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September 9, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1807–P
P.O. Box 8016
Baltimore, MD 21244–8016

RE: CMS-1807-P: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments, published in Vol. 89, No. 147 Federal Register 61596-62648 on July 31, 2024.

Submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure:

UnityPoint Clinic appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services (CMS) proposed rule for the 2025 Physician Fee Schedule (PFS). UnityPoint Clinic is comprised of 1,180+ physicians and advanced practice providers in 370+ physician clinics located in Iowa, Illinois, South Dakota and Wisconsin and provided more than 4.8 million clinic visits in 2023. UnityPoint Clinic offers services in family medicine, internal medicine, obstetrics/gynecology, pediatrics, and a wide variety of specialty services, and is the ambulatory arm of UnityPoint Health. UnityPoint Health is one of the nation's most integrated health care systems. UnityPoint Health has more than 29,000 employees and, aside from UnityPoint Clinic, offers services through 36 hospitals in urban and rural communities and 13 home health areas of service throughout our 8 Midwest markets.

In addition, UnityPoint Health and UnityPoint Clinic are committed to payment reform and are actively engaged in numerous initiatives that support population health and value-based care. UnityPoint Accountable Care is the accountable care organization (ACO) affiliated with UnityPoint Health and UnityPoint Clinic 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. In total, UnityPoint Accountable Care provided services to 361,855 covered lived in 2023.

UnityPoint Clinic respectfully offers the following comments to the proposed regulatory framework.

REVISIONS TO PAYMENT POLICIES

Conversion Factor

CMS proposes a 2025 physician conversion factor (CF) of $32.3562, a decrease of approximately 2.8% from the 2024 CF of $33.2875.

Comment: According to data from the Medicare Trustees[1], Medicare physician pay has increased just 9% over the last 23 years, or 0.4% per year on average. This paltry average has not been achieved in the last eight years, and the consistent erosion of the physician CF devalues providers who are the most educated and skilled within the health care workforce. Notably the actuarial statement in the Medicare Trustee report cautions "*Uncertainty remains, however, regarding adherence to current-law payment updates, particularly in the long range. This concern is more immediate for physician services, for which a negative payment rate update is projected for 2025 and updates are projected to be below the rate of inflation in all future years."*[2] These cuts coexist in a challenging financial backdrop of pandemic recovery, inflationary pressures, and exponential increases to health care labor and supply costs, as well as an escalation in regulatory burdens (e.g., prior authorization, interoperability requirements, and participating in Medicare quality programs such as MIPS). These cuts ultimately threaten access to vital services provided to Medicare beneficiaries and Medicaid members. **UnityPoint Clinic strongly requests CMS adequately increase the physician CF to reflect the current financial landscape of health care.**

Medicare Physician Conversion Factor (2017–2025)		
Year	CF	Actual Update (%)
Jan 1, 2017	35.8887	0.24
Jan 1, 2018	35.9996	0.31
Jan 1, 2019	36.0391	0.11
Jan 1, 2020	36.0896	0.14
Jan 1, 2021	34.8931	-3.32
Jan 1, 2022	34.6062	-0.82
Jan 1, 2023	33.8872	-2.08
Jan 1, 2024	33.2875	-1.77
Jan 1, 2025	32.3562*	-2.8*

**proposed*

Evaluation and Management (E/M) Visits Add-On Code for Complexity

In CY 2024, CMS finalized a new E/M visit complexity add-on code, G2211. In CY 2025, CMS proposes to allow G2211 to be billed when the E/M base code is reported by the same practitioner on the same day as an annual wellness visit, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting.

Comment: UnityPoint Clinic supports this proposal, which better recognizes care delivery by providers serving an aging population.

Enhanced Care Management

CMS proposes three new G codes to describe Advanced Primary Care Management (APCM) services that

[1] *2024 Annual Report of the Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, p. 4, accessed at https://www.cms.gov/oact/tr/2024 - "Physician payment update amounts are specified for all years in the future, and these amounts do not vary based on underlying economic conditions, nor are they expected to keep pace with the average rate of physician cost increases. These rate updates could be an issue in years when levels of inflation are high and would be problematic when the cumulative gap between the price updates and physician costs becomes large."

[2] Id.

incorporate care management services and communication technology-based services (CTBS). These tiered codes may only be furnished by one practitioner and payment related to services provided during a calendar month.

Comment: We appreciate that enhanced care management is being revisited through the lens of APCM services, which better recognizes the resources required to deliver advanced primary care and the need to reduce administrative burdens associated with time-based billing. While we understand and support that APCM codes represent bundled services and may only be reported once per calendar month for services rendered, we have operational concerns and request that CMS consider these revisions:

- Concurrent billing. **We encourage CMS to revise this policy such that the *same practitioner* could not bill duplicative services, rather than an *entire practice*.** As a backdrop, multi-specialty practices are becoming more prevalent. Under the umbrella of one tax identification number (TIN), multi-specialty practices may be comprised of hundreds of providers at multiple locations and often employ primary care providers as well as specialists. As proposed, a TIN cannot currently bill for APCM services and certain other care management and CTBS, including chronic care management (CCM), transitional care management (TCM), remote evaluation of patient images/videos, and virtual check-ins. There are instances in which specialty services should be reimbursed outside the constructs of enhanced care management for primary care services (such as a virtual check-in). Additionally, this proposal arbitrarily restricts billing for specialty services on the basis of how a physician practice is organized for taxation, as a specialist under a separate TIN could bill for these services.
- Patient complexity in coding. **We encourage CMS to revisit patient complexity to reflect the additive impact of multiple chronic conditions.** There is a significant number of Medicare beneficiaries with more than 2 conditions and, as the number of chronic condition increases, the types of support and time needed to manage these patients increases. We do not believe that the current codes appropriately resource care for beneficiaries with multiple complex conditions and CMS could consider additional tiers and/or increases in RVU assumptions to include all possible services.
- APCM service elements and practice-level capabilities. CMS delineates 10 APCM elements and capabilities that billing practitioners must have the ability to furnish monthly as appropriate for a beneficiary. **The documentation requirements remain unclear and the potential burden may counteract the benefits of these codes**. For MSSP ACO providers, CMS will assume three of these elements (initiating visit for new patients; patient population-level management; and performance measurement) without documentation. We support; however, we believe that CMS has missed other elements that ACOs provide intrinsically – comprehensive care management; patient-centered comprehensive care plan; and enhanced communication opportunities – and that CMS should also assume those elements as well. Lastly, we request that CMS clarify documentation requirements and minimize associated administrative burden.

Cardiovascular Risk Assessment and Risk Management

CMS proposes a code and payment for Atherosclerotic CVD (ASCVD) Risk Assessment (GCDRA). The assessment is to be furnished by the practitioner on the same day they furnish an E/M visit, and risk

assessment findings are to be incorporated by the practitioner into the patient's diagnosis and treatment plan established during the visit. CMS also proposes a code and payment for ASCVD Risk Management Services (GCDRM) that incorporate the "ABCS" of CVD risk reduction (aspirin, blood pressure management, cholesterol management, and smoking cessation) for beneficiaries at medium or high risk for ASCVD (>15 percent in the next 10 years). GCDRM may be provided by auxiliary personnel under the general supervision of the billing practitioner, must have patient consent, and is to be billed no more than once per month for one practitioner per beneficiary.

Comment: This proposed MIPS improvement activity is informed by the results of the CMMI Innovation Center Million Hearts Model, and ASCVD Risk Assessment is recommended by both the American College of Cardiology (ACC) and American Heart Association (AHA). CMS anticipates that GCDRA and GCDRM will be billed by primary care providers in order to improve care coordination and care management, and as such, CMS has proposed to include these codes within the definition of primary care services for purposes of MSSP beneficiary assignment. The proposed rule does not require a specific assessment but leaves this to practitioners to determine which tool best fits the needs of their patients and practice.

