Explanation of Provisions of the

340B Fund Act of 2021

Page and Line References to Confidential Discussion Draft Dated June 17, 2021

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Page | Lines |
| Title | The short title of the bill is the 340B Fund Act of 2021 | 1 | 3-5 |
|  | This bill would amend the Public Health Service Act to add a new program to the subpart that includes the 340B drug discount program. | 2 | 1-3 |
|  | The new program is entitled the 340B–P (Patient) Assistance Fund. | 2 | 4 |
| Establishment of New Program | The program will reimburse eligible providers for a portion of unreimbursed costs of 340B covered drugs dispensed to eligible individuals with limited incomes beginning on January 1, 2023, from a new patient assistance fund | 2 | 5-13 |
| Patient Eligibility for Financial Assistance | Eligible individuals with insurance and with incomes below 200% of the Federal poverty line are eligible for a 65% in their out-of-pocket costs for 340B covered drugs | 2 | 18-27 |
|  | Eligible individuals with insurance and with incomes between 200% and 300% of the Federal poverty line are eligible for a 55% discount in their out-of-pocket costs for 340B covered drugs | 2-3 | 28-9 |
|  | Eligible individuals with insurance and with incomes between 300% and 400% of the Federal poverty line are eligible for a 45% discount in their out-of-pocket costs for 340B covered drugs | 3 | 10-20 |
|  | Uninsured eligible individuals with incomes below 400% of the Federal poverty line are eligible for an 80% discount in their out-of-pocket costs for 340B covered drugs | 3 | 21-25 |
|  | Only costs owed by the individual and not reimbursable by insurance or any other party are reimbursable out-of-pocket costs | 3-4 | 26-3 |
|  | Eligible individuals are individuals with income below 400% of the Federal poverty line, who are not eligible for discounted drugs under the 340B program and who are not covered under Medicaid. | 4 | 5-19 |
|  | Eligibility determinations are made in a manner similar to eligibility determinations for the low-income subsidy under Medicare Part D | 4-7 | 20-18 |
| Creation of Patient Assistance Fund | A patient assistance fund is established using manufacturer discount funds to reimburse eligible providers for unreimbursed out-of-pocket expenses. It is modeled on the prescription drug account established under Medicare Part D. | 7-9 | 19-27 |
| Manufacturer Payments to Fund | The amount charged by a manufacturer to an eligible health care provider is limited to the Medicaid average manufacturer price and the manufacturer is required to pay an amount equal to the 340B discount off that price into the patient assistance fund used to reimburse out-of-pocket expenses | 9 | 8-29 |
|  | Manufacturers would be required to enter into a contract similar to the contract they are required to enter into under the 340B program | 10-19 | 1-24 |
| Eligible Health Care Providers | Eligible health care providers are subsection (d) hospitals, physician practices, and pharmacists that provide 340B covered drugs to patients, but that are not eligible to participate in the 340B program | 19-21 | 26-11 |
| 340B Covered Drugs | 340B covered drug is a drug that would be eligible for a discount under the 340B drug discount program (if they were provided under that program instead of the program created by this bill). | 21 | 12-24 |
| Pharmaceutical Manufacturers | Manufacturer means a pharmaceutical manufacturer | 21-22 | 25-6 |
| Transition of Hospitals to the New Program | Subsection (d) hospitals would no longer be eligible to participate in the 340B drug discount program because they are eligible to participate in the patient assistance fund program established by this bill instead | 22-23 | 7-5 |
| Effective Date | The bill would take effect on January 1, 2023. | 23 | 6-8 |
| GAO Report | The GAO would be required to submit a report to Congress on whether hospitals changed their charity care policies and whether employers changed their health insurance coverage in response to the establishment of the patient assistance program created by this bill. | 23-24 | 9-12 |