



March 7, 2022

Secretary Xavier Becerra  
Centers for Medicare & Medicaid Services (CMS)  
Health and Human Services (HHS)  
Attention: CMS-4192-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

RE: CMS-4192-P- Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefits Program; published in Vol. 87, No. 8 Federal Register 1842-1960 on January 12, 2022.

*Submitted electronically via [www.regulations.gov](http://www.regulations.gov)*

Dear Secretary Becerra,

UnityPoint Health appreciates the opportunity to provide comments on this proposed rule related to Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefits Programs. UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 33,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health provide a full range of coordinated care to patients and families through more than 8.4 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 Health also participates in a Medicare Advantage provider-sponsored health plan through HealthPartners UnityPoint Health.

UnityPoint Health appreciates the time and effort of CMS in developing this proposed rule and respectfully offers the following comments on specific topics outlined below.

## **PHARMACY PRICE CONCESSIONS TO DRUG PRICES AT THE POINT OF SALE**

*CMS proposes to eliminate the exception for pharmacy price concessions that cannot reasonably be determined at the point of sale. CMS is also proposing to delete the existing definition of "negotiated*

*prices” and adopt a new definition for the term of which is defined as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor of the sponsor’s intermediary. Lastly, CMS proposes to add a definition for “price concession”.*

**Comment:** We are encouraged that CMS is again considering this area for pricing reform. The pharmacy industry via pharmacy price concessions has been bearing the brunt of direct or indirect remuneration (DIR) cost increases. The magnitude of this growth – 107,400 percent increase between 2010 (\$8.9 million) and 2020 (\$9.5 billion) – continues to be a cause for alarm and is particularly detrimental to operating margins for small, independent pharmacies. Overall, **UnityPoint Health is supportive of CMS’s proposals.**

- **Sponsor/PBM Performance Measures** – As noted within the proposal, negotiations between pharmacies and sponsor or their PBMs have become increasingly prevalent and are tied to pharmacy performance. It has been our experience that performance measures, as defined by the sponsor/PBM, are often based on metrics outside the control of pharmacies yet remain the second largest category of DIR received by sponsors/PBMs. A measure of statin use in beneficiary with diabetes is a prime example. The pharmacy cannot prescribe a statin for a beneficiary, ultimately relying on the provider to write this prescription and the beneficiary to fill at the pharmacy. In this situation the pharmacy would be docked if too many beneficiaries, not on statins, fail to fill their prescriptions. While sponsors/PBMs continue to benefit from beneficiaries falling below these performance thresholds, pharmacies absorb the adverse impact of performance measure recoupments to an overall net-negative program. **We encourage CMS to review the benefits beneficiaries gain on contract performance measures as defined by the sponsor or PBM.**

The single largest category of DIR received by sponsors and PBMs are manufacturer rebates (non-pharmacy price concession), while CMS is following an incremental approach and only proposing policies related to pharmacy price concessions at this time, **we encourage CMS to review regulations on the application of manufacture rebates to negotiated prices in the near future.**

- **Transparency and Competition** –Sponsors may choose how to calculate their DIR fees for plans. For example, a beneficiary may be attempting to compare plans where one has a reduced premium due to DIR fees and another has a premium not reduced by DIR fees. In this situation, each plan has a different downstream effect including varying deductibles and co-pays. In our experience we’ve found while lower premiums maybe achieved initially, this leads to undue confusion in the plan selection process. In some cases, this leaves beneficiaries with higher co-pays and deductibles and, as a result unable to pay for their drugs. Similarly, approaches by plan sponsors vary when beneficiaries are within the donut hole verses before entering the donut hole. **UnityPoint Health strongly supports a standard approach to sponsor plans and calculations.** Driving consistency for beneficiaries is key to medication adherence and disease management.
- **Non-interference Clause** – The non-interference clause, which restrict agency authority, has allowed sponsors/PBMs to dictate terms that effectively hamstring pharmacies. Negotiations are one-sided and, in our experience, most often only benefit the sponsor/PBMs. Pharmacies are left with undesirable contract terms in order to keep access to beneficiaries. **UnityPoint Health**

**recommends pairing down the non-interference clause and adding an appropriate level of oversight into the practices of this highly consolidated industry.**

- **Drug Manufacturer Assistance Programs** – While drug prices continue to soar, pharmacies grapple with limited – and shrinking - avenues to help beneficiaries gain access to medications they can no longer afford. **Drug manufacturers have been unlawfully restricting access to 340B-priced medications at contract pharmacies and we applaud the agency’s ongoing efforts to enforce the statute, including referring the issue to OIG to assess for Civil Monetary Penalties.** While limiting access to 340B, many of these same manufacturers are also ending or reducing the value of the co-pay coupon cards they offer. This directly increases the out-of-pocket costs for many of our patients. Manufacturers are also making the criteria for their need-based patient assistance programs more stringent, often leading patients to lose eligibility unexpectedly. **We appreciate the efforts the agency is making to combat high drug prices and encourage the agency to continue to explore ways to make access to prescriptions more affordable for all Americans.**

## **PART D CHOICE FOR PACE PARTICIPANTS**

*Participants in the Program of All-Inclusive Care for the Elderly (PACE) are required to enroll in the Medicare Part D prescription drug plan offered by their PACE program and are prohibited from selecting an alternative stand-alone Part D plan that may offer more affordability.*

**Comment:** With the implementation of the Part D benefit in 2003, PACE organizations are required to include prescription drug coverage to all PACE participants and to become established as Part D plans. Prior to that time, prescription drugs were covered by Medicaid or as part of the PACE private pay premium. While UnityPoint Health supports the inclusion of prescription drug coverage as part of the PACE benefit, Part D premiums are often cost prohibitive for Medicare-only PACE participants. For Siouxland PACE, total annual participant out of pocket costs<sup>1</sup> for Part D coverage in 2022 is more than twice the mean cost for the marketplace plans offered in our service area<sup>2</sup>. This represents more than \$550 per month. High costs for PACE Part D plans are driven by multiple factors: Inability of PACE Part D plans from charging participants deductibles and coinsurance; coverage gap exemptions that disallow manufacturer discounts for brand-name drugs and federal reinsurance for drug costs exceeding the catastrophic benefit limit; higher drug acquisition prices for PACE Part D plans; higher average Hierarchical Condition Categories (HCC) score for PACE participants; lack of a common formulary in PACE Part D plans; and small PACE Part D plan pools result in higher administrative costs.

In the agency’s advisory role to Congress, UnityPoint Health encourages CMS to include this issue among its punch list for Part D reforms. In particular, the PACE Part D Choice Act, H.R. 4941, proposes a resolution to this issue. This legislation would allow Medicare-only PACE participants to choose between the PACE

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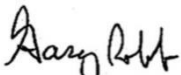
<sup>1</sup> Total Annual Participant Out of Pocket is defined as the total cost of premium + deductible + cost sharing.


<sup>2</sup> Our service area represents all plans available in zip code 51103 where PACE Center for Siouxland PACE is located in Sioux City, Iowa.


Part D plan as currently designed, with an all-inclusive premium and no deductible or coinsurance, or a marketplace Part D plan with a lower premium and related deductible and coinsurance amounts.

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

Sincerely,

  
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