



HOUSE COMMITTEE ON WAYS & MEANS

CHAIRMAN RICHARD E. NEAL

The Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019 **H.R. 2113** **Section-by-Section**

Section 1. Short Title.

The short title for the bill is the Prescription Drug Sunshine, Transparency, Accountability and Reporting Act of 2019, or the Prescription Drug STAR Act.

Section 2. Drug Manufacturer Price Transparency.

This section is substantively similar to H.R. 2069, the *Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019*, introduced by Rep. Horsford (D-NV) and Rep. Reed (R-NY). Section 2 requires drug manufacturers to justify large price increases and high launch prices for drugs, and requires the Secretary of Health and Human Services (HHS) to publicly post a summary of the justification.

Beginning in 2021, a manufacturer will be required to submit a justification to the Secretary if a drug price increases by more than 10 percent or \$10,000 over one year or 25 percent or \$25,000 over three years, or if the manufacturer launches a new drug at or above \$26,000. The dollar amounts that trigger the requirements of Section 2 would be adjusted by the consumer price index for urban customers (CPI-U) over time. Additionally, section 2 includes an exemption from the justification requirement if a drug increases by an amount greater than the dollar threshold but such amount is not higher than the drug price if increased by CPI-U.

The justification the drug manufacturer would submit includes information applicable to the drug price increase or high launch price, such as costs of manufacturing the drug, research and development costs, manufacturer revenue, and executive compensation. The manufacturer must include a summary of the justification to be posted publicly and that summary may exclude any proprietary information, as determined by the manufacturer. The manufacturer must also report the justification in a return filed with the Department of Treasury.

Section 3. Requirement for Manufacturers of Certain Drugs, Devices, Biologicals, and Medical Supplies to Report on Product Samples Provided to Certain Health Care Providers.

This section is substantively similar to H.R. 2064, the *Sunshine for Samples Act of 2019*, introduced by Rep. Chu (D-CA) and Rep. Nunes (R-CA). Section 3 requires manufacturers of certain drugs, devices, biologics, or medical supplies to annually report to the Secretary of HHS the total aggregate value and quantity of samples they give to certain health care providers each



year. The data would be reported on an aggregate basis by drug, device, or medical supply – not by health care provider. Section 3 provides that this aggregate data will be posted on the Open Payments Database beginning in 2023. Additionally, manufacturers are required to report to the Department of Treasury the aggregate value of the samples and the portion of such aggregate amount for which they claimed a business expense deduction.

Section 4. Analysis and Report on Inpatient Hospital Drug Costs.

This section requires the Secretary of HHS to submit a Report to Congress that includes analyses of drugs furnished in the inpatient setting, including data on inpatient hospital drug costs, spending, and volume, spending per admission by hospital type (e.g., urban or rural), and hospital size. The Secretary would also examine the impact of drug shortages on furnishing services in an inpatient hospital setting. Section 4 requires that the report be submitted no later than January 1, 2021, and specifies that \$3 million from the Federal Hospital Insurance Trust Fund will be provided to the Secretary to conduct the analysis.

Section 5. Public Disclosure of Drug Discounts.

This section is substantively similar to H.R. ___, the *PBM Accountability Act of 2019*, introduced by Rep. Spanberger (D-VA), Rep. Arrington, (R-TX), and Rep. Boyle (D-PA). Section 5 requires the Secretary of HHS to publicly disclose the *aggregate* rebates, discounts, and other price concessions achieved by pharmaceutical benefits managers (PBMs). This information is already reported under current law but is not public. Section 5 also requires the Secretary to disclose generic drug dispensing rates by PBM. Beginning in 2020, information on rebates by class of drug would be made publicly available with a one-year lag, to the extent the disclosure would not display confidential information regarding rebates achieved for an individual drug.

Section 6. Requiring Certain Manufacturers to Report Drug Pricing Information with Respect to Drugs under the Medicare Program.

This section is substantively similar to H.R. 2087, the *Reporting Accurate Drug Prices Act of 2019*, introduced by Subcommittee on Health Chairman Doggett (D-TX) and Rep. Buchanan (R-FL). Section 6 requires that by 2020 all drug manufacturers to submit information to the Secretary on the average sales price (ASP) for physician-administered drugs covered under Medicare Part B. Currently, most – but not all – manufacturers for drugs covered under Medicare Part B report their ASP data to HHS. This section also authorizes the Secretary to fine a manufacturer a civil money penalty of \$10,000 for each day the manufacturer fails to report the information and up to \$100,000 for each item of false information. Section 6 additionally requires the Inspector General of HHS to issue a Report to Congress on the accuracy of ASP information that manufacturers submit.