UnityPoint Clinic supports the addition of these tools/services, but requests that CMS consider modifications suggested by the American Medical Association. Specifically, timing of the ASCVD Risk Assessment should be flexible – either paired with any preventive service/visit (not solely an E/M visit) or as a preventive follow-up if lab services are required. As for ASCVD Risk Management Services, hypertension control could be clarified to include interventions such as blood pressure medications and SMBP devices. It should also be specified that ASCVD Risk Management Services may be additive for certain patients and not simply a substitute/replacement for other CCM services. We reiterate AMA's request for "*CMS to confirm that physicians will still be able to report CPT code 99474 for SMBP data collection and interpretation and/or the appropriate CCM services for patients who need them in the same month as ASCVD risk management. For example, a patient who has chronic obstructive pulmonary disease and/or diabetes would be eligible for CCM due to these conditions, but if the patient also has elevated ASCVD risk with hypertension or high cholesterol, they may need all three services*."

TELEHEALTH AND REMOTE SERVICES

In general, **UnityPoint Clinic 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 Clinic 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.

Frequency Limitations

For CY 2025, CMS proposes to suspend the frequency limitations for subsequent inpatient visits, subsequent nursing facility visits, and critical care consultation services to gather additional data.

Comment: During the PHE, these frequency limits were waived and, since that time, CMS has suspended their enforcement through 2024. **UnityPoint Clinic supports not only the continuation of this suspension through 2025, but urges its permanent suspension**. Although Medicare data indicates that telehealth was the modality for less than five percent of these services, this demonstrates that utilization is measured

and has not opened up a Pandora's Box of fraud, waste, and abuse. When used, it is vital for those beneficiaries and respects patient choice and convenience.

Definition of "Interactive Telecommunications System"

*For audio-only services furnished to established patients in their homes for purposes of diagnosis, evaluation, or treatment under certain circumstances, CMS proposes to expand this definition to include **any** telehealth service, not just mental health disorders, and to require a modifier to be appended to the claim. This CMS regulatory authority is based on statutory waivers and, in the absence of Congressional action, will sunset after December 31, 2024.*

Comment: UnityPoint Clinic supports allowing physicians and their patients to decide whether audio-only services are appropriate to deliver care. This is an important tool to include in a physician's toolbox and can be vital in areas in which broadband coverage is limited.

Provider Home Address

CMS proposes to permit distant site practitioners to use their currently enrolled practice location, instead of their home address, when providing telehealth services from their home through CY 2025.

Comment: It is not practical, workable, or safe to require a provider to publicly report their home address as their practice location. Medicare providers should not be compelled to share their personal information, especially when it relates to their home addresses. This enrollment structure is outdated and does not support providers new operational and privacy concerns faced in a digital age. **We support the continued use of a provider's currently enrolled practice location**.

DIRECT SUPERVISION THROUGH VIRTUAL PRESENCE

CMS proposes to temporarily extend direct supervision through virtual presence flexibilities through CY 2025, except for a permanent flexibility for services that are nearly always performed in entirety by auxiliary personnel. Additionally, CMS proposes to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings when the service is furnished virtually through CY 2025 .

Comment: Given workforce shortages, UnityPoint Clinic applauds this proposal to support 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.

As for the supervision of residents by teaching physicians, we differ to the Accreditation Council for Graduate Medical Education (ACGME).

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 health care 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 health care 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 19 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.

Inflation Reduction Act

CMS proposes a method to identify Medicare Part B and Part D claims for 340B drugs in order to exclude them from inflation-related Medicare drug rebates established under the Inflation Reduction Act.

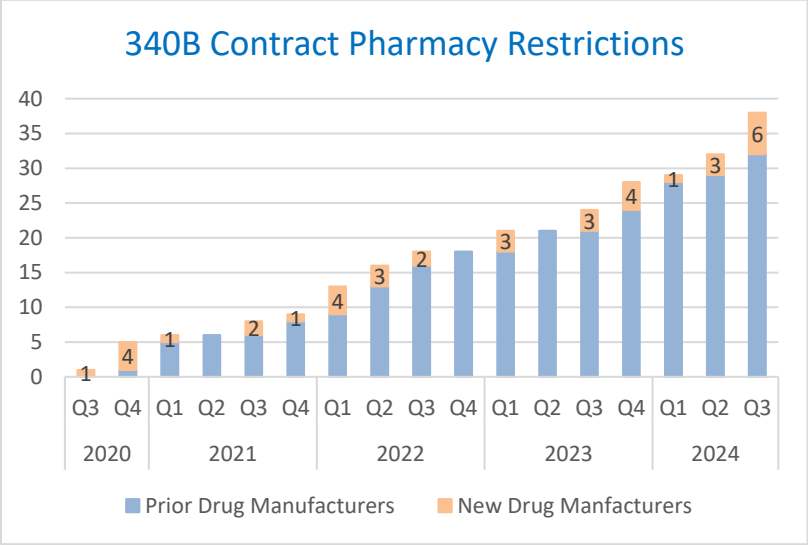
Comment: Given our network of 340B covered entities, **we support CMS' proposal to implement the Inflation Reduction Act** to preserve our ability to use 340B drugs for Medicare beneficiaries and avoid unreasonable burden on covered entities. More specifically, we support CMS' decision not to pursue a policy of modifiers for 340B Part D claim identification at this time and the agency's proposed methodology to estimate what portion of Part D rebatable units are 340B. We also support CMS' consideration of a retrospective methodology for 340B claim identification if the agency were to no longer use the estimation methodology. An alternative retrospective approach has been used successfully by Oregon's Medicaid program, Oregon Health Plan. The Oregon approach requires a quarterly data file submission of 340B-eligible claims rather than a real-time approach using modifiers. We strongly encourage CMS to also consider adopting a similar retrospective 340B claim identification methodology for the IRA's maximum fair price (MFP) provisions.

Manufacturer Restrictions on Contract Pharmacies

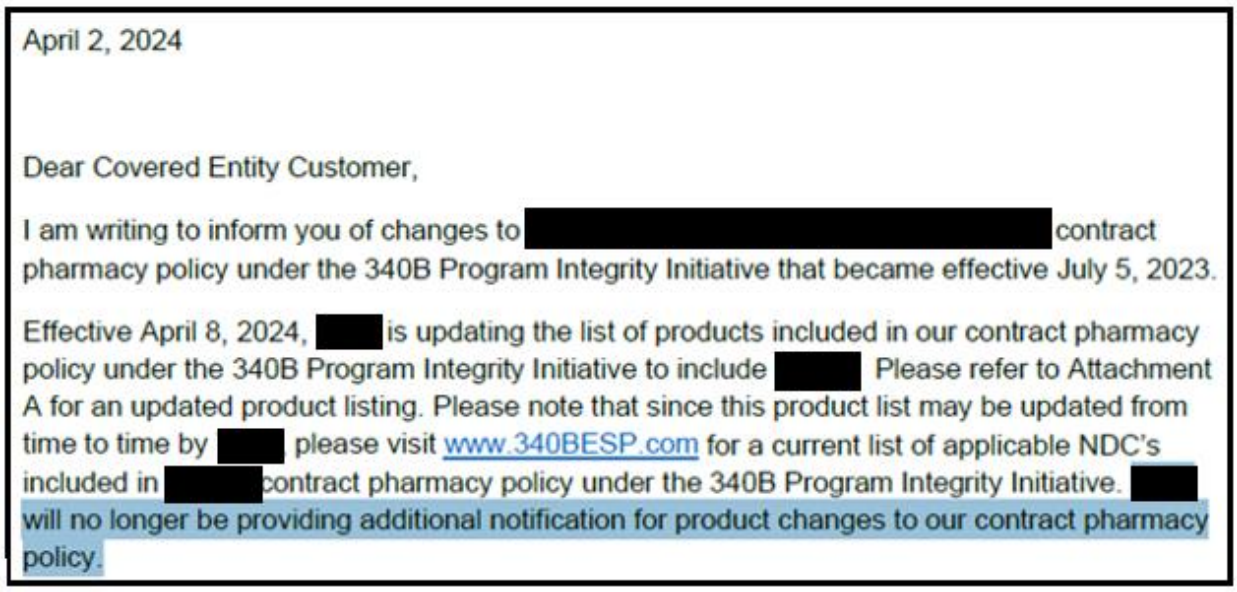
An important way covered entities are able to get 340B drugs to beneficiaries is through contract pharmacy arrangements. Under these arrangements, covered entities purchase drugs at 340B prices and contract with pharmacies in the community to dispense the drugs to covered entity patients on the covered entity's behalf. Since July 2020, 38 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. During last year's PFS public notice and comment period, there were 25 major drug manufacturers engaging in actions to limit the distribution of certain 340B drugs by hospitals (up from eight in 2021); at the time this comment letter was submitted, there are now **38**. In fact, Alkermes is the most recent addition and announced comprehensive contract pharmacy restrictions, with an effective date of July 22, 2024. At this time, drug manufacturers with contract pharmacy restrictions are 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; Incyte Corp.; Jazz Pharmaceuticals; Johnson & Johnson; Liquidia; Mallinckroft; Merck; Novartis; Novo Nordisk; Organon; Pfizer; Sandoz; Sanofi; Sobi; Sumitomo; Takeda; Teva; UCB; United Therapeutics; Vertex; and Viatris (red text represents manufacturers added to the list since the CY 2024 PFS comment letter). *This number keeps*

