National Indian Health Board

Submitted via: http://www.regulations.gov

July 16, 2018

Alex M. Azar II
Office of the Secretary
U.S. Department of Health and Human Services
Attention: RIN 0991-ZA49
200 Independence Ave. SW, Room 600E
Washington DC, 20201

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (0991-ZA49) Comment

Dear Secretary Azar:

On behalf of the National Indian Health Board (NIHB), I write to submit comments on the proposed rule, published in the Federal Register on May 16, 2018, entitled "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." NIHB has provided input into the dialogue surrounding the HHS blueprint and they are outlined in the subsequent sections.

Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

The following comments were created by gathering feedback from Tribal Health Directors and representatives from across Indian Country. We address our comments according to the four key strategies in the blueprint.

Improved Competition

On page 22693 of the Federal Registry it says, "…changing Part D plan formulary standards to require a minimum of 1 drug per category or class rather than two." In a scenario where a patient has Part D coverage and is only covered by 1 specific drug by their Part D plan, we believe there would actually be a decrease in competition, not an increase. Theoretically, this could save money for that one drug, but it may negatively impact patient care and place additional burden on the business aspect of patient care. If this patient is not able to take this drug, Tribal health programs would normally send a request for it to be covered and if the insurance company denies it, then they are able to submit another appeal to an Independent Review Contractor (IRC) that could overturn the insurance companies' decision based upon

the medical need for a different class of drug. This change would take the IRC out of the scenario and would then leave the ultimate decision to the insurance company to deny the drug, leading the patient to have to pay for a drug that the Part D plan will not cover. This would mean more out of pocket costs for the patient and less third party reimbursement for the Tribe; it will give more power to the insurance company and would create more denials for third party billing. This would also allow the plans more power to control their formulary by restricting patients to the medication that pays them the largest rebate, and the Tribal/VA Temporary Price Reduction influenced formulary rarely aligns with Part D plan formularies.

We appreciate the Blueprint's proposal to prevent manufacturer gaming of regulatory processes such as Risk Evaluation and Mitigation Strategies (REMS). With regards to measures to promote innovation and competition for biologics, we are not certain of the advantages for moving biosimilars to Part B only. Tribes receive higher reimbursements from Part D and support to move as many Part B medications over into Part D.

The Blueprint calls for developing proposals to stop Medicaid and Affordable Care Act programs from raising prices in the private market. According to our constituents, the Affordable Care Act required an increase in rebates paid to Medicaid and extended this to Medicaid Managed Care Organizations. This could have caused drug manufacturers to increase the Average Wholesale Price (AWP), which also increased prices across the board. We recommend looking into this cause-and-effect.

Better Negotiation

In terms of experimenting with value-based purchasing in federal programs, we believe this will require the diagnosis code to be attached with the prescription and not all Electronic Health Record's (EHR) will be able to perform this. This could cause an increase in Prior Authorizations that the pharmacy will have to complete. This will cause an administrative burden on the providers and the pharmacists. We also wonder who is making the decision of what diagnosis codes are going to pay. If a Pharmacy Benefit Manager has control over it, it may not be good.

We agree with allowing more substitution in Medicare Part D to address price increases for single source generics. Increasing generic drug dispensing rates should be a larger focus if the overall goal is to bring the expenditures down across the board. In terms of reforming Medicare Part D to give plan sponsors significantly more power when negotiating with manufacturers, we believe giving Pharmacy Benefit Managers (PBM) more power to negotiate rebates, will only increase overall expenditures as it has in the past with inflated Average Wholesale Price (AWP) manufacturers. Allowing further restrictions to formularies should be focused on increasing the generic dispense rate within each class that has a generic available. If PBM's were eliminated from the healthcare system prices would most likely decrease. PBMs are taking a larger amount of money each year to be an intermediary, between drug manufacturers, plans, and providers; therefore they are a substantial part of the administrative costs our country has that others do not. In addition, the name brands that make it to the formularies have been the manufacturers who have paid the highest rebates, we disagree that "few drugs were excluded from coverage". A large majority of the time, there is only one preferred name brand product on formulary; even while there is sound medical evidence to show that another name brand product in the class has evidence to show it is medically superior.

The Blueprint proposes to send a report to the President on whether lower prices on some Medicare Part B drugs could be negotiated for by Part D plans. We believe this would probably increase collections. It would also change the workflow of how Part B drugs are dispensed and billed versus how Part D drugs are dispensed and billed.

The Blueprint considers further use of value-based purchasing in federal programs, including indication-based pricing and long-term financing. We believe this will require the diagnosis codes to have to be attached with the e-prescription, causing an increase in prior authorization that the pharmacists' will have to complete. Currently, many EHRs will not perform this, causing administrative burdens on the providers and the pharmacists.

Incentives for Lower List Prices

The Blueprint proposes reforms to the 340B drug discount program. We strongly urge caution on any changes to the 340B program. The 340B program is hugely important to Tribal health programs, which are severely underfunded and face with enormous need. Both the 340B and the VA prime vendor discount program are the two primary ways that Tribes and Tribal organizations purchase prescription drugs at a discount, saving the federal government millions of dollars in drug costs to serve AI/ANs. The number of health sites that utilize the 340B program — currently about 38,000 nationwide—has almost doubled in the past 5 years and over 150 Tribal sites have participated in the program, including 34 urban Indian programs. The intent of the 340B program is "to permit covered entities 'to stretch Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" 80 Fed. Reg. at 52300. We are concerned with any regulatory action that could affect the purposes of the 340B program and reduce the ability of Tribes and Tribal organizations to provide much-needed care to their patients. Therefore, before any reform is implemented, we request Tribal consultation per Executive Order 13175.

The Blueprint also proposes changes to HHS regulations regarding drug copay discount cards. We believe that it would be good if Tribal Health Departments could use the drug co-pay discount cards for drugs that they don't get a Temporary Price Reduction (TPR) on.

Conclusion

NIHB and Tribes stand ready to work with HHS to develop this comprehensive blueprint that addresses may of the challenges and opportunities impacting American patients and consumers. We thank you for the opportunity to provide our comments and recommendations for the HHS Blueprint to lower drug prices and reduce out-of-pocket costs and look forward to further dialogue with HHS in regards to how this blueprint may have ramifications for Tribal communities. Please contact NIHB's Director of Policy, Devin Delrow, at ddelrow@nihb.org if there are any additional questions or comments raised in this letter.

Sincerely,

Vinton Hawley
Chairman, National Indian Health Board