State of Connecticut
Department of Social Services

Report Regarding the Drug Discount Program Established Pursuant to Section 340B of the Federal Public Health Service Act

January 31st, 2024

1. BACKGROUND

Section 16 of Public Act 23-171 (https://cga.ct.gov/2023/ACT/PA/PDF/2023PA-00171-R00HB-06669-PA.PDF) requires the Department of Social Services (DSS) to hold a working group and prepare this report. That legislation provides as follows:

> (a) The Commissioner of Social Services shall convene a working group to evaluate (1) the current status of the federal 340B drug pricing program authorized by 42 USC 256b, as amended from time to time, (2) national efforts to strengthen and sustain such program, and (3) opportunities for state action to protect 340B revenues of federally qualified health centers from unfair administrative barriers or unnecessary conditions based on such centers' status as a 340B covered entity. Such evaluation shall consider (A) the ability of and any legal precedent for states to regulate the conduct of drug manufacturers and pharmacy benefits managers, as defined in section 38a-479aaa of the general statutes, (B) opportunities to facilitate patient access to on-site pharmacies of a federally qualified health center, (C) opportunities to establish on-site pharmacies across federally qualified health centers, and (D) national trends to sustain such program. As used in this subsection, "340B covered entity" means a provider participating in the federal 340B drug pricing program authorized by 42 USC 256b, as amended from time to time.
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> (b) Not later than January 31, 2024, the Commissioner of Social Services shall report, in accordance with the provisions of section 11-4a of the general statutes, on the findings and recommendations of the working group to the joint standing committees of the General Assembly having cognizance of matters relating to insurance, public health and human services.

DSS convened the working group, which met in November and December 2023. Related materials are posted on DSS' webpage: https://portal.ct.gov/DSS/Health-And-Home-Care/340B-Workgroup. DSS asked working group members to provide information related to the items in the legislation quoted above. Documents received are in the appendix to this report.

This report primarily is a brief summary of information from the working group, although it does not necessarily reflect the views or position of any individual or entity that participated in the working group. To the extent feasible, this report follows the framework of the legislation. DSS does not have the capacity to conduct independent research or evaluation regarding the 340B program. DSS' experience over drug pricing is limited to its role in reimbursing for covered drugs provided to Medicaid members as Connecticut's single state Medicaid agency.

2. CURRENT STATUS OF 340B DRUG PRICING PROGRAM

The 340B program requires drug manufacturers participating in Medicaid to provide discounted drugs to eligible "covered entities" serving financially vulnerable patients, including community health centers, children's hospitals and disproportionate share hospitals, and Ryan White HIV/AIDS clinics. These "covered entities" can either dispense discounted drugs to low-income patients through their in-house pharmacies or through outside pharmacies with which they contract, also known as "contract

pharmacies." The federal Health Resources and Services Administration (HRSA) under the U.S. Department of Health and Human Services (HHS) does not require drug manufacturers or the "covered entities" to articulate how these savings are passed along to the vulnerable populations that the 340B program was intended to serve. For more detail, see the references below and the materials in the appendix.

Federal requirements prohibit states from claiming Medicaid rebates on drugs that were purchased with 340B discounts. States must exclude from invoicing for federal rebate those claims where the drugs have been acquired through the 340B program. The reason for the exclusion is the 340B program drugs are purchased at discounted prices and claiming a rebate would result in a duplicate discount whereby the manufacturer is discounting the product twice.

Connecticut's Medicaid program uses a managed fee-for-service structure and does not use managed care organizations. Connecticut Medicaid downloads the Medicaid Exclusion File from HRSA, which identifies those providers who have an agreement with HRSA to obtain certain medications at discount 340B pricing. Once these entities are identified from the file, all claims submitted from and paid to these entities are excluded from the federal rebate invoicing process.