growing (see timeline below – 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 39 340B drug pricing programs to administer, including the one authorized by Congress and administered by the Health Resources and Services Administration (HRSA).** The 38 manufacturer programs are subject to frequent change with little notice, if any, and the frequency of changes is increasing. The example below is an excerpt from a drug manufacturer's notice which announced a contract policy change with less than one-week notice but also declared that the manufacturer will no longer provide specific notifications of policy changes. This



April 2, 2024

Dear Covered Entity Customer,

I am writing to inform you of changes to [redacted] contract pharmacy policy under the 340B Program Integrity Initiative that became effective July 5, 2023.

Effective April 8, 2024, [redacted] is updating the list of products included in our contract pharmacy policy under the 340B Program Integrity Initiative to include [redacted] Please refer to Attachment A for an updated product listing. Please note that since this product list may be updated from time to time by [redacted] please visit www.340BESP.com for a current list of applicable NDC's included in [redacted] contract pharmacy policy under the 340B Program Integrity Initiative. [redacted] will no longer be providing additional notification for product changes to our contract pharmacy policy.

manufacturer is not alone in this practice. This results in compliance chasing activities that detract 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 – a 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 health care 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 overcharged safety-net health care 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 23, 2024, Johnson & Johnson notified 340B end customers of its intent to replace upfront 340B price discounts on certain eligible drugs with a back-end rebate model for disproportionate share hospitals (DSHs) effective October 15, 2024. The initial drugs subject to rebate – Stelara® and Xarelto® – are among the company's highest priced and most-used products and are on CMS' list of drugs subject to Medicare price caps beginning January 2026. The rebate will require 340B DSH hospitals to purchase drugs at wholesale acquisition cost (WAC), resulting in higher costs to maintain an inventory. The notice sets forth a new and separate data submission rebate platform with different data collection and validation processes.

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. In August this changed, not from HRSA or Congress, but rather through the unilateral actions of a drug manufacturer. Starting October 1, J&J has unilaterally declared its intention to establish a rebate mechanism for certain 340B-eligible drugs, including a separate claims data submission platform and third-party evaluation. J&J will essentially replace HRSA for determining 340B compliance and require DSH hospitals to float revenues to drug manufacturers pending self-imposed processes to approve the rebate payments. The two drugs in question, Stelara and Xarelto, contributed a combined $3.4B in J&J sales during the second quarter of 2024[4]. All UPH DSH covered entities prescribe these popular medications and will be subject to this rebate program. For one of our DSH covered entities, these rebates will comprise nearly 6% of their 340B program savings. **We urge the Department of Health and Human Services and the HRSA to take "immediate enforcement action," including assessing civil monetary penalties on J&J for intentionally overcharging 340B hospitals**. We fear that unless the Department of Health and Human Services and

[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/

[4]J&J beats in Q2 as pharma segment outperforms - https://www.msn.com/en-us/money/companies/j-j-beats-in-q2-as-pharma-segment-outperforms/ar-BB1q8UUt#:~:text=JNJ%E2%80%99s%20blockbuster%20drugs%20Stelara,%20Invega%20Sustenna,%20and%20Darzalex%20contributed%20to

HRSA act quickly, these unauthorized rebate mechanisms to impose further restrictions and delay payments will be employed by other drug manufacturers similar to the contract pharmacy quicksand started by Eli Lilly in the summer of 2020.

RURAL HEALTH CLINICS (RHC)

CMS proposes changes in care management payment policy (including Advanced Primary Care Management services), telecommunications service requirements, Intensive Outpatient Program services, preventive vaccine costs, and productivity standards. CMS also proposes to revise Conditions for Certification to indicate that RHCs must provide primary care services instead of "being primarily engaged in furnishing primary care services."

Comment: UnityPoint Clinic has 35 RHCs in Iowa, which are vital to providing access to health care for our rural residents. **UnityPoint Clinic appreciates and supports the operational flexibilities proposed in the rule and the Conditions of Certification revision will support access to specialty services. In addition, we request that RHC telehealth services be reimbursed at the full all-inclusive rate (AIR)**, instead of the fee-for-service physician office rate. AIR is a cost-based payment put in place to help address the inadequate supply of providers who serve Medicare beneficiaries and Medicaid enrollees in rural areas.

CLINICAL LABORATORY FEE SCHEDULE: REVISED DATA REPORTING PERIOD AND PHASE-IN OF PAYMENT REDUCTIONS

The data reporting period is proposed to be revised - for the data reporting period of January 1, 2025, through March 31, 2025, the data collection period is January 1, 2019, through June 30, 2019. Reporting will be required every 3 years beginning January 2025. There is also phase-in of payment reductions. Specifically, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023, and for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

Comment: UnityPoint Clinic continues to oppose the drastic CLFS cuts resulting from a flawed data reporting and rate setting methodology implemented by the Protecting Access to Medicare Act (PAMA). At issue is insufficient reimbursement for tests used to diagnose and manage common conditions likes heart disease, cancer, and diabetes. Without congressional action this year, laboratories will face tough decisions impacting day-to-day care and emergency response (such as COVID-19 and Monkeypox), and industry investments will lag for innovations, including new screening and diagnostic tests. To preserve laboratory and testing access, **UnityPoint Health supports the bipartisan Saving Access to Laboratory Services Act (SALSA), H.R. 2377 / S. 1000 and encourages Congress will prioritize this fix for laboratory services beginning in CY 2025**.

MEDICARE COVERAGE FOR OPIOID USE DISORDER (OUD) TREATMENT SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS (OTPS)

CMS proposes to (1) permanently allow periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available, (2) allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for methadone treatment initiation, (3) update the payment rate for intake activities, and (4) establish payment for new opioid agonist and antagonist medications.

Comment: Since 1999, the number of opioid-related deaths has been rising continuously, and an opioid was involved in more than 75% of the nearly 107,000 drug overdose deaths in 2022.[5] These figures are staggering and demand action. **UnityPoint Clinic appreciates additional tools and flexibilities to help combat this crisis and create access to services for patients in need**.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

CMS proposes several changes including a new "prepaid shared savings" option, modifications to the financial methodology, changes to quality measure reporting, and a process for recalculating certain improper payments.

Comment: For context, UnityPoint Accountable Care is the accountable care organization (ACO) affiliated with UnityPoint Health and UnityPoint Clinic. UnityPoint Accountable Care has participated in Medicare ACO agreements since 2012 including the Center for Medicare and Medicaid Innovation's (CMMI) Global and Professional Direct Contracting (GPDC) Model, the Next Generation ACO Model, and the Pioneer ACO Model. During this time, UnityPoint Accountable Care has enjoyed partnering with CMS and CMMI in the testing and developing of value propositions, including benefit enhancements. Starting in 2023, UAC has participated in the ENHANCED track of the Medicare Shared Savings Program.

In addition to the following comments, **UnityPoint Accountable Care is a member of the National Association of Accountable Care Organizations (NAACOS) and the Accountable For Health (A4H) Coalition. Both organizations have also submitted comment letters to this proposed rule, and we encourage CMS to consider their input**.

