Section by Section Summary

The bill amends the Public Health Service Act to add a new section 310B, titled "Manufacturing of Drugs":

Sections 310B(a)(1) and (2):

This section establishes an Office of Drug Manufacturing within the Department of Health and Human Services. The Office's three main purposes are:

- to increase competition, lower prices, and address shortages in the market for prescription drugs, including insulin, naloxone, and antibiotics;
- to reduce the cost of prescription drugs to Federal health programs and taxpayers; and
- to increase patient access to affordable drugs.

Section 310B(a)(3):

This section specifies that the Office shall be headed by a Director, who shall be appointed by the President and confirmed by the Senate. This section also specifies that the director shall be compensated at level III of the Executive Schedule. The director, in consultation with the HHS Secretary, may fix the number of employees of the Office and appoint and direct all employees.

This section also places restrictions on the employment of drug company lobbyists and senior executives of drug companies operating under a Federal settlement or the subject of a Federal enforcement action. These individuals are banned from serving as Director of the Office and are subject to a 6-year cooling off period before they can otherwise be employed by the Office of Drug Manufacturing.

Section 310B(a)(4)(A):

This section enumerates the duties of the Office:

- preparing and submitting applications for FDA approval for the manufacture of applicable drugs, or entering into contracts with other entities for such submission;
- manufacturing applicable drugs or entering into contracts with other entities to manufacture drugs;
- determining a fair price for each applicable drug sold;
- selling manufactured pharmaceuticals at a fair price;
- manufacturing, or entering into contracts with other entities for such manufacture, active pharmaceutical ingredients for use by the Office or for sale to other entities.

Section 310B(a)(4)(B):

This section directs the Office to consider the following factors when determining a "fair price":

- the impact of price on patient access to the drug or product;
- the cost of the applicable drug to Federal or State health care programs;
- the cost to manufacture the applicable drug
- the administrative costs of operating the Office;

- the cost to acquire or manufacture other applicable products under this section;
- the impact of price on market competition for the applicable drug.

Section 310B(a)(4)(C):

This section authorizes the Office to acquire the rights to manufacture and market applicable drugs.

Section 310B(a)(4)(D):

This section specifies that the Office shall manufacture active pharmaceutical ingredients if:

- the Office determines that an ingredient is not readily available from existing suppliers;
- the manufacture of the ingredient would improve the ability of other entities to enter the generic drug market or expand the manufacture of generic drugs; or
- the manufacture of an ingredient is necessary for the Office to carry out its duties under this section.

This section further specifies that in setting a price for the sale of active pharmaceutical ingredients, the Office shall consider the cost of manufacturing the ingredient, the administrative costs of the Office to produce it, and the impact of the price on the market competition for such ingredient.

Section 310B(a)(5):

This section requires the Director to prepare and submit to the President and Congress an annual report assessing the major problems faced by patients in accessing affordable generic drugs. This report must also include a description of the status of all medications for which manufacturing has been authorized and an analysis of how public manufacture of drugs where such manufacture is authorized by this bill would increase access to drugs, lower their cost, and impact public health. The report must also include, in the case of antibiotics manufactured by the Office, an assessment from the Centers for Disease Control and Prevention and the Food and Drug Administration on the impact of the manufacturing of the antibiotics on antimicrobial resistance.

Section 310B(a)(6):

This section requires the Office to prioritize the manufacturing of applicable drugs that would have the greatest impact on:

- lowering drug costs to patients
- increasing competition and addressing shortages in the prescription drug market;
- improving public health; or
- reducing the cost of prescription drugs to Federal and State health programs.

Section 310B(a)(7):

This section requires the Office of Drug Manufacturing to produce at least 15 applicable drugs by the end of its first year and at least 25 applicable drugs by the end of its third year.

Sections 310B(b)

For each applicable drug that the Secretary determines should be manufactured, this section directs the Secretary to either:

- submit an application or notification under section 505(j) [generic drugs], 510(k) or 515 [devices – necessary for the approval of combination products] of the Federal Food Drug and Cosmetic Act, or section 351(k) of the Public Health Service Act [biosimilars]; or
- acquire from the holder of an application approved under these same sections the right to manufacture the drug.

Section 310B(c):

This section specifies that the Secretary shall sell these drugs at a fair price to other entities. This section also stipulates that revenue from such sales shall be used for the activities of the Office.

This section further requires the Office, beginning three years after the date on which the Office undertakes manufacturing of the drug and annually thereafter, to offer for sale the ANDA for each applicable drug to any person who commits to manufacturing and marketing the drug. If a company purchasing the application fails to market the applicable drug within 6 months or raises the average manufacturer price above the fair price (adjusted by CPI-U), the Office retains the right to revoke the application and resume production of the drug.

Section 310B(d):

This section directs the Office to begin the public manufacturing of insulin, naloxone, and antibiotics no later than one year following the enactment of this section.

Section 310B(e):

This section defines "applicable drug" as a drug, biological product, or combination product that has been approved by the FDA and –

- each patent claiming the drug or product has expired, and any period of regulatory exclusivity has expired, and –
    - that is not being marketed in the United States; or
    - that is being marketed by fewer than 3 manufacturers and –
        - for one of the years in the previous 5-year period, the price has spiked by more than CPI-U; or
        - the drug is on the FDA shortage list; or
        - the Secretary determines the average wholesale acquisition cost to be a barrier to patient access and the drug is listed by the World Health Organization as an essential medicine; or
- that is licensed, or where patent use is authorized, under any licensing authority of the Federal Government, including 28 USC 1498 (compulsory licensing), 35 USC 202

(Bayh-Dole), 35 USC 203 (march-in rights), or 35 USC 209 (licensing of federally owned inventions).

Section 310B(f):

This section authorizes the appropriation of such sums as may be necessary to carry out this section.