STATE OF CONNECTICUT

DEPARTMENT OF SOCIAL SERVICES

55 FARMINGTON AVENUE • HARTFORD, CONNECTICUT 06105

Working Group for the Prescription Drug Pricing Program Pursuant to Section 340B of the federal Public Health Service Act (Established by Connecticut Public Act 23-171, Section 16)

MEETING MINUTES for December 19, 2023 Meeting

1. Introductions

Mehul Dalal, DSS, summarized the agenda for the meeting.

2. Brief Summary of November 28, 2023 Meeting

Mehul Dalal, DSS, briefly summarized the previous meeting.

3. Presentation from Attorney General's Office (AGO) (see presentation document for more details and context)

Patricia McCooey, AAG, AGO Health and Education Unit, presented an overview of the CT AGO's (also known as OAG) actions regarding 340B. OAG has been working to facilitate 340B covered entities to be able to obtain 340B drugs and the position that drug manufacturers should not be able to unilaterally impose their own conditions on acquisition of 340B drugs. The program has grown substantially due to federal allowance of 340B contract pharmacies for covered entities.

Summary of timeline of the OAG's involvement during 2020-2023, including letters to pharmaceutical manufacturers and engagement with HHS and amicus briefs in two federal court cases arguing that the manufacturers are not authorized to impose unilateral changes to program participation requirements. Multistate letter from various state attorneys general arguing that Congress should authorize more regulatory authority to HHS HRSA in order to ensure integrity and sustainability of the 340B program.

Rahul Darwar, AAG, AGO Antitrust and Government Fraud Unit, summarized various aspects of recent litigation regarding 340B, including:

Contract pharmacy litigation: HRSA issued violation notices to pharmaceutical manufacturers and they challenged in federal court arguing that 340B does not require delivery of drugs to an unlimited number of contract pharmacies. 3rd circuit held that it was not required; the other two circuits considering that question have not yet ruled.

Federal preemption litigation: Pharmaceutical manufacturers argued that various state statutes seeking are preempted by 340B, trial court held that the Arkansas statute was not preempted, currently on appeal to the 8th circuit. Similar case in Louisiana.

Patient definition litigation: definition of eligible patients, federal trial court in S. Carolina.

State Transparency Requirements: Minnesota and Maine recently passed state transparency laws, neither has yet been challenged in court.

Q. Bill Smith, Pioneer: Has CT OAG looked at duplicate discounts where a covered entity contract pharmacy has claimed both Medicaid rebate and 340B discount.

A. Rahul Darwar, AAG: Not aware of CT OAG looking into that issue.

A. Patricia McCooey, AAG: Confirmed that CT OAG has not investigated; aware that CT DSS takes steps to ensure that there are not duplicate discounts to comply with federal prohibition on duplicate discounts. Simpler to administer in CT because there are no Medicaid managed care organizations.

A. Herman Kranc, DSS: Both HRSA and manufacturers have a right to rebate. CT DSS uses a Medicaid exclusion file from HRSA to ensure compliance with the prohibition on duplicate discounts to ensure that DSS is not invoicing for rebate when the pharmacy is on the HRSA exclusion file.

Q. Drew Gattine, NASHP: In addition to Maine and Minnesota, Washington State also recently passed a statute requiring its state health authority to develop regulations to require transparency. Will send a link to the new state statutes and side-by-side comparison.

4. Presentation from Pharmaceutical Manufacturer

Daniel Vigil, Director of State Policy, Novartis: Concerns with some of the growth of 340B and reasons why states should not place restrictions on requiring pharmaceutical manufacturers to provide unlimited 340B discounts to contract pharmacy. 2nd largest drug program and significant increase. Believes there is essential federal reform.

Data points: of the 1041 contracts between 16 hospitals, only 19% of the contract pharmacies are in CT; important that there is no restriction on the hospitals charging the discount price to patients, which enables hospitals to have a large profit from that margin; more than half of the profits are retained Walgreens, Walmart, CVS, Creedo (Express Scripts and Cigna), which are for-profit entities, more than $10 billion in profits. Pharmacy benefit managers often involved in these arrangements and get over $2 billion in profits and often own the third party administrators.

Believes that states should pause and not adopt mandates on pharmaceutical manufacturers related to contract pharmacies. There is no federal statute regarding contract pharmacies, only federal HRSA guidance. Federal government has a pervasive and nationwide federal regulatory structure under 340B, if states adopt individual requirements, can be unmanageable for manufacturers. Some of the state statutes' mandates are being challenged as unconstitutional; and requiring additional contract pharmacies will even further distort the 340B program by not actually benefiting the intended beneficiaries; GAO report on 340B covered entities that more

than half of the hospital covered entities did not share their discounts with patients for contract pharmacies; JAMA (?) article showing that the contract pharmacy arrangements are concentrated in affluent communities with significant rates of commercial insurance.

Q. Paul Kidwell, CT Hospital Association: What is the definition of "medically underserved" referenced by Mr. Vigil.

A. Daniel Vigil: PhRMA report cross-referenced other report; will provide the reference.

Q. Sabrina Griswold: Novartis is a for-profit company, so by restricting access to contract pharmacy 340B discounts, that discount would go to Novartis rather than being discounts available to low-income individuals.

A. Daniel Vigil: Novartis supports a variety of patient assistance programs, including participation in 340B, Medicaid and other.

Q. Sabrina Griswold: How do low-income patients become aware of the drug discount programs? Pharmacy itself may not necessarily be in an underserved area but patients may be accessing from other locations; more nuanced in terms of how to show actual low-income individuals' access to drug discounts, especially if the person is not on Medicaid and significant impact in restrictions in 340B discounts. But a number of other manufacturers do not exempt FQHC.

A. Daniel Vigil: there is a hub showing availability of discount programs. Arguing for federal reform of 340B. This manufacturer does not apply its restrictions on contract pharmacies to FQHCs.

Q. Gui Woolston, CT DSS: Does Novartis have a position on state transparency legislation?

A. Daniel Vigil: Generally believes that improved transparency is helpful, although no specific position on the particular state statutes but generally supports that intent.

Q. Felipe Moreno, CHC, Inc.: For contract pharmacies for uninsured patients, the proximity matters significantly in order to enable meaningful access. Most of the pharmaceutical manufacturers have blocked access except to one contract pharmacy location for this FQHC's patients and restricts access. Trying to improve access for uninsured patients.

Q. Paul Kidwell, CT Hospital Association: Outside of the 340B program, significant discounts that pharmaceutical manufacturers provide to pharmacy benefit manufacturers.

A. Daniel Vigil, Novartis: Discounts for PBMs is distinct from 340B, although general challenges with PBMs influencing the 340B and commercial insurance discounts. General concerns about PBM tactics.

Sen. Heather Somers: Her question was already answered.

5. Other Discussion About Statutory Provisions in PA 23-171, sec. 16

Dr. Dalal briefly referenced the statutory provisions.

6. Process for Gathering Feedback from Workgroup Members and DSS Preparing Report

Dr. Dalal briefly summarized the process for workgroup members to submit written materials.

Heather Ferguson-Hull, OPM: Asking if there would be an opportunity for workgroup members to review the draft report.

Jennifer Herz, Boehringer Ingelheim: Asking for ability to have more time to submit written materials.

Dr. Dalal/Joel Norwood: Limited time to complete the report and limited ability to incorporate additional substantive information beyond the existing deadlines.

7. Other Business

There was no other business identified.

8. Adjourn

The meeting was adjourned.