Eligibility Requirements and Application Procedures

For the minimum beneficiary threshold, CMS proposes that ACOs maintain at least 5,000 assigned beneficiaries by the end of the performance year if specified by CMS in a Compliance Action Plan request. Additionally, CMS proposes that newly formed ACOs allow CMS to share a copy of their application with antitrust agencies. **UnityPoint Accountable Care supports these proposals**.

Beneficiary Assignment

Beneficiary "assignment" is the process CMS uses to determine whether a beneficiary receives a sufficient level of specified primary care services from participants in an ACO, indicating that the ACO qualifies as responsible for that beneficiary's care. CMS proposes to expand the definition of "primary care services" by including additional HCPCS and CPT codes. **UnityPoint Accountable Care appreciates that CMS is reviewing the assignment methodology and updating to include replacement or similar services**.

Quality Performance Standards and Other Reporting Requirements

Aside from the quality performance topics immediately following, other relevant comments are contained within the *Quality Payment Program (QPP)* responses (page 17).

Quality Payment Program Reporting Mechanisms – CMS proposes to sunset the Web Interface and MIPS CQM reporting options for MSSP ACOS in PY 2025. **UnityPoint Accountable Care opposes this sunset and**

[5] CDC, Understanding the Opioid Overdose Epidemic, April 5, 2024, accessed at https://www.cdc.gov/overdose-prevention/about/understanding-the-opioid-overdose-epidemic.html

encourages CMS to extend the transition of reporting options. Specifically, we request that Web Interface reporting be maintained for another three years while ACOs continue to make investments to support and pilot the eCQM reporting approach. Transitioning to new eCQMs and Medicare CQMs is challenging for ACOs with independent providers on disparate EMRs, and these challenges are multiplied when faced with the rapid expansion of metrics (i.e., APM APP Plus quality measure set) and new MVPs.

Alternative Payment Model (APM) Performance Pathway (APP) Plus Quality Measure Set – CMS proposes to incrementally add quality measures to the APM APP Plus quality measure set from PY2025 through PY2028. We reiterate our concern with the rapid expansion and revisions of quality measures. For the PY 2028 APM APP Plus quality measure set (Table 36), CMS included two eCQM measures that do not yet appear on the Eligible Clinician eCQM list. CMS underestimates the time and resources to adopt an eCQM, integrate reporting, and test it at an eCQM reportable level prior to having financial implications. Software vendors need time to develop and implement into the EMR before providers then develop workflows, test, and validate. **We urge CMS to consider lengthier voluntary reporting periods and, at minimum, a pay-for-reporting period for new measures**. Ideally, there should be at least a year for reporting-only status before pay-for-performance status is instituted, especially for ACOs with many disparate EMRs.

Performance Threshold and Data Completeness Criteria – CMS proposes to maintain current performance threshold policies; the performance threshold is set at 75 points for CY 2025 and the data completeness criteria is set at 75% through CY 2028. **UnityPoint Accountable Care supports maintenance of these thresholds but seeks clarification related to the audit/verification process for eCQM submissions**. The challenge for ACOs with independent providers and multiple TINs and software platforms is limited submission visibility especially if performed by a third-party vendor.

Prepaid Shared Savings Option

Starting January 1, 2026, CMS proposes to establish a new "prepaid shared savings" option for eligible ACOs with a history of earned shared savings. Eligible ACOs include those participating in Levels C-E of the BASIC track or the ENHANCED track with consistent prior success in earning MSSP shared savings. At least 50 percent of prepaid shared savings would be required to be spent on direct beneficiary services not otherwise payable. In last year's comment letter, UnityPoint Accountable Care had requested that "*CMS consider expanding 'loans' or AIPs to all ACOs regardless of performance-based risk level, experience, or high-revenue status*." **We thank CMS for listening and providing an option; however, we are concerned that this proposal is too prescriptive and missed the point**. As rationale for our initial request, we stated:

> *The rate at which MSSP rules and guidance (including performance measures, quality reporting processes, CEHRT requirements, data collection on SDoH risk assessment and health equity, and interoperability standards) change and grow make it extremely challenging for even experienced ACOs to keep pace. To effectively serve attributed beneficiaries, these evolving requirements and programmatic needs puts ACOs in a continuous state of upgrading technology platforms, investing in new technology or technology enhancements, and expending staff and provider time and resources for additional beneficiary outreach targeting vulnerable populations. Every new and updated requirement posed by CMS has an associated investment dollar. While these*

requirements are intended to be budget neutral for CMS, they are not budget neutral for ACOs and threaten financial sustainability.

By restricting at least 50 percent of funds to be spent on direct beneficiary services not otherwise payable, CMS places limitations on prepayments that are not present for shared savings distributions and removes operational flexibility to enable financial stability as well as innovation. Costs are increasing due to CMS regulatory changes – reporting and interoperability requirements, data collection, survey/screen distribution, etc. The costs associated with technology and vendors to assure MSSP compliance is staggering. Shared savings distributions are a key incentive to keep providers as participants in the program. Successful, experienced ACOs should be provided the maximum flexibility to determine how to spend funds to meet the needs of their population; some of which may be required to be distributed to keep ACO participants engaged in MSSP. Lastly, this restriction does not necessarily support value-based care as many direct beneficiary services do not reduce overall Medicare cost of care. For Medicare Advantage, plans are re-evaluating and reducing supplemental benefits due to cost.[6] Aside from the restrictions on fund expenditures, CMS also proposes that this prepaid option would only be available at the beginning of a new participation agreement. Any new agreement would reset the benchmark, which would not be favorable to many ACOs. **Despite our request for a 'loan' program, UnityPoint Accountable Care would not utilize this option as proposed with conditions that require direct beneficiaries services percentages and a new participation agreement**.

Financial Methodology

As an early ACO adopter of two-sided risk, UnityPoint Accountable Care has been challenged year-over-year to improve beneficiary access and quality, while being cost efficient. As CMS strives to engage more providers in the transition to value, CMS should also balance initiatives to support providers that have partnered with CMS over the long haul and contributed to health care value and innovation.

Health Equity Benchmark Adjustment (HEBA) – CMS proposes a HEBA applicable to ACOs in agreement periods beginning on January 1, 2025. The HEBA is designed to assist ACOs disproportionately serving underserved communities and will factor in assigned beneficiaries enrolled in the Medicare Part D Low Income Subsidy (LIS) or dually eligible for Medicare and Medicaid. **While UnityPoint Accountable Care foundationally supports the concept of health equity, CMS has not provided compelling information for this mechanism.** According to CMS' estimates, this is a complex adjustment and will have little impact to increasing or continuing participation in APMs, especially for the underserved population. The HEBA is projected to increase benchmarks for less than 5% of ACOs (i.e., 20 ACOs in 2023), and those increases will amount to 1.57%. The proposed targeted approach misses the mark for meaningful health equity support/change – health equity and SDoH require significant investments, the funding amount seems grossly inadequate to entice new ACO participants, and assuming an uptake of 20 new ACOs, it is

[6] L. Berryman*, Medicare Advantage vendors brace for supplemental benefits cuts* , Modern Healthcare, September 4, 2024, accessed online at https://www.modernhealthcare.com/insurance/aetna-humana-medicare-advantage-benefits-cuts

questionable whether the magnitude of uptake justifies the adjustment. Instead, we urge CMS to consider a broader initiative to enable funding and incentives for all ACOs to prioritize health equity.

Reopening ACO Payment Determinations – CMS proposes a methodology to account for the impact of identified improper payments to correct financial reconciliation calculations. CMS retains sole discretion to grant reopening requests and will consider the amount and impact on performance year expenditures and historical benchmarks. Improper payments outside the ACO may also be considered if there is a "significant" change to ACO financials. **UnityPoint Accountable Care supports this concept but as described we are unable to ascertain whether it will be meaningful** – it is difficult to model how this may specifically impact our ACO, and how this may impact regional/national trends and affect providers and ACOs holistically**. In terms of process, we urge transparency on how requests will be prioritized, considered timely, and decisions communicated to the requestors and ACO participants**. While CMS seeks to retain sole discretion to grant a reopening process, CMS should communicate the rationale for denials or approvals to help guide ACOs in appropriately seeking this remedy. Transparency is also important for ACO operations to notify participants of the outcome and impact and to timely adjust downstream payments/incentives. Overall, CMS transparency and timely action will enhance agency credibility, promote sustainable ACO financial planning and budgeting, and impact participants willingness to participate in ACO models future years.

