ENERGY & COMMERCE
CHAIR RODGERS

The Stop Drug Shortages Act

Title I. Medicaid.

Sec. 101. Exempting Certain Specified Drugs from Certain Increases in Rebates Under the Medicaid Program; Rebate Cap for Certain Drugs.

- Generic drugs in Medicaid are subject to a statutory rebate of 17.1% plus an inflationary rebate equal to amounts by which the cost of the drug grows faster than inflation.
- This section would suspend the additional inflationary rebates for generic, sterile injectable drugs with at least one indication for a serious disease or condition made by more than one manufacturer.
- This section would also suspend the additional inflationary rebates for all generic drugs that are in shortage or at risk of experiencing shortages.
- This section would prohibit total rebates for generic drugs that are in shortage or at risk of experiencing shortages from having total rebates (the statutory rebate plus the inflationary rebate) exceeding 100% of the drug's average manufacturer price.

Title II. 340B Drug Discount Program.

Sec. 201 Exempting Generic, Sterile Injectable Drugs from the 340B Drug Discount Program.

- This section would exempt generic, sterile injectable drugs with at least one indication for a serious disease or condition that are made by more than one manufacturer from being required to provide 340B rebates.

Sec. 202. Study on Penny Pricing and Other Price Setting Policies.

- This section would task the Government Accountability Office (GAO) with examining the number of generic drugs that are subject to 340B penny pricing, or that have costs equal to $1 or less, and evaluating the number of such drugs that have experienced shortages within the past decade.

Sec. 203. Guidance on Preventing Diversion During Shortages.

- This section would task the Health Resources and Services Administration (HRSA) with issuing guidance to covered entities on permissible ways to share drugs during shortages without violating prohibitions on diverting drugs purchased through the 340B Program to patients not otherwise eligible in the Program.

Title III. Medicare.

Sec. 301. Reducing Inflation Rebate Amounts for Certain Shortage Drugs Subject to Rebate Waivers under the Medicare Program.

- The section requires CMS to gradually phase-out the rebate reduction or waiver for drugs exiting a shortage. There is a 75% reduction in their penalty in the first quarter post-shortage; a 50% penalty reduction in the second quarter post-shortage; a 25% penalty reduction in the third quarter post-shortage; and a 10% penalty reduction in the fourth quarter after a drug comes out of shortage for Part B drugs and a 40% penalty reduction for Medicare Part D drugs.
- Prohibits the Secretary of Health and Human Services from conditioning waivers or reductions of the rebate penalties on the duration of a supply chain disruption or shortage.

Sec. 302. Study on Market-Based Pricing for Shortage Drugs Under Medicare Part B.

- This section requires HHS to study Medicare reimbursement of generic sterile injectable drugs, and other Part B drugs in shortage, for the purpose of recommendations on how to transition these drugs to market-based pricing.

Sec. 303. CMI Model on Alternative Payment for Generic Sterile Injectable Drugs.

- This section requires CMMI to test market-based pricing reimbursement policy for generic sterile injectable drugs, which will receive payment based on commercial net pricing or a drug's wholesale acquisition cost (WAC).

Sec. 304. Study on Medicare Coding for Drugs in Shortage or in Danger of Shortage.

- This section will require HHS to study Medicare coding policies for generic sterile injectables and other Part B drugs in shortage, for the purpose of providing recommendations to update Medicare billing and coding policies to mitigate drug shortages.

Sec. 305. Hospital Reporting of Group Purchasing Organization Remuneration under Medicare.

- This section requires that hospitals, on their Medicare Cost Report, must report remuneration from GPOs, including remuneration tied to an ownership stake in a GPO, as a condition of participation in Medicare.

Sec 306. Study on Flat Fee Payment.

- This section requires the Medicare Payment Advisory Commission to make recommendations for changing the add-on payment for Medicare Part B drugs to a flat fee-based payment from the current structure, which bases the add-on payment as a percentage of a drug’s price. MedPAC will make specific recommendations for ensuring such a payment change holds physicians harmless and ensure the physician fee schedule more accurately accounts for the cost of storing and administering certain medications.

Sec. 307. Clarification of Medicare Average Sales Price Payment Methodology.

- This section provides a statutory definition for bona fide service fees, narrowing it for the purpose of ASP reporting.

Title IV. Transparency.

Sec. 401 Group Purchasing Organizations Reporting.

- Requires Group Purchasing Organizations to report annually to the HHS OIG and the HHS Secretary their written agreements and disclosures for the purpose of review under the safe harbor.

Title V: Food and Drug Administration.

Sec. 501. Noncompliance Letters Relating to Volume Reporting.

- This section would require the Secretary to issue a noncompliance letter to any person failing to comply with volume reporting requirements under FDCA Section 510(j) and make public on the FDA website such letter and any written responses within 60 days after issuing a noncompliance letter.

Sec. 502. Incentive for Shelf-life Extension Studies.

- This section would allow the Secretary to award an additional month of exclusivity for shelf-life extension studies conducted if they are completed and accepted in response to a written request from the Secretary.

Sec. 503. Providing for a Lag Period for Outsourcing Facilities to Compound and Distribute Drugs in Shortage.

- This section would allow 503B compounding facilities to compound a drug within 30 days of appearing on FDA's drug shortage list and to distribute and dispense a compounded drug within 180 days of such drug appearing on the drug shortage list.

Sec. 504. Additional Information on Generic Drug Active Pharmaceutical Ingredients (API).

- This section would require that generic drug application holders include information related to the API manufacturer upon which they rely on for more than 60 percent of API supply and requires a sponsor to report annually on the volume of API used in the manufacturing of a drug.

Sec. 505. Reporting on Use of New Authorities and Requirements with Respect to Drug Shortages.

- This section requires the Secretary to report to Congress no later than 90 days after the date of enactment of this act the extent to which FDA has implemented its authorities and required guidance with respect to drug shortages.

Sec. 506. New Domestic Facility Inspection Pilot Program.

- This section establishes a pilot program under which FDA conducts preapproval inspections for a new domestic pharmaceutical manufacturing facility for the purposes of expediting the licensure and distribution of domestically manufactured generic drugs