening measures, and ED timeliness measure; (3) extending voluntary reporting for computed tomography measure; and (4) revising the extraordinary

circumstances exception (ECE) policy.

Comment:

Emergency Care Measures Modification:

CMS proposes to adopt the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM). Voluntary reporting would start CY 2027 and mandatory reporting would begin CY 2028. The eCQM measure is intended to replace both the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure and the Left Without Being Seen measure. These chart-abstracted measures would cease to be reported in CY 2028.

Comment: While the eCQM measure is conceptually sound, we request that CMS consider a two-year period for voluntary reporting (2027 and 2028) to enable a smooth transition from the chart-abstracted measures to the new eCQM. Current measures should be continued through CY 2028. The current measures represent discrete fields, but the specific timeframes in the proposed measure pose issues for accurate data capture. Although we appreciate the stratification by age and behavioral health in the proposed measure, its timeframes are inconsistent with how many facilities currently track patient movement and triage activities. For instance, when an individual presents at the Emergency Department, the proposed measure does not consider the overall population being served at the time. Further, when vitals are performed during triage, depending upon results, this may not always equate to Emergency Department services starting. To assure accurate data capture for this new measure, adequate time is needed for EMR vendors to develop, test, and implement the new measure prior to providers operationalizing the new measure. Hospitals will also need time to transition measure protocol, including staff retraining and potentially adding new tracking locations or even beds.

Excessive Radiation eCQM:

CMS proposes to modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) measure (Excessive Radiation eCQM) from mandatory reporting to voluntary reporting beginning with the CY 2027 reporting period.

Comment: UnityPoint Health wholeheartedly supports the extension of voluntary reporting. The mechanics of capturing radiation dosing is extremely difficult and may not be collected in standard EMRs efficiently or effectively. As most of this eCQM data is stored in software used to program CT machines, this measure will require extra software builds as well as applications to bridge the gap in data between CT machine and EMR. This will be particularly burdensome for smaller hospitals.

Measure Removal:

CMS is removing measures for Hospital Commitment to Health Equity, COVID-19 Vaccination Coverage among Healthcare Personnel (HCP), as well as both Screening and Screen Positive for Social Drivers of Health. This mirrors what was finalized in the FY26 Inpatient Prospective Payment System Final Rule.

Comment: Despite investing in infrastructure to capture and report the four standardized patient assessment data elements, **UnityPoint Health agrees that the CMS mandate to capture these data elements across multiple care settings is burdensome and duplicative for patients and staff**. In particular, the COVID-19 Vaccination Coverage among HCP measure definition has become challenging, inaccurate, and essentially meaningless. As vaccines developed and different versions were approved,

version approval and administration did and do not fall neatly within one CMS data capture and reporting period. As a result, reporting and data capture tied to the administration of the most recent vaccine version created arbitrary time demarcations and failed to recognize/credit past efforts to administer former vaccine versions.

ECE Policy:

CMS proposes to update the ECE Policy to explicitly include extensions as a type of extraordinary circumstances relief option, in addition to exceptions. The ECE process remains unchanged.

Comment: This is consistent with the FY26 Inpatient Prospective Payment System Final Rule. **We support**.

PRO–PM Measures:

There are two patient-reported outcomes-based performance measures within the OQR measure set.

Comment: Patient experience is important, and CMS has recently chosen to capture this through patient-reported outcome-based performance measures. UnityPoint Health reiterates our concerns with these measures as constructed.

(1) Information Transfer PRO–PM measure. The 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) is a 9-question, 3-domain survey. Its purpose is to assess a patient's understanding of clear and personalized recovery information after a facility-based outpatient procedure or surgery. It is to be administered on days 2 through 7 post-procedure.

UnityPoint Health recommends that the Information Transfer PRO-PM measure be incorporated into the OAS CAHPS survey. This measure is duplicative and creates unnecessary administrative burden, including additional costs related to third-party vendor distribution. This survey exacerbates "survey fatigue" that is commonplace within the patient experience. The Information Transfer PRO–PM is not just a separate survey, but 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 **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.
- Data Collection Responsibility: Due to the elective nature of these procedures and the data collection length, the party responsible for this measure should be the specialist/provider and perhaps their accreditation agencies, but not hospitals. While hospitals serve as the procedure site, it is the provider that handles pre- and post-procedure follow-up and care coordination. **This measure is a missed opportunity for CMS to engage specialists in the transition to value**. It is the providers/specialists, not hospitals, who will have the ability to use or act on the data for quality improvement. By having the providers engaged, this may also help to streamline patient surveys and reduce overall survey fatigue for Total Hip Arthroplasty and/or Total Knee Arthroplasty procedures.