Aside from process questions, **we request that CMS limit restrictions on this remedy intended to right a wrong that harms ACOs' and providers' financial bottom line**. First, we encourage CMS to enable this process to apply for performance years prior to January 1, 2025. CMS has already instituted guardrails that the reopening must be deemed significant or greatly affecting other ACOs. ACOs have identified additional improper payments, including billings for skin substitutes, ventilators, diabetic supplies, and collagen dressings. Second, ACOs should be held harmless when the judiciary overturns agency regulations for actions outside its statutory authority. We request that CMS reopen and adjust benchmark periods, trends, and performance year expenditures in situations when ACOs are without recourse from improper agency actions significantly impacting ACO reconciliation and for which there is no opportunity to otherwise mitigate reconciliation impact. This situation is different from a change of legal interpretation[7], and is instead the direct result of judicial review of an agency action. For example, several ACOs experienced significant benchmark discrepancies as the result of the Supreme Court of the United States unanimous decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022).[8]

Mitigating the Impact of Significant, Anomalous, and Highly Suspect (SAHS) Billing Activity on MSSP Financial Calculations in CY 2024 or Subsequent Calendar Years – Starting with performance year 2024 for all ACOs, CMS proposes a new process to be used on "rare and extreme cases" to mitigate the financial

[7] 42 CFR 425.315(3) - A change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a payment determination under this section.

[8] 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; comment letter submitted on September 11, 2023 – tracking number lmf-2d7j-f5ns

impact of fraudulent activities**. We thank CMS for partnering with ACOs to mitigate SAHS billing activity for specific catheter codes and we generally support this process as a positive step forward**. Foremost, ACOs should not be held accountable for lack of oversight, errors, or erroneous payments nor should CMS place arbitrary limits on when relief can be sought (i.e., performance year 2024 and beyond). Like our feedback on reopening ACO payment determinations, we also urge CMS to provide greater transparency on how mitigation requests will be prioritized, considered timely, and decisions communicated to the requestors and ACO participants.

Beneficiary Notification Requirements

CMS proposes to remove the follow-up communication at the next primary care service. **UnityPoint Accountable Care supports this change** which varied by member and was administratively burdensome to track. That said, **we also respectfully request that CMS reconsider current beneficiary notification requirements**. Presently, CMS dictates the message, which is not patient-friendly and creates beneficiary confusion, and then requires that ACO send it twice – an initial communication and then follow-up at 180 days – which doubles the confusion and associates this poorly written letter (with its propensity for beneficiary dissatisfaction and distrust) to our providers.

Request for Information: ENHANCED Track

CMS seeks comment on a participation option that would allow for higher risk and reward than currently available under the ENHANCED track. This participation option would replace the existing ENHANCED track to avoid self-selection issues.

Comment: As envisioned to replace and not supplement the current MSSP ENHANCED track, UnityPoint Accountable Care opposes this replacement participation option. This "option" offers fundamentally different financial methodology or shared savings arrangements and would be disruptive to current ENHANCED track participants. Instead of promoting financial planning and stability, this new track moves the goalposts for providers that have already bought into the value-based proposition and agreed to take on heightened risk. We offer input on the select items below:

Potential features of a revised ENHANCED track

These attributes all target mechanisms to minimize CMS' exposure to shared savings payments. **We agree with NAACOS that the success of any APM/ACO is ultimately driven by clear, consistent, predictable benchmarks that are sustainable**. When CMS ratchets benchmarks with each model revision or contract renewal, this undercuts any momentum for providers to stay engaged and committed to the value movement.

- *Benchmark discount rate*: We do not support discounts applied prior to earning shared savings.
- *Tapered sharing arrangements*: If a new higher risk option is implemented, this arrangement is preferred over discounts.
- *MSR/MLR*: While UAC supports a symmetric MSR/MLR at 0, ACOs differ on this topic and may prefer to retain this flexibility to mitigate risk. To encourage greater participation and risk taking, we recommend that CMS maintain current MSR/MLR options from which ACOs can choose.
- *Cap on regional adjustment weight*: We do not support caps that impact benchmark setting.

- *Payment mechanism*: We support CMS in providing ongoing flexibility in payment models that allow ACOs to build their own network, engagement, and collaboration models. Specifically, All-Inclusive Population-Based Payment (AIPBP) allows ACOs the greatest flexibility to develop value-based purchasing arrangements with their network and invest in collaborative and innovative care initiatives across the care continuum. AIPBP provides a structure for ACOs to develop contracts with providers that ensure tighter collaboration and to enter into malleable payment arrangements across each sector. In contrast, Population-Based Payments (PBPs) to primary care providers force all primary care providers to work within one structure, and this one-size-fits-all approach may not work across providers. For example, PBPs hamstring ACOs from providing a different structure for critical access hospitals or rural providers than for urban providers.

  As for capitated payments or withholds, we are cautiously optimistic. While these mechanisms hold promise in the future, CMS has made historical errors when processing various capitations/withholds to the detriment of ACOs. Additionally, fraudulent claims continue to be a problem and, without payer status, ACOs are left at financial risk without avenues to timely address. At this point, CMS could offer as an "option" to allow ACOs to determine whether to accept the risk.

What would the option of a revised ENHANCED track allow an ACO to do that they are unable to do currently?

As a current ENHANCED track participant, we reiterate our opposition to a revised ENHANCED track as opposed to a new ENHANCED+ track. If proposed as a new ENHANCED+ track "option," this higher risk model opportunity might be viable with the addition of a payment mechanism whereby ACOs could receive 90-100% of the benchmark intended to pay for all claims for attributed lives. This mechanism would enable flexibility for ACOs to engage and create greater collaboration and accountable payment arrangements. Presently, fee-for-service providers outside of network have little incentive to engage with ACOs in a collaborative manner.

What types of organizations, including but not limited to ACOs and providers, are interested in a higher risk and reward option in the Shared Savings Program?

Higher risk models are likely more attractive for primary care provider (PCP)-driven ACOs as they typically perform better than health system/integrated delivery system models. Additionally, ACOs new to value-based care with high-baseline costs with venture capital support for infrastructure are interested in higher risk options. ACOs that have been in the program for many years may be interested in higher risk models, but not without substantive changes to the financial methodology. Benchmark ratcheting continues to be an issue. That said, adding a new model that would allow the ACO to become the payor for all services might attract additional interest for those experienced with capitated and delegated financial and care models. Negotiating new care and payment models will allow ACOs to continue to develop more collaborate arrangements across provider types, enhancing performance beyond that of the PCP.

What additional flexibilities or features (for example, benefit enhancements, advance payments, capitation payments, etc.) would ACOs in a revised ENHANCED track with higher risk and potential reward want CMS to offer to help them be successful in improving the quality of care and reducing costs?

See feedback under *Potential features of a revised ENHANCED track – Payment mechanism* above.

How should a revised ENHANCED track with higher risk and potential reward also require additional accountability for quality? Should ACOs in this revised track be required to report all payer/all patient quality measures?

We do not believe that CMS should require a different quality reporting approach for a potential future new track. ACOs participating in higher tracks typically have high quality scores, so additional requirements seem unwarranted. A different quality paradigm would also make comparisons across APMs more difficult. As for all-payer/all-patient quality reporting, this is regulatory overreach. As CMS imposes eCQM reporting, ACO payment (i.e., shared savings) will not target care and services to Medicare beneficiaries, but instead encompass patients covered by other insurance including those not attributed to the ACO. All-payer/all-patient quality reporting imposes additional burden and expectations that would discourage participation in any new model.

How might CMS improve beneficiary assignment and are there different considerations for different types of ACOs (for example, low revenue, high revenue, health system-based, safety net, etc.)?