3. NATIONAL EFFORTS/TRENDS TO STRENGTHEN AND SUSTAIN THE PROGRAM

There were divergent views within the working group on how best to strengthen and sustain the program. In general, working group members sharing the perspective of 340B covered entities (mostly hospitals and federally qualified health centers (FQHCs)) and those individuals and entities benefitting from an expanded scope of discounts provided to covered entities, focused on efforts to expand the number of contract pharmacies eligible for the discounts and increasing patients' access to discounted drugs through contract pharmacies. In contrast, working group members focused on the perspective of pharmaceutical manufacturers emphasized that the policy purpose of the 340B program is to increase access to drugs for low-income individuals and focused on efforts to ensure the discounts were provided only to such individuals. For more detail on various views about the 340B program, see the references below and the materials in the appendix. There was also significant discussion about improving transparency in the 340B program to help ensure discounted drugs purchased through the 340B program actually help the individuals and communities the program was intended to serve.

Working group members shared that, in response to the increase in the use of contract pharmacies, drug manufacturers have taken the position that they do not have to deliver medications to an unlimited number of contract pharmacies. In addition, HRSA sent violation letters to drug manufacturers, which prompted manufacturers to file a series of lawsuits in multiple federal jurisdictions challenging HRSA/HHS for issuing violation letters. These suits resulted in three consolidated appeals, with one court ruling that the drug manufacturers do not have to deliver drugs to an unlimited number of contract pharmacies. The other court cases are still pending.

4. OPPORTUNITIES FOR STATE ACTION TO PROTECT 340B REVENUES OF FEDERALLY QUALIFIED HEALTH CENTERS FROM UNFAIR ADMINISTRATIVE BARRIERS OR UNNECESSARY CONDITIONS BASED ON SUCH CENTERS' STATUS AS A 340B COVERED ENTITY

FQHC representatives on the working group discussed the need for and value of FQHCs using contract pharmacies and stated that contract pharmacies enable the FQHCs' patients to have broader access to necessary medications. They also stated that FQHCs have had challenges with pharmaceutical manufacturers not providing access to 340B discounts at certain FQHC contracted pharmacies. There was limited discussion about issues unique to the FQHCs' status as 340B covered entities that was different from other categories of 340B covered entities. Working group members discussed that the 340B program is a federal program underpinned by federal statutes and regulations, so there are certain limitations on potential opportunity for state action in this area.

5. THE ABILITY OF AND ANY LEGAL PRECEDENT FOR STATES TO REGULATE THE CONDUCT OF DRUG MANUFACTURERS AND PHARMACY BENEFITS MANAGERS, AS DEFINED IN SECTION 38A-479AAA OF THE GENERAL STATUTES

Members shared that the 340B program has expanded at a rapid rate, especially resulting from the increased use of 340B covered entities' contract pharmacies. As a result of that increase in contract pharmacies and the reluctance of manufacturers to deliver drugs to multiple contract pharmacies associated with a single covered entity, there has been a dramatic increase in states enacting transparency and "antidiscrimination" legislation to prohibit restrictions by manufacturers and pharmacy benefit managers (PBMs). According to the National Academy for State Health Policy (NASHP), which participated in the workgroup, twenty-eight states have enacted legislation to prohibit reimbursing covered entities/contract pharmacies at lower rates, charging fees to covered entities/contract pharmacies and removing barriers for consumers to access contract pharmacies.

Arkansas and Louisiana passed laws requiring drug manufacturers to provide 340B medicines to pharmacies that have a contract with a 340B entity. Both states' laws are being challenged in Federal Court. In 2023, Maine, Minnesota, and Washington State enacted transparency legislation to try to understand the value of 340B programs in their states. The legislation required reporting on a variety of requirements, including estimated annual savings from the 340B program, the top drugs used by the 340B covered entities, and how 340B savings benefited the community. Connecticut Governor Lamont proposed legislation in the 2023 state legislative session that, among other things, would have imposed transparency requirements on hospitals that are 340B covered entities, although that language was ultimately not included in the version of the bill that passed (and resulted in the legislation requiring DSS to prepare this report). A link to the bill is included in the references below, which in the initial, Governor's Bill version, included section 19 regarding transparency requirements.