RURAL EMERGENCY HOSPITAL QUALITY REPORTING (REHQR) PROGRAM

CMS proposes the following updates: (1) Adopting an alternative emergency care access and timeliness eCQM beginning with the CY 2027; (2) removing health equity commitment measure and social drivers of health screening measures; and (3) revising the extraordinary circumstances exception policy.

Comment: The Center for Healthcare Quality & Payment Reform recently reported that "More than 700 rural hospitals – one-third of all rural hospitals in the country – are at risk of closing because of the serious financial problems they are experiencing. Over 300 of these rural hospitals are at immediate risk of closing because of the severity of their financial problems."[6] The REH designation could serve as a solution to avert some closures and retain local healthcare services for rural residents. We echo our OQR comments on the emergency care access and timeliness eCQM and request that CMS consider a two-year period for voluntary reporting (2027 and 2028) to enable a smooth transition from the chart-abstracted measures to the new eCQM.

Aside from quality measures, UnityPoint Health 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**

[6] *Rural Hospitals At Risk of Closing* (August 2025) accessed at https://chqpr.org/index.html

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**.

HOSPITAL QUALITY STAR RATING

CMS proposes updates to the overall hospital quality star rating to increase the importance of the safety of care measure group. In Stage 1, CMS would implement a 4-star cap – limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of 4 stars out of 5. In Stage 2, CMS would implement a Blanket 1-Star Reduction – reduce the Overall Hospital Quality Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measure scores) by 1 star, to a minimum 1-star rating.

Comment: UnityPoint Health believes that quality is our best strategy, and we agree that the Safety domain within the Star Ratings is important. We do have concerns that the domain with its 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). **We are disappointed that CMS has elected to recalculate current efforts instead of evaluating whether the Safety domain's 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.[7]

UnityPoint Health expressed our preference for a one-star reduction for hospitals in the lowest quartile of the Safety domain in last year's comment letter – with the caveat that only hospitals with at least three metrics in the Safety domain would have the reduction applied. **We do urge caution in implementation**

[7] 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.

to 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, even with a threshold of at least three metrics in the Safety domain, small and/or rural hospitals may be overly penalized from a rare, one-time adverse event that could cause a ratings drop into the bottom quartile. Smaller facilities have smaller measure denominators. This subjects them to severe measurement swings that can be skewed from one adverse event in one quarter's data. Time lags in reporting Star Ratings also compound this impact because often efforts to correct an adverse event have already been successfully undertaken and the issue ceases to exist when ratings are released**. To mitigate impact from delayed reporting, CMS could consider providing bonus points for maintaining or improving scores on the Inpatient Hospital patient safety structural measure**. This new foundational measure demonstrates more timely efforts by hospitals to improve quality and safety for patients and could be incorporated for all hospitals without additional reporting burden.

PRICE TRANSPARENCY

CMS again proposes to use the reported median payer-specific negotiated charge by MS-DRG from Medicare Advantage plans in a market-based MS-DRG relative weight methodology.

Comment: When choosing healthcare providers, consumers consider a number of factors in their value equation, including location, experience, services, quality, outcomes, and cost. **UnityPoint Health is committed to meaningful price transparency for patients.** Our approach to price transparency focuses on providing each patient or prospective patient personalized information for them to understand their benefit plans and their out-of-pocket responsibility, enabling them to be educated consumers. To further empower patients with meaningful data to make decisions about their healthcare, there are more appropriate avenues outside this proposed rule, such as targeting data on actual out-of-pocket costs through Transparency in Coverage Rule requirements on payers.

The current proposal's added burden does not equate to better consumer information. To improve this process, we request that CMS consider the following.

- Data Elements: The addition of new data elements to the MRF—including median, 10th percentile, and 90th percentile allowed amounts, and the count of allowed amounts—introduces unnecessary complexity. Hospital pricing is inherently variable and context-specific, influenced by patient acuity, bundled services, and payer-specific cost-sharing rules. The proposed methodology also raises issues - calculating percentile values from remittance data may not yield meaningful or comparable results across hospitals, and using EDI 835 electronic remittance advice (ERA) data may not be feasible for all hospitals, particularly smaller and rural providers with limited technical capacity. Finally, CMS continues to underestimate the time and effort for providers to comply with rapid-fire changes to data reporting. For UnityPoint Health hospitals, not one of our hospitals will be able to comply with these requirements for a one-time cost of $478 per hospital, despite any economies of scale that exist for health systems. **We request that CMS allow hospitals at least one year to adopt the new data elements.**
- Attestation Concerns: **We urge CMS to retain the current "good faith effort" attestation, which represents realistic expectations**. Instead, CMS proposes attestation language requiring hospitals

to affirm they have provided "all necessary information" for the public to derive service prices. This standard does not account for the complex billing framework that is based on external factors, including Medicare regulations and guidance and insurer behavior and calculations. CMS also proposes to require hospital CEOs or other senior executives to sign the attestation. This places unnecessary burdens on hospital leaders, when CMS should rely in good faith on hospital subject matter experts over the information in the attestation. **We encourage CMS to retain the current attestation signature requirements.**