CMS should allow MSSP ACOs to include providers at NPI-level participation versus whole TIN participation. These provider rosters are allowed in CMMI models and are beneficial for ACOs that include multispecialty practices and/or integrated or large health care systems operating under one TIN. Additionally, it would be advantageous to include preferred providers in global models, without impacting MACRA threshold calculations, to encourage greater collaboration in APMs. This is a case of the tail wagging the dog – some provider groups have intentionally restructured their NPIs to separate TINs to get around this dated roster submission practice. This is a technical, burdensome, costly, and unnecessary exercise for health care systems to achieve intended/desired provider participation for value-based arrangements.

CMS is interested in ways to increase participation by healthcare providers and suppliers in the Shared Savings Program and future Innovation Center ACO models, including how an ACO model requiring provider participation or stronger participation incentives might be designed.

Thank you for this question. To increase APM participation, the models need to have stable and predictable financial underpinnings balanced with programmatic/operational flexibilities. To entice MSSP ACO participation, we suggest the following: (1) a stable, reliable benchmark to support financial planning and budgeting; (2) improved reporting with more timely and actionable data; (3) more timely risk score levels/trends to apply to in-year forecast; (4) access to more waivers, benefit enhancements, and programmatic flexibilities to enable clinical innovation – ENHANCED track ACOs should have access to all the REACH ACO waivers; (5) enable specialist engagement in ACOs outside of attribution to promote coordinated care delivery and manage costs; and (6) develop a thoughtful hierarchy of beneficiary attribution as new episodic Advanced APMs erode the patient base of global models, such as ACOs.

We also believe that there is an opportunity to better support health equity initiatives. CMS should strengthen health equity adjustments to encourage taking on underserved areas. At present, this is hampered by the 3% cap on risk adjustment that limits the ability to receive a fair amount to cover the cost of serving this population.

While this question is aimed to increase Advanced APM participation, CMS must also consider how to retain providers within Advanced APMs. UnityPoint Accountable Care has participated in Medicare ACO

agreements since 2012 including various CMMI models and two stints with the CMS MSSP model. As an early adopter of the ACO model, our providers have contributed to Medicare benefit enhancements and program improvements; yet at least annually, Medicare ACOs models have been subject to regulatory and sub-regulatory changes – sometimes with little transparency and provider input. During the CMMI Direct Contracting Model, CMMI refused to forgive losses for participating ACOs during the PHE, when CMS forgave similar losses for MSSP participants. When ACOs are being asked or forced (if the ENHANCED track is replaced) to take higher risk, ACOs are not provided with tools to redress events outside our control. Recent examples include inflated 340B historical benchmarks and various fraudulent and erroneous claim payments for catheters and skin grafts. Under a shared savings construct, early adopters are also challenged to continue to find savings in an environment of diminishing shared savings returns. It would behoove CMS to work with early adopters to consider how longevity in Advanced APMs, including ACO models, can be rewarded financially as well as programmatically.

RFI: BUILDING UPON THE MIPS VALUE PATHWAYS (MVPs) FRAMEWORK TO IMPROVE AMBULATORY SPECIALTY CARE

CMS seeks public input regarding the design of a future ambulatory specialty model.

Comment: UnityPoint Accountable Care is interested in strategies to increase specialist engagement. However, expanding MVPs and exponentially developing new specialist-driven quality measures should not be prioritized over value-based care and service delivery innovation. Rather, practitioners should be encouraged to work together on behalf of beneficiaries under holistic quality constructs. ACOs are an existing vehicle if CMS would provide flexibilities for specialty participation. Due to MACRA constraints, UnityPoint Accountable Care removed thousands of specialists from our Medicare ACO on two separate occasions. **CMS should allow specialists to also be included in two-sided Medicare ACOs and qualify for all incentives without additional data reporting outside the ACO and without requiring attribution.** ACOs need more performance data on specialists. The addition of a payment model or incentive that enables partnerships between primary care providers and specialists (such as a care compact) is a more sustainable and proven approach for engaging specialists while continuing to tie care back to the primary care provider. A PMPM should be considered to support this work.

We offer further input on the current MVP program in the *Quality Payment Program* narrative and the *RFI: MVP Adoption and Subgroup Participation* response.

EXPAND COLORECTAL CANCER SCREENING

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-on 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 Clinic supports the updates to CRC screening coverage**.

QUALITY PAYMENT PROGRAM (QPP)

CMS proposes updates to the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), a new Alternative Payment Model (APM) Performance Pathway (APP) Plus quality measure set, revisions to the MIPS measure/activity inventories and scoring methodologies, and policies related to the performance threshold and data completeness criteria.

Comment:

MIPS Value Pathways (MVPs)

CMS proposes six new MVPs around the following topics: Complete Ophthalmologic Care, Dermatological Care, Gastroenterology Care, Optimal Care for Patients with Urologic Conditions, Pulmonology Care, and Surgical Care. Also, CMS proposes modifications to all existing 16 MVPs with the addition and removal of measures and improvement activities based on the MVP development criteria.

First, CMS has changed every MVP proposed for 2025. Regardless of whether changes are well-intended, every modification relates to time, effort, and costs for providers. This sheer volume of changes adds to provider reluctance to transition to MVPs. This magnitude also seems to suggest that MVPs are being implemented prematurely and that this construct is not for mandatory status.

We urge CMS to retain the voluntary reporting status for MVPs to allow ACOs flexibility to engage with specialists in ways that are meaningful and clinically relevant for each ACO. We understand the drive to make the MIPS program a value-based program, but the cost implications and resource burden for reporting MVPs in multi-specialty groups is overwhelming. Where MVP reporting may be a preferred option for a single specialty practice, for multi-specialty practices it quickly becomes complex with ever-changing requirements equating to a heightened potential for reporting errors. In our system, one of our TINs is a multi-specialty practice with roughly 1200 providers across 45 specialties. Of these providers, about two-thirds are in an Advanced APM and the remaining 400 are MIPS eligible clinicians representing 35-40 specialties. If we assume MVP reporting for half or 20 specialties, we would be reporting for 120 different measures, not including the collective blanket measures used for the remainder. MVP measures cross multiple collection methods (eCQM, MIPS CQM) and require large resource teams for upkeep and maintenance in an ever-changing system. To reiterate, each of the 120 measures requires map data points, design workflow, data capture tools and audits as well as clinical workflow design and training for providers and staff. It is a challenge to maintain and perform well on 100+ measures. **To lessen reporting burden, we encourage CMS to consider excluding any MSSP TIN participant from any mandated MVP reporting for specialists**.

We have not chosen to report MVPs for any of our 45 TINS across the organization. Factors influencing this are detailed in our *RFI: MVP Adoption and Subgroup Participation* response.

Alternative Payment Model (APM) Performance Pathway (APP) Plus Quality Measure Set

CMS proposes an additional quality measure set expanding from the current six APP measures to eleven measures by the 2028 performance period. Reporting would be through eCQMs and/or Medicare CQMs.

We reiterate our concern with the rapid expansion and revisions of quality measures. While we appreciate Table 36 (AAP Plus for PY 2028+), two eCQM measures do not appear on the Eligible Clinician eCQM list, which trigger vendor and provider workflows. We urge CMS to consider lengthier voluntary reporting periods and, at minimum, a pay-for-reporting period for new measures.

For 2025, CMS proposes two APP reporting options – the original APP quality measure set and the APP Plus quality measure set. We are unclear the rationale for this option and believe it inserts unnecessary complexity and potential for reporting errors. We also caution CMS from drawing any conclusions related to entities that select AAP Plus reporting, as rationale for this choice may vary.

Merit-based Incentive Payment System (MIPS)

Performance Threshold and Data Completeness Criteria – **We support** the CMS proposals to maintain both the threshold and criteria levels.

Medicare CQM Benchmark Calculations – CMS proposes to use flat benchmarks for an ACO's first two performance years in MIPS. **UnityPoint Accountable Care supports this change to make scoring more predictable and equitable for ACOs**.

Cost Performance – CMS proposes six new episode-based cost measures, revisions to two existing episode-based cost measures, and changes to cost measure scoring methodology. While this year's proposals are more significant, CMS annually changes this category making it difficult for providers to model and predict potential scores. **We request that CMS provide better transparency and visibility into this category throughout reporting year to reduce unexpected surprises and better gauge performance**.

