

July 16, 2018

Alex M. Azar II, Secretary
Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

RE: RIN 0991–ZA49 – HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; published at Federal Register, Vol. 83, No. 95, May 16, 2018.

Submitted electronically via www.regulations.gov

Dear Secretary Azar,

UnityPoint Health (“UPH”) appreciates this opportunity to provide feedback on the request for information to help shape future policy development and agency action. 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 home care services 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 has been an advocate for drug pricing reforms and is encouraged that the Administration is attempting to tackle this difficult issue. Most recently, UPH joined the Academy Advisors and several other large health systems at a meeting with Daniel Best, Senior Advisor to the Secretary for Drug Pricing Reform on June 26, 2018. This meeting focused on the interest and challenges of providers in this discussion. For provider organizations, drug pricing has significant daily impacts on clinical care decisions and operations. Despite its impact, providers have little impact and influence on drug pricing. This is particularly frustrating for healthcare organizations like UPH that have entered into risk-bearing contracts for total cost of care with Medicare and other payers. While at-risk organizations are responsible for result-driven outcomes and controlling costs (and CMS is encouraging providers to increasingly transition more of their caseloads to value-based arrangements), drug manufacturers are not held to these same value-based tenets.¹ We enthusiastically support efforts by HHS to “hold manufacturers accountable for outcomes” and to “align

¹ The 2016 UPH Federal Legislative Agenda included an item to “Address Drug Pricing to Reduce the Total Cost of Care,” which encompassed the concept that Pharmaceuticals should be transitioned to outcome-based payment.
https://www.unitypoint.org/filesimages/GovernmentAffairs/2016_Federal_Legislative_Agenda.pdf

with CMS’s priorities of value over volume.”²

Through this Blueprint, HHS is soliciting stakeholder comment. As providers, we are very appreciative of this first step to combat high pharmaceutical costs; however, providers are handicapped in our ability to thoroughly respond as most lines of inquiry rely on data and information within the sole control of manufacturers. As a result, many providers are limited to the 340B Drug Pricing Program as a venue to contribute to this conversation. In turn, this involvement in a relatively small provider program (i.e. 340B Program) has become the provider platform for drug pricing and the manufacturers’ focal point for drug pricing abuse. We would like to recognize upfront that the 340B Program should be subject to enhanced transparency to assure discounted pricing is appropriately captured and targeted. Given this acknowledgement, the debate on drug pricing should shift squarely upon the drug manufacturers and the need for simple, upfront pricing.

In general, UPH urges HHS to fully utilize market forces and economies of scale to decrease drug prices. In particular, we support:

- **Direct negotiation on drug prices by the federal government for Medicare** (and states for Medicaid), and the inclusion of 340B Drug Pricing Program in this negotiation.
- **Removing trade barriers** to permit the purchase of drugs from other countries.
- **Market-based solutions** set forth in the Campaign for Sustainable Rx Pricing agenda, developed by a membership that includes health plans; pharmacists and pharmacy groups, hospital and physician groups; employers; and consumer organizations. Key market-based solutions include:
 - Provide resources to **speed up FDA approval** for 4,000-case backlog of generic drug applications, especially for expensive drugs without competition.
 - **Shorten the 12-year market exclusivity period** for costly biologic drugs.
 - **Oppose “pay for delay” settlements** to keep generic products off the market.
 - **Require manufacturers to disclose more drug cost information**, report any planned drug price increases, and provide comparison information related to drug safety and effectiveness with others on the market. In addition, disallow significant drug price increases associated with shortage situations.

In addition to the above, we respectfully offer the following comments to specific questions raised in the RFI.

REDUCING PATIENT OUT-OF-POCKET SPENDING

CMS is soliciting information on the best method to disseminate pricing information to beneficiaries. The options include the potential expansion of pharmacist roles and responsibilities:

- **Part D end-of-year statement on drug price changes and rebates collected.** *Alternatively, could pharmacists be empowered to inform beneficiaries when prices for their drugs have changed? Would this information be best distributed by pharmacists at the point of sale, by Medicare as an annual report, or by the health plan on a more regular basis, or some combination of these approaches?*
- **Federal preemption of contracted pharmacy gag clause laws.** *What other communication barriers are in place between pharmacists and patients that could be impeding lower drug prices, out-of-*

² RFI, page 22694.

pocket costs, and spending? Should pharmacists be required to ask patients in Federal programs if they'd like information about lower-cost alternatives?