Connecticut Attorney General Tong, in collaboration with other Attorneys General, sent letters to drug manufacturers urging them to honor contract pharmacy orders and to HHS calling on the agency to hold drug manufacturers accountable for refusing to provide discounts to contract pharmacies. Attorney General Tong also filed amicus briefs in support of HHS' enforcement actions against manufacturers and authored a multistate letter in response to the U.S. Senate's request for information seeking to improve integrity and sustainability of the 340B program. In this letter, several state Attorneys General urged Congress to stop manufacturers from placing restrictions on access to the savings that are outside the scope of the law. The Attorneys General urged Congress to reform and strengthen the 340B program to ensure that essential "safety net" health providers can more effectively provide affordable medicines and a comprehensive range of health-related services to financially vulnerable patients. The letter asked Congress to pass federal legislation to give HRSA the tools necessary to effectively monitor and oversee the program—including the authority to promulgate regulations regarding contract pharmacies, program transparency and integrity, and affirmative civil enforcement tools against noncompliant actors. A link to the related press release is included in the references below.

Finally, based on working group discussions and additional research and consideration, there are other options that states, including Connecticut, could explore. For example, as a condition of ongoing Medicaid participation, the state could require every 340B covered entity to publicly report on how it is using savings to benefit patients, with the report to be updated annually or on another periodic basis. Connecticut could also pursue transparency legislation modeled on recent efforts in Maine, Minnesota, and Washington. As another set of examples, the state could explore ways to maximize value for the state's Medicaid program from the 340B program, including to: (1) develop enhanced procedures to ensure that, in accordance with the federally approved Connecticut Medicaid State Plan, Medicaid payments to in-house pharmacies of providers that are 340B covered entities are based on the 340B actual invoice price, not to exceed the 340B ceiling price plus the applicable dispensing fee, (2) establish clearer guidelines and procedures for potential enrollment and payment of contract pharmacies of providers that are 340B covered entities, including consideration of potential adjustments to the applicable payment methodology designed to ensure that the cost-based component of payment for drugs is as close as possible to the provider's actual cost to acquire the drugs under the 340B discount, and (3) explore alternative options for payment methodologies and associated documentation requirements for providers enrolled in Medicaid that are 340B covered entities, such as those used in other state Medicaid programs, to minimize the likelihood of the cost-based component of the Medicaid rate exceeding the amount that the provider paid under the 340B program.

6. OPPORTUNITIES TO FACILITATE PATIENT ACCESS TO ON-SITE PHARMACIES OF A FEDERALLY QUALIFIED HEALTH CENTER AND OPPORTUNITIES TO ESTABLISH ON-SITE PHARMACIES ACROSS FEDERALLY QUALIFIED HEALTH CENTERS

Each FQHC (or any other 340B covered entity) makes its own business decisions on whether to establish and operate an on-site pharmacy at each location (subject to all applicable licensure and other requirements for pharmacies). This may enable certain 340B covered entities to address some of the challenges they have experienced with contract pharmacies. There was limited information shared about this topic during the working group meetings.

7. **RESOURCES**

Additional resources regarding the 340B program include, but are not limited to, the following:

- https://www.hrsa.gov/opa
- https://www.aha.org/fact-sheets/fact-sheet-340b-drug-pricing-program
- https://www.nachc.org/policy-advocacy/policy-priorities/340b-drug-pricing-program/
- https://www.nashp.org/wp-content/uploads/2017/03/Transparency-Web-Blog.pdf
- https://www.proxsysrx.com/a-comprehensive-guide-to-the-340b-drug-pricing-program/
- https://medicaiddirectors.org/wp-content/uploads/2023/07/NAMD-Comments-Signed-Misclassification-of-Drugs-Program-Administration-and-Program-Integrity-Updates-Under-the-Medicaid-Drug-Rebate-Program-CMS-2434-P1.pdf
- https://www.ncsl.org/health/state-options-for-managing-the-340b-drug-pricing-program
- https://www.aha.org/talking-points/2023-04-04-talking-points-ensuring-protection-vital-340b-program-patients-and-providers
- https://340breform.org/patientsjourney/
- https://www.gao.gov/products/gao-18-556t
- https://files.kff.org/attachment/How-State-Medicaid-Programs-are-Managing-Prescription-Drug-Costs.pdf
- https://nyhealthfoundation.org/wp-content/uploads/2017/12/pharmacy-services-community-health-center-case-study-march-2012.pdf
- https://portal.ct.gov/-/media/AG/Press_Releases/2023/07-28-23-William-Tong---Letter-to-US-Senate-340B-Working-Group_FINAL.pdf
- https://cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&which_year=2023&bill_num=6669