Improvement Activities (IA) – **We applaud** both the weighting and activity reporting changes. **Additionally, we seek clarification for TINS with some practitioners in an APM and some practitioners in the traditional MIPS program**. This is typical for TINs with individual providers who did not make the APM snapshot report. For non-QP providers who are defaulting to MIPS, how will CMS determine the appropriate IA measure set? Can these individuals assume the APM's score, or should reporting reflect a single provider's IA category score?

Promoting Interoperability (PI) Performance – As finalized last year, all MSSP participants must report MIPS PI data in 2025, and Advanced APM CEHRT criteria will increase from 75% of eligible clinicians to 100% of eligible clinicians. **We echo NAACOS opposition** as this requires duplicative reporting – both in APP and MIPS; the policy remains unclear regarding implementation and shared savings impact; and PI reporting is being prioritized over meaningful information sharing. We are particularly concerned about potential discrepancies in reporting between TINS (or subgroups) and the ACO and resulting impacts to shared savings. It also should be noted that some practice areas, like behavioral health, have not adopted this technology and some ACOs are removing them from MSSP participation despite their value to patient care and service delivery. **NAACOS offers alternatives – use of the REACH model attestation, leverage ONC data, or gradually increase Advanced APM CEHRT criteria – and we urge your strong consideration of these**.

For a potential change in 2026, CMS is also considering a revision to the SAFER Guides measure to permit use of an updated version of the SAFER Guides at that time. There is risk to naming specific versions of rapidly changing guides within quality measures. Out-of-date SAFER Guides pose a threat to the EMR systems and would add confusion to providers regarding the threats and levels of expected safety of data. Instead of requiring providers to review and acknowledge the SAFER Guides in an outdated state, **we request that CMS resort back to the previous submission definitions, which simply asked entities if they reviewed SAFER Guides but did not require them to be implemented as part of that review.**

Specific Measures – We have concerns with the following measures:

- Depression Remission at Twelve Months (CMS159v13) – We urge CMS to consider the removal of this measure. For patients with clinical depression, remission rates at twelve months may not be an appropriate measure as many individuals requiring long-term therapy.
- Diabetes: Eye Exam (CMS131.13) – We request that CMS further refine this measure. It is defined as requiring an eye exam every 12 months. Numerator includes "diabetics who had one of the following: - Diabetic with a diagnosis of retinopathy in any part of the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period; - Diabetic with no diagnosis of retinopathy in any part of the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period or the year prior to the measurement period." While this this time interval is appropriate for patients with diabetic retinopathy, for patients without retinopathy, the American Diabetes Association recommends once every 24 months. It is unclear how interplays with the second category of patients in the numerator.

RFI: MVP ADOPTION AND SUBGROUP PARTICIPATION

CMS seeks comment on approaches that include expanding finalized MVPs to include more specialties or subspecialties related to a care condition; developing new, broader MVPs with a different emphasis from current MVPs focused on a single specialty or clinical condition; and developing MVPs for non-patient facing MIPS eligible clinicians.

Comment: We are opposed to the MVP approach and mandatory subgroup reporting. The MVP approach further fractures the premise of population health and promotes siloed care by rushing to develop quality measures that promote episodic care and volume to the detriment of health care value. It is a disservice to Medicare beneficiaries to promote that specialist engagement can only occur through extremely specific measure sets that largely target process-based measures. Rather, providers should be encouraged to work together on behalf of beneficiaries under holistic quality constructs. **CMS should allow more flexibilities for specialists to participate in an MSSP ACO and qualify for all incentives without additional data reporting other than requirements for ACO**. ACOs likewise need more performance data on specialists. The addition of a payment model or incentive that enables partnership between primary care providers and specialists (such as a care compact) is a more sustainable and proven approach for engaging specialists while continuing to tie care back to the primary care provider. An additional Per-Member, Per-Month (PMPM) payment should be considered to support this work.

For those who did not submit an MVP, what key barriers impacted your decision to continue to report traditional MIPS?

Due to reporting complexity and expense, we did not submit MVPs. **Being a large multi-specialty TIN, upkeep and monitoring of MVP measures is operationally tedious – MVP requirements often overlap eCQMs, MIPS CQMs, and CAHPS for MIPS requirements – and requires exponentially more resources and costs than traditional MIPS**. Factors influencing this decision include:

- MVPs are extremely complex measure groups that involve multiple methods of data collection, including MIPS CQMs and eCQMs as well as cost measures.
- The drive to utilize MVPs does not reduce burden for organizations with a multi-specialty practice.
- Each specialty has their own set of measures (including up to 6 separate measures), which must be updated, mapped, and reviewed annually. CMS has proposed changes to all MVPs this year.
- MIPS CQMs require report writing within our EMR and are not supported directly, like eCQM reporting. For MIPS CQMs, staff need to map, validate, and build measures in another form for reporting.
- A single file must be utilized for submission, and therefore MIPS CQMs and eCQMs would need to be combined into a single reporting method (QRDA III) file or manually attested per measure per specialty increasing the burden of reporting submission. In the absence of a third-party vendor at additional cost, group reporting also requires subgroup validation and individual reporting requires manual submission of their measures subset.
- All MVPs contain CAHPS for MIPS surveys – an increased cost burden for administrative overhead, survey distribution, and vendor use.

What does meaningful MIPS participation look like for clinicians in the future? Should CMS consider developing a more global MVP with broadly applicable measures? Should flexibilities or alternative policies be considered?

MVP should remain voluntary and traditional MIPS available until a critical mass has transitioned to value. That critical mass would be comprised of practitioners reporting MVP measures (possibly by increasing reporting incentives) and participants in Advanced APMs that are reporting APP measures. At this point, practitioners should not have to invest in additional builds and engage support to create an MVP (and subgroup) for submitting a broad-spectrum set of measures that are less targeted than current self-selected traditional MIPS measures.

As subgroup participation becomes mandatory for multispecialty groups reporting an MVP beginning in CY 2026, how can CMS balance the increase in burden for groups while allowing comprehensive reporting on the diverse range of services provided by the clinicians in a group? For example, should CMS consider limiting the number of subgroups that a group must form based on group size and composition?

We oppose mandatory subgroup reporting. Subgrouping practitioners is innately complex, as organizations must determine how to classify eligible clinicians by subgroup along with their CMS designation (rural, hospital based, non-patient facing, etc.). This information is not easy to obtain, and changes occur from year-to-year based on claims. For multi-specialty TINs, this is challenging as a single

practice could contain 40+ specialties/subspecialties. Even a specialty practice like cardiology is often comprised of physicians with different focus areas. The measures in the Cardiology MVP may not be appropriate for both an interventional cardiologist and an electro-physicist.

The concept of limiting subgroups within practices/organizations begs the question of why CMS would mandate subgroups. **Limits on subgroups would ultimately result in arbitrary groupings for the purpose of quality measurement, and arbitrary groupings will likely not engage all practitioners**. For small independent practices or multi-specialty practices, this could force one or two subgroups of disparate practitioners with a broad-spectrum MVP – similar to the current self-selected measure process for traditional MIPS eCQM reporting now.

Are there alternative approaches CMS could consider for setting limits on the minimum and maximum number of subgroups per group TIN?

CMS should streamline quality reporting by enabling specialists to participate in Advanced APMs without requiring attribution. Instead of continually expanding MVPs and exponentially developing new measures, CMS should concentrate on population health constructs and pivot away from MVPs and MIPS.

Could CMS consider establishing a process during MVP registration for groups to self-identify if the group is considered a single specialty or multispecialty group? Are there any barriers that CMS should be aware of if CMS established a process for a group practice to identify the overall specialty composition of a group TIN?

Across our integrated health care system, we have 45 TINs with almost 8000 CMS-identified eligible clinicians. **The administrative burden of having to register each practitioner and their specialty within each TIN for large systems would be astronomical**. The complexity continues as it is uncertain how a practitioner who works across multiple TINs should be registered, given that each TIN will likely have different subgroups. If registered with different subgroups, a single practitioner could also submit more than six measures during a reporting period due to different MVP measure sets.

Are there additional approaches CMS should consider for providing guidance to groups on appropriately placing clinicians into subgroups based on the scope of care provided?