- **Inform Medicare beneficiaries with Medicare Part B and Part D about cost-sharing and lower-cost alternatives.** *Should Medicare require the use of systems that support providing this information to patients? Does this create unreasonable burden for prescribers or pharmacists?*

Comment: We understand the desire for beneficiaries to have clear upfront pricing and to be engaged in the solution to reduce total healthcare costs. That said, **we are concerned with solutions that shift responsibility to pharmacists, away from clinical support for the patient, to medication pricing outreach and advocacy.** Beneficiaries should appropriately rely on pharmacists for preparing, dispensing, and educating patients on correct medication use and encouraging medication use safe outcomes, but pricing decision points should not be added to their repertoire. This incorrectly assumes that pharmacists have complete pricing information and alternative comparisons, places pharmacists in a “spokesperson” position for manufacturer/PBMs/insurance plans list prices, diverts highly trained healthcare professionals from the practice of pharmacy, and depending upon enforcement mechanisms, may jeopardize licensure for issues related to pricing. We believe that pricing should be transparent before a pharmacist may intervene or inform and should be handled well upstream by the manufacturers or health plans.

CREATING INCENTIVES TO LOWER LIST PRICES

Direct To Consumer (DTC) advertising. *HHS may call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising.*

Comment: We support a HHS review of the impact of Direct To Consumer (DTC) advertising on drug pricing. The United States is only one of two countries that permits DTC advertising for prescription medications. In 2015, the American Medical Association called for a ban on DTC advertising of prescription drugs and medical devices.³ 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.” Last year, the AMA adopted several policies targeting prescription cost transparency,⁴ including one for manufacturers to list the suggested retail prices of drugs when running direct-to-consumer ads. We would urge HHS to work with the FDA and stakeholders to consider DTC advertising regulations that include price transparency.

Fiduciary duty for Pharmacy Benefit Managers. *Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices? Should PBMs be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits?*

Comment: While drug manufacturers ultimately are responsible for drug pricing, PBM contracts do appear to be an area that may benefit from further transparency. UPH has a self-insured health plan for

³ 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>

⁴ American Medical Association, AMA Adopts Policy Aimed to Bolster Transparency of Prescription Costs, dated June 15, 2017, accessed at <https://www.ama-assn.org/ama-adopts-policy-aimed-bolster-transparency-prescription-costs>

our employees with more than 37,000 covered lives. As a large employer, our ability to negotiate favorable contractual terms with insurers and PBMs may be atypical. As PBM market share continues to become concentrated, PBM contracts have more “standard terms” not subject to negotiation. In addition, “maximum allowable cost list” provisions are common and enable PBMs to charge payers, such as federal health programs, higher rates while paying lower reimbursement rates to pharmacies. **We would encourage HHS to examine further transparency of PBM arrangements and actual costs/payments, similar to pricing transparency initiatives being undertaken for the 340B program.**

Incentives to lower or not increase list prices. *Should manufacturers of drugs who have increased their prices over a particular lookback period or have not provided a discount be allowed to be included in the protected classes? What should CMS consider doing, under current authorities, to create incentives for Part B drugs committing to a price over a particular lookback period?*

Comment: We question whether HHS should create incentives for what should be equitable price setting and market increases. A lookback process may result in more administrative burden without addressing the underlying issue of how pricing was initially established.

Copay discount cards. *Does the use of manufacturer copay cards help lower consumer cost or actually drive increases in manufacturer list price?*

Comment: Although the premise of copay discount cards is to reduce and/or negate out-of-pocket expenses; in practice, **it has been our observation that out-of-pocket costs remain the same and drug prices are kept high through these manufacturer supports.** For some consumers with insurance (depending upon PBM), the cost-share program does not count copay assistance dollars toward a consumer’s deductible and out-of-pocket maximum. As a result, it takes longer to reach out-of-pocket maximum amounts – costing consumers more and also increasing the duration that the copay discount cards are used and the manufacturer pays higher costs.

The 340B drug discount program.

Twelve UnityPoint Health hospitals participate in the 340B Program at 33 locations and 141 contract pharmacy sites.

