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December 12, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4187–P
P.O. Box 8013
Baltimore, MD 21244–1813

RE: CMS–4187–P – Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency; published at Federal Register, Vol. 83, No. 202, October 18, 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.

DIRECT-TO-CONSUMER (DTC) TELEVISION ADVERTISEMENT REQUIREMENTS FOR PRESCRIPTION DRUGS

CMS is proposing that DTC television advertisements must include the Wholesale Acquisition Cost (WAC), known as the list price, for certain prescription drugs and biological products. Specifically, the advertisement must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of quarter during which the advertisement is being aired or otherwise broadcast, as follows: ''The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.''

Comment: UnityPoint Health does not believe that broadcast DTC advertising by drug manufacturers is a preferred or effective method to provide drug pricing information to consumers. The United States is only

one of two countries that permits DTC advertising for prescription medications. In 2015, the American Medical Association (AMA) called for a ban on DTC advertising of prescription drugs and medical devices.[1] In part, the AMA's proposed ban was to counter the "negative impact of commercially-driven promotions, and the role that marketing costs play in fueling escalating drug prices." We would support the ban as proposed by the AMA, regardless of the proposed inclusion of list prices.

Given our preference to ban DTC advertising in this arena, we encourage CMS to adopt policies that will help pop the gross-to-net bubble for drug pricing. We are particularly concerned with uninsured patients who have the least access to medications and often forego medication treatment regimens due to cost. The current drug pricing structure does not promote transparency or shine light on out-of-pocket costs. As proposed, we are not convinced that this rule will remedy the lack of transparency nor create an incentive to lower prices by changing either manufacturer or consumer behavior. And at worse, we can envision that this proposal could have unintended consequences of driving unnecessary utilization or even discouraging needed care based on perceived affordability. Underlying these concerns is the proposed use of list price or wholesale acquisition cost (WAC). While we agree that consumers should be engaged in healthcare choices and that cost should be included in this equation, we do not agree that prescription drugs are akin to a new car, new house or new coffee maker. Prescriptions drug dosage and administration frequency often vary by individual, making standardized or typical courses of treatment not applicable in many cases. The pricing for prescriptions themselves is multifaceted, involving numerous health plans and their various coverage options and making it highly unlikely that WAC pricing on its face applies to any consumers (even those without insurance). Overall, we are concerned that list prices are not meaningful for most consumers in making healthcare choices and will do little to reduce out-of-pocket costs. In addition, without an enforcement mechanism for manufacturers, we believe that there will be little to no impact on manufacturer pricing strategy.

OTHER APPROACHES TO PRICE TRANSPARENCY AND INFORMED DECISION MAKING

CMS is considering additional solutions to provide beneficiaries with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs but also expenditures borne by Medicare and Medicaid. Among these approaches are: (1) an enhanced CMS drug pricing dashboard, (2) a new payment code for drug pricing counseling, and (3) intelligent plan selection or use of intelligent assignment.

Comment: Of the alternative approaches suggested by CMS, UnityPoint Health supports the enactment of a new payment code for drug pricing counseling. This approach recognizes the importance of provider communications and that this process must be individualized – a one-size-fits-all dosing or course of treatment is often not appropriate. To promote top of licensure practice, we would further suggest that this code be applicable to providers beyond physicians. For instance, it would be quite appropriate for pharmacists and care coordination professionals to engage in these one-on-one conversations with consumers.

[1] American Medical Association, AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices, dated November 17, 2015, accessed at https://www.ama-assn.org/content/ama-calls-ban-direct-consumer-advertising-prescription-drugs-and-medical-devices

As for the enhanced CMS drug pricing dashboard, which is focused on consumers, we believe that GoodRx has already created an effective tool for consumers. If CMS were to enhance their dashboard, we believe that this should be paired with the proposed drug pricing counseling code. The targeted audience for enhanced information, including therapeutic alternatives and pharmacoeconomic research, should be trained healthcare professionals who can assist consumers in deciphering options and weighting pricing information as it relates to their situation.

Finally, while we applaud CMS for describing the increasing role of price concessions in the form of rebates that are paid after the prescription is filled, the proposed rule fails to address the role of rebates in obscuring price transparency and inflating consumer out-of-pocket costs. We urge CMS to address manufacturer rebates within this rule, as this would squarely focus the transparency debate on the gross-to-net bubble. We believe that the absence of regulating rebates or making their role on pricing transparent is an oversight that needs correcting.

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 and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

Gary Robb RPh, MBA
VP, Chief Pharmacy Officer

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