MVP subgroup reporting should remain voluntary. As currently developed, they are not perfect or comprehensive – nor is that likely to occur soon. Scope of care is extremely vast even within a specialty designation. As an example, the Cardiology MVP includes BMI, Depression screen and follow up, and High-risk meds as 3 of the 4 quality measures selected. None of these measures are cardiac specific and overlap with other MVP measure options. The outcome measures available for selection are (1) Pericardiocentesis following Atrial Fibrillation Ablation or (2) Infection within 180 days of Implant Device. Both outcome measures target electrophysiologists specific scope of practice, and do not target other cardiologists (interventionalists, non-invasive, vascular, etc.).

RFI: PUBLIC HEALTH REPORTING AND DATA EXCHANGE

CMS is working in partnership with the CDC and ONC to explore how the Promoting Interoperability performance category could advance public health infrastructure through more advanced use of health IT and data exchange standards.

Comment: UnityPoint Health administers some local Public Health Agencies (PHAs) – mostly in rural

geographies with limited resources. In addition, as an integrated health care system, we report MIPS for numerous practitioners.

Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting. Omitted from Goal #1 but foundational is meaningful reporting. **When data reporting is redundant and inconsistent (unable to be standardized), this goal seems hollow and the level of performance will likely not meet expectations. As proposed, the numerator denominator values would be extremely tedious**. Case in point is the Immunization Registry Reporting measure, which is duplicative and may result in inconsistent reporting. In the State of Iowa, providers only submit "administered" vaccines as the State lacks the capabilities to support and deduplicate historical immunization tracking. For CMS, childhood immunization reporting is already reportable under the quality measures category, and adult immunization status is proposed under the APP Plus quality measure expansion. The potential for confusion is high when measures are repetitive, and numerator denominator values may not align or be cohesive due the variance across reporting structures – whether data is captured for quality measures versus outcomes, or based on historical immunizations versus vaccines administered.

As for the use of FHIR APIs in support of information exchange, until FHIR is a national standard and PHAs are also required to follow the same standards for technology and data sharing as health care organizations, the increased burden of reporting numerator denominator values will continue to exist. Our organization submits to five state PHAs and none have the same standards for submission of public health data. **We encourage CMS to streamline and standardize PHA's ability to accept data before setting performance expectations for providers**.

While we appreciate CMS' desire for continued expansion of measures, we request that CMS pause expansion in favor of assuring the measures are meaningful and can be received. PHAs at the state level already require supplemental data under various components of USCDI. Additionally, each PHA has different capabilities for what they can receive. To add measures under this objective may be duplicative, unnecessary, and burdensome. We reiterate our request that CMS first standardize data exchange requirements for PHAs prior to mandating health care providers to take on the burden of submitting more data in a specific value format where standards may not be the same. Instituting a national standardized approach to submission would facilitate submission of more cases and promote rapid expansion of submission during a PHE or other perceived threat.

Goal #2: Flexibility and Adaptability of the Public Health Reporting Enterprise. While we appreciate the need to quickly respond to adapt to new threats, the weakest reporting link is often PHAs. **Our greatest challenge to sharing data is the variability across PHAs relating to how and what data they accept**.

Goal #3: Increasing Bi-directional Exchange With Public Health Agencies. **CMS should reconsider the data PHAs must push and pull in a bi-directional exchange with deference towards a targeted exchange**. As we view the Health Information Exchange measure, it is intended as a provider-to-provider exchange accompanying a transition of patient care and would not trigger sending data to PHAs in most circumstances. We also question whether bonus points should be offered for enabling an exchange under Trusted Exchange Framework and Common Agreement (TEFCA). Only a subset of PHAs may ever

participate in TEFCA, so attaching bonus points to this agreement may not be an effective incentive.

Goal #4: Significantly Reduce Reporting Burden for Healthcare Providers. We concur that reducing reporting burden should be a goal. Any time a new technology is introduced, all health care providers must invest both finances as well as time and effort to implement and operationalize. **To reduce burden, CMS could consider extending timeframes to adopt and integrate new data requirements to enable providers to plan for that cost and resource burden**. Furthermore, multiple PHAs have fees associated with data submission – costs that fall back on health care providers and are financially burdensome. We encourage CMS to review PHAs use of third-party vendors to meet submission requirements, including oversite of the fees for integrating with these vendors.

RFI: GUIDING PRINCIPLES FOR THE DEVELOPMENT OF PATIENT-REPORTED OUTCOME QUALITY MEASURES

CMS seeks input on incorporating Patient-Reported Outcome Measures (PROMs) and Patient-Reported Outcome Performance Measures (PRO–PMs) in CMS quality reporting and payment programs and CMMI Models.

Comment: UnityPoint Clinic agrees that patient-reported outcomes can be extremely insightful when evaluating service delivery and medical procedures. At a glance, the guiding principles suggested by CMS appear reasonable, but we would respectfully suggest that there is a gap between CMS and provider perceptions of how these principles are applied and industry readiness and most importantly public perception.

Foremost, as PROMs and PRO-PMs are rolled out in isolation, CMS has historically applied these guiding principles in silos to each measure without assessing overall patient experience related to the totality of mandated CMS beneficiary outreach. With PROMs as well as screening tools, the cumulative effect creates "survey fatigue" that adversely impacts the patient experience across surveys. Ironically, this over-solicitation of feedback reflects adversely in patient responses to measures related to provider communications and whether providers are listening. In an effort to increase response rates, CMS may be inadvertently exacerbating this issue by mandating multiple distribution modalities – sending the same survey to patients multiple times. We suggest that CMS evaluate the cumulative effect not just in the ambulatory setting but across health care settings as many identical or similar PROMs and screenings are mandated in multiple settings. It is not uncommon for patients to express frustration about continued outreach when they believe it has been asked and answered or they simply prefer not to respond.

The TKA/THA Pro-PM measure is one such measure that CMS is pushing across health care settings, yet we do not believe that it meets the proposed guiding principles. This measure presents operational challenges when surveying patients pre- and post-surgical events, is overly burdensome, is limited to a subset of patients, and lacks exclusions for small sample sizes. The potential for survey fatigue and patient frustration is heightened with this measure. And with this measure, instead of being within the purview of the specialist, this measure has fallen to hospitals to collect. We have detailed concerns in past

comment letters.[9] In the 2025 OPPS rule, 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) has been proposed. As proposed, this measure is largely duplicative of OAS CAHPS and creates unnecessary administrative burden, including additional costs related to third-party vendor distribution. It appears that the vendor also developed the instrument.

RFI: CONSUMER ASSESSMENT OF HEALTHCARE PROVIDERS AND SYSTEMS (CAHPS) FOR MIPS SURVEY

CMS seeks public comment on the potential expansion of the survey modes of the CAHPS for MIPS Survey. The expansion to the protocol would include an initial administration of the survey by web, followed by mail, and then by phone.

Comment: UnityPoint Health acknowledges and agrees that the patient perspective is extremely important to capture to facilitate performance improvement. CAHPS survey response rates across the nation are trending downward and becoming more expensive to administer due to language requirements without a solid return of investment due to lower response rates. Although CMS is proposing to add another CAHPS modality (web-based) to the survey administration protocol, we have actually reverted from electronic to a paper CAHPS survey distribution for some settings to bolster response rates due in part to the public's concern with cybersecurity and phishing. We are also concerned as this will likely add costs, but an IRC is yet to be calculated. **To improve patient experience survey response rates, we suggest CMS either: (1) shorten the CAHPS survey itself; or (2) authorize real-time survey alternatives to CAHPS**. We have found real-time alternatives to CAHPS gather broader patient feedback and are timelier, more actionable, and less costly.

UnityPoint Clinic is pleased to provide comments on this proposed rule. To discuss our comments or for additional information, please contact Cathy Simmons, Government and External Affairs, at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

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[9] UnityPoint Health comment letter to CMS-1808-P – FY2025 IPPS, comment letter submitted on June 10, 2024 – tracking number lx9-g166-pr90; UnityPoint Health comment letter to CMS-1735-P FY2024 IPPS, comment letter submitted on June 9, 2023 - tracking number lio-z31d-u37u