

January 24, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-1813

RE: CMS-4180-P – Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses; published at Federal Register, Vol. 83, No. 231, November 30, 2018.

Submitted electronically via www.regulations.gov

Dear Administrator Verma,

UnityPoint Health (“UPH”) appreciates this opportunity to provide feedback on the proposed rule. UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 38 hospitals in metropolitan and rural communities and 15 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

UPH appreciates the time and effort of CMS in developing and proposing this rule and respectfully offers the following comments.

PROVIDING PLAN FLEXIBILITY TO MANAGE PROTECTED CLASSES

CMS is proposing three exceptions to the current protected class policy that would allow Part D sponsors to: (1) Implement broader use of prior authorization (PA) and step therapy (ST) for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

- **Comment:** Due to guardrails in place for protected class drugs to promote innovation and access, these drugs are more prone to potential manufacturer gaming resulting in higher prices. We believe that CMS should pursue efforts to push value propositions to manufacturers. Protected classes include drugs that have been re-formularized to extend patent life or “me too” drugs that do not offer

significant therapeutic gains over existing products and we question whether their status within protected classes. Generally, we support price transparency efforts that enable consumers to become more engaged in healthcare decision making and, while access to protected class drugs should be appropriately maintained, we agree that some management tools could be employed without jeopardizing access or healthcare outcomes. As such, we view the first two exceptions, within reason, as options that could yield cost savings without significant restrictions on access.

Step therapy and prior authorization are standard tools used by commercial health plans to control costs using evidence-based protocols. That said, while we are generally supportive of this regulatory flexibility, we do not believe that prior authorization is universally appropriate nor should be used by Part D sponsors across the board. In some cases, we believe that prior authorization should be eliminated altogether to outright avoid these administrative costs, remove third-party administrators from healthcare decisions and reduce service delay. Under the proposed flexibility for Part D sponsors, we remain adamant that sponsors should include meaningful provider input in plan design and coverage decisions to balance cost reduction objectives with quality and access outcomes. As a provider organization, we are committed to working with Plan D sponsors to facilitate appropriate use of these tools. We would also encourage Part D sponsors to work with providers to streamline operationalizing these tools to prevent undue service delay. This could include assisting providers with embedding related decision support tools within electronic medical records and providing best practices with respect to internal practice workflow. To CMS, we would urge vigilant monitoring of the use of prior authorization and step therapy for access to protected classes drugs and any unintended consequences.

In terms of the second exception on formulary exclusion for re-formulations of an existing single-source drug or biological product, we believe this is an appropriate means to prevent manufacturer gaming and will result in reduced drug pricing. Again, we urge CMS to monitor impact of this regulation to assure medication access is maintained.

As for the last exception (formulary exclusion if the drug price beyond a certain threshold over a specified look-back period), the proposal is limited to single-source drug and biological products, defines price using the Wholesale Acquisition Cost (WAC) and calculates the threshold, or rate of inflation, based on the Consumer Price Index for all Urban Consumers (CPI-U). For drugs eligible for formulary exclusion, this proposal would still permit manufacturers and Part D sponsors to negotiate rebate arrangements for formulary placement for protected class drugs. As proposed, we have misgivings due to lack of information. Foremost, we are concerned this will result in drugs being unavailable to Medicare beneficiaries. CMS has not provided projections as to the number or percentage of single-source drugs and biological products that will be potentially impacted by this exception. For beneficiaries with impacted anticonvulsants, antidepressants and antipsychotics, we are concerned that an annual process for formulary exclusions may be a means for Part D sponsors to remove high-cost beneficiaries. Additionally, although the preamble to the proposed rule lists alternative thresholds for measuring inflation, any projections using these different thresholds were not included. Although we are supportive of price constraints where justified, CMS has not provided sufficient data to support the justification for this exemption and the scope of its impact.

PROHIBITION AGAINST GAG CLAUSE IN PHARMACY CONTRACTS

To conform to the statutory change made by the “Know the Lowest Price Act of 2018” (Public Law 115-262), CMS is proposing to provide that a Part D sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee’s Part D plan.