- Overlapping Mandates: Hospitals are subject to overlapping federal and state transparency mandates, including the Hospital Price Transparency Rule, the Transparency in Coverage Rule for insurers, and the No Surprises Act. Each regulation uses different methodologies and formats, leading to inconsistent information and patient confusion. Patients may receive pricing data from hospital MRFs, cost estimator tools, insurer platforms, and Good Faith Estimates. **We urge CMS to work with other agencies and stakeholders to align and streamline transparency requirements, ensuring that patients receive consistent, understandable information.**

MARKET-BASED MS-DRG DATA COLLECTION

CMS revives its proposal to use the reported median payer-specific negotiated charge by MS-DRG from Medicare Advantage plans in a market-based MS-DRG relative weight methodology. Reporting would be required for fiscal year (FY) 2026 cost reports submitted by hospitals paid under the Inpatient Prospective Payment System (IPPS) and utilized in the MS-DRG weight calculation for FY 2029.

Comment: UnityPoint Health urges CMS to withdraw this proposal. We agree with the American Hospital Association and its position that this proposal raises policy and legal issues and should not be pursued.

This proposal would impose a significant new regulatory burden with no rational basis and ignores critical issues associated with the use of MA negotiated rates to set Medicare fee-for-service MS-DRG relative weights.

- Negotiated Charges as Rate Setting Basis: ***Rate setting should be rooted in resource intensity rather than contracted rates***. The latter is a fundamentally flawed approach which will create an expectation of lower costs over access to care and quality care. Lower reimbursement without reference to resources will result in employment cuts and ultimately a reduction in access to care, including service line and hospital closures. Rate setting based on negotiated charges fails to recognize economies of scales or that some service lines subsidize other negative margin but needed service lines.

  Specifically, the assertion that median MA negotiated rates embody market-based prices is inaccurate and overlooks the fact that most MA markets do not resemble competitive marketplaces. In fact, this proposal could result in new pricing distortions rather than driving market-based IPPS rates. Although CMS highlights its concerns that hospital chargemasters do not reflect true market costs, CMS presumes that MS and commercial rates reflect competitive negotiations between hospitals and private health insurance plans. While this may be the case for some markets and individual hospitals, other factors may contribute to the rates paid by MA plans and private insurers,

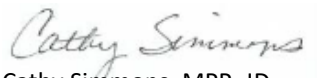
including whether rates are set based on a percentage of Medicare fee-for-service or the level of competition (between either hospitals or payers) in the individual hospital's market. For instance, in the State of Iowa, one MAO has 43% market share and another MOA has an estimated market share of between 15-25%.

- Provider-Based Arrangements: Some hospitals include ambulatory settings within provider-based arrangements. ***CMS does not describe how posting of charges and development of median rates will account for these arrangements***.
- Value-Based Arrangements: UnityPoint Health, through UnityPoint Accountable Care, is an early adopter of Medicare valued-based arrangements – portions of our health system have participated in the Pioneer ACO Model, Medicare Shared Savings Program, Next Generation ACO Model, REACH ACO Model, Bundled Payment Care Initiative, Medicare Care Choices Model, Home Health Value-Based Purchasing Model, and the Increasing Organ Transplant Access (IOTA) Model. CMS has mandated participation by some of our hospitals in the future Transforming Episode Accountability Model (TEAM). ***CMS does not describe how posting of charges and development of median rates will account for episodes of care and risk arrangements, which often contain claw-back provisions***. In addition, bundling is defined differently among insurers and is not easily conducive to comparison pricing. These rules intended for Fee-For-Service providers do not align with a transition to value and raise challenges that underscore the importance of health plans as the nexus for pricing information.

Lastly, the use of Part C (Medicare Advantage) data to overhaul the inpatient hospital (Part A) PPS relative weights is improper and raises concerns about the substantial negative impacts for our hospital and the communities we serve. **We oppose this data collection and MS-DRG reweighting methodology**.

We appreciate the opportunity 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,



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