December 31, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-5528-ANPRM (Medicare Program; International Pricing Index Model for Medicare Part B Drugs)

Dear Administrator Verma:

BioUtah appreciates the opportunity to comment on the Advance Notice of Proposed Rulemaking with Comment (ANPRM) with respect to creation of an international pricing index (IPI Model) for Medicare Part B drugs and biologicals (hereafter called "drugs"). Under the IPI Model, payments for Part B drugs, which are physician-administered medications, would shift to align more closely with prices in other countries. The model would apply to 50% of the country and be mandatory for providers in randomly selected geographic areas.

BioUtah is Utah's only trade association dedicated solely to supporting the state's life sciences industry. **On behalf of our Utah-based biotechnology, drug discovery and pharmaceutical companies, we write in opposition to the IPI Model as proposed in the ANPRM and urge CMS to withdraw consideration of this model.**

BioUtah is committed to advancing medical innovation to combat serious disease, improve care for Medicare beneficiaries and deliver cost-effective solutions. While we recognize the administration's concerns about keeping medications affordable to patients, we believe the IPI Model is fundamentally flawed. The model, if advanced and ultimately implemented through further rulemaking, would impose foreign price controls on the U.S. drug market, put the brakes on innovation, and threaten access to critical cancer drugs and other therapies.

Our comments on these points are further detailed below.

I. Use of Foreign Country Price Controls and Impact on Innovation

BioUtah is deeply concerned about the adverse impact of the IPI Model on continued innovation and investment in new and better medicines.

The proposed IPI Model is a sweeping departure from the current Part B "Average Sales Price" (ASP), plus 6%, drug payment formula. This formula is based on market pricing and reflects discounts negotiated between payers, hospitals and health plans.

In contrast, the IPI Model would import foreign price controls to the U.S. drug market by tying the payment rate for Part B drugs to the prices set by 14 European countries with socialized healthcare systems. These countries often use arbitrary policies to set prices and offer little opportunity for negotiation on price. As a result, prices are distorted, controlled by the

government and bear little relation to market-driven innovation and the significant investment and risk inherent in drug research and development.

The IPI Model, linked to the drug pricing of these foreign countries, would be tantamount to government price controls. When imposed on drugs, such price controls would impede innovation and potentially deter investment in novel life-saving medicines. Utah boasts many startup companies focused on developing new and better drugs for cancers, multiple sclerosis, HIV, and other serious diseases. Furthermore, these companies are pioneering new technologies to accelerate every step in drug discovery and bring down costs.

Basing the price of Part B drugs on the drug prices of government-run healthcare systems would undermine the innovation of these and other companies that hold the promise for new cures and that have made the U.S. a world leader in drug research and development.

II. Model Vendors

BioUtah questions whether the establishment and role of third-party vendors would protect access to care and result in lower out-of-pocket costs for Medicare beneficiaries.

The IPI model contemplates that third-party commercial entities such as group purchasing organizations, wholesalers, distributors, specialty pharmacies, physicians and hospitals, manufacturers, Part D sponsors and/or other entities could be considered vendors under the IPI Model. Model vendors would negotiate prices for drugs, but would not have to take physical possession of the products. Model vendors would enroll purchasers and receive compensation from them for their services.

However, the role of these vendors is not well-defined in the ANPRM. Furthermore, there is no guarantee that introducing this "middleman" element into the IPI process to negotiate drug prices will actually reduce the amount that seniors pay for their medications. Like PBMs, these vendors may lack meaningful transparency and not pass through to patients the drug cost-savings. The administration has previously raised concerns about the role of PBMs in Part D. Similar concerns should be carefully examined regarding the use of these vendors in price negotiations.

III. Access to Choice of Drugs

BioUtah believes that the IPI Model could threaten patient access to life-saving innovative drugs.

Foreign countries, such as those identified for reference pricing under the IPI Model, often refuse to cover drugs depending on price and government determinations of their value. This means certain drugs that sell in the United States, including new drugs, might not be available in other countries. As a result, patients may not have access to the most effective drugs for their condition. We are concerned that implementation of the IPI Model could lead to fewer drug choices for patients, and moreover, make it more difficult for new drugs to come on the market.

New, innovative drugs that give patients hope are more expensive due to the need to recoup the high cost of research and development. Pricing will ultimately determine the extent to which more dollars are put into research and development for new cures.

The IPI model would also change the way physicians and hospitals are paid for Part B drugs. Instead of the current ASP with add-on payment, they would receive a set payment amount for storing and handling drugs that is not tied to the price of the drug. This payment change could make it more difficult for small and rural providers to maintain Part B drug treatments for patients.

Conclusion

BioUtah opposes the IPI Model as proposed in the ANPRM and urges CMS to fully withdraw this model. Reducing the costs of these drugs is a laudable goal and the policy challenge is complex. However, the IPI Model, which adopts drug pricing from countries whose socialized healthcare systems lack market-based principles that spur innovation and give patients choice, is not the answer. BioUtah is pleased to respond to the ANPRM and we appreciate your consideration of our comments.

For questions regarding BioUtah's comments, please contact Denise Bell at denise@bioutah.org or 202-680-3030.

Respectfully submitted,

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