- **Comment:** We support this proposal. It embodies common sense and good practice.

E-PRESCRIBING AND THE PART D PRESCRIPTION DRUG PROGRAM

CMS is proposing to require that each Part D plan implement at least one electronic real-time benefit tool (RTBT) of its choosing that is capable of integrating with prescribers’ e-Rx and EMR systems to provide prescribers who service its beneficiaries complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit (F&B) information (including cost, formulary alternatives and utilization management requirements) by January 1, 2020.

- **Comment:** We believe that RTBTs offer promise in providing prescribers and dispensers, and ultimately consumers, with timely formulary and pricing information. We can envision this tool being used by prescribers and pharmacies to assist consumers with weighing decisions related to drugs on different formulary tiers, including more subtle formulary differences that sometimes distinguish capsule versus tablet forms of the same drug.

This proposal will require significant infrastructure investments for Part D plans under a relatively aggressive timeframe. Because each plan will be able to choose their own RTBT, we do have concerns related to the degree of RTBT solution variability, implementation costs including prescriber / dispenser training and downstream impact on medical record and eRx vendors. As part of an integrated health system, we do not fully understand the direct cost impact of this proposal upon providers. We do anticipate that there will be indirect costs; many providers have backlogs of medical record builds from EHR vendors currently and we would expect that this proposal will only increase timeframes and costs for existing needs.

PART D EXPLANATION OF BENEFITS (EOB)

CMS is proposing to require sponsors to include in the Part D EOB (1) negotiated drug pricing information, which is the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim; and (2) lower-cost therapeutic alternatives, meaning drugs with lower cost-sharing or lower negotiated prices. Lower-cost therapeutic alternatives would not be limited to therapeutically equivalent generics and could include a different drug, not within the same category or class, that has a medically-accepted indication to treat the same condition.

- **Comment:** The inclusion of negotiated drug pricing is an extension of CMS price transparency efforts that are being proposed across Medicare payment systems, including inpatient charges. We support this proposal for Part D drug prices.

MEDICARE ADVANTAGE AND STEP THERAPY FOR PART B DRUGS

CMS is proposing certain new requirements for when MA plans may apply step therapy as a utilization management tool for Part B drugs, including the modification of Part C adjudication time periods. For

contract year 2020 and subsequent years, coupling drug management coordination with rewards and incentives remains an option for MA plans to pass back savings to beneficiaries.

- **Comment:** As referenced in our discussion under *Providing Plan Flexibility to Manage Protected Classes*, step therapy is a management tool commonly used by commercial payers. As these tools are implemented, cost savings to Medicare and beneficiaries will undoubtedly accrue from the use of lower-cost drugs; however, there will be healthcare delivery implications and associated costs with increased overhead. Given our experience with commercial payers, we support this provision but encourage CMS to monitor the continued access to needed drugs and the avoidance of unintended consequences, including declining health outcomes. Particularly in light of other proposals from the administration, namely the International Pricing Index model, we encourage CMS to ensure that hospital reimbursement for Part B drugs allows us to support staff and services that will help patients navigate these utilization criteria.

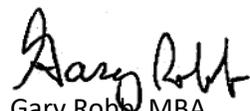
PHARMACY PRICE CONCESSIONS TO DRUG PRICES AT THE POINT OF SALE

CMS is proposing to redefine negotiated price as the baseline, or lowest possible, payment to a pharmacy for a future plan year, which may be as early as 2020. In addition, the proposal also includes a defining price concession in a broad manner to include all forms of discounts and direct or indirect subsidies or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors.

- **Comment:** We are encouraged that CMS is 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 – 45,000 percent increase between 2010 and 2017 – is cause for alarm and is particularly detrimental to operating margins for small, independent pharmacies. We support reform in this area and urge its adoption. Furthermore, we believe that CMS should explore metrics that could serve as a basis of contractual agreements which would provide more predictability to a pharmacy's revenue.

We are pleased to provide comments to the proposed regulations and their impact on our patients and integrated healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government & External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,



Gary Robb, MBA
VP, Chief Pharmacy Officer



Sabra Rosener, JD
VP, Government & External Affairs