- **Program growth.** *How has the growth of the 340B drug discount program affected list prices? Does the Group Purchasing Organization (GPO) exclusion, the establishment of the Prime Vendor Program, and the current inventory models for tracking 340B drugs increase or decrease prices? What are the unintended consequences of this program?*

Comment: Since list prices are set by manufacturers, covered entities cannot be certain of the direct impact of the 340B program on list prices, but we would agree that as more covered entities register and participate, the volume of eligible 340B purchases will increase. In the context of overall drug pricing, we would suggest that 340B discounts are a small portion of the \$153 billion in reduced list price revenue for 2017 as reported by manufacturers of brand-name drugs.⁵ While different stakeholder groups cite different discount amounts due to the 340B program, their estimates generally range from \$6 billion to \$16 billion, or just 4-10% of the total discounts to list price.

⁵ IQVIA, [Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022](#)

In terms of the GPO exclusion, both the statutory prohibition against group purchasing and HHS’s implementation of the exclusion since 2013 have increased UPH’s pharmacy and inventory management costs significantly. For more than 20 years, Health Resources and Services Administration (HRSA) permitted 340B hospitals to use “two-inventory” systems in which we purchased our initial drug inventory through a GPO and then replenished those drugs with either a 340B or GPO drug depending on whether the drug was used for a 340B eligible patient or not. In 2013, HRSA issued Policy Release 2013-1,⁶ which abruptly prohibited hospitals from making initial purchases through a GPO account, forcing us instead to buy our initial inventories at non-GPO, non-340B prices. This was accomplished by buying the drugs at wholesale acquisition cost (WAC), usually more expensive than either a GPO or 340B price. The practical effect has been to maintain three inventories (340B, GPO, and WAC) rather than just two (340B and GPO). Costs have increased related to higher WAC prices and greater resources needed to maintain a third inventory system. Although not an impact on list prices, these administrative burdens divert funding for direct care to vulnerable populations.

As for unintended consequences, we believe the administrative complexity of the program diverts program resources to administrative and compliance functions rather than to stretch federal resources for DSH and rural entities. By focusing operations at a dose dependent level, this creates a highly error-prone system. While program simplification would assist with reducing administrative costs, we are doubtful that these steps would reduce manufacturer list prices and question whether 340B in its entirety has a meaningful impact on manufacturer list prices.

- **Program Eligibility.** *Would changing the definition of “patient” or changing the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (i.e., child sites) help refocus the program towards its intended purpose?*

Comment: When developing the 340B program, Congress intended that lower drug prices would help safety net providers to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”⁷ **Program eligibility is appropriately related to DSH or rural status and reflects the covered entity’s overall commitment to vulnerable populations. We do not believe that changing either the definition of “patient” or covered entity contracting requirements will help to clarify the program’s intent.** Instead, these changes would just add more compliance complexity, thereby requiring more resources to be diverted to program compliance/administration versus direct services.

While we urge Congress to maintain eligibility criteria, we do believe that the 340B registration process is flawed and overinflates data regarding program scope. Currently, a covered entity must individually register each separate service offered in a clinic/location, instead of by location. As a result, we have one physical address that contains 18 child sites and another physical address that contains 17 child sites. Rather, **we would recommend that covered entity registration target locations where 340B drugs are used, and not individual service lines.**

⁶ HRSA, 340B Drug Pricing Program Notice, Release No. 2013-1, “Statutory Prohibition on Group Purchasing Organization Participation,” dated February 7, 2013, accessed at <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf>.

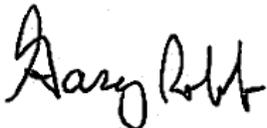
⁷ U.S. House, Committee on Veterans Affairs, “Establishment of Limits on Prices of Drugs Procured by the Department of Veterans Affairs (to accompany H.R. 2890),” H. Rept. 102-384, Pt. 2, 1992.

- **Duplicate Discounts.** *Manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Are the current mechanisms for identifying and preventing duplicate discounts effective?*

Comment: We would encourage the use of retrospective claims identification models as these support program integrity and compliance functions. Oregon uses one such model, which involves quarterly retrospective reporting, as opposed to prospectively applying a modifier and then monitoring for adjustments.

We are pleased to provide input on this RFI and its impact on our 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,



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