U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

March 20, 2015

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Examining the 340B Drug Discount Program"

I. INTRODUCTION

On Tuesday, March 24, 2015, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled, "Examining the 340B Drug Pricing Program." The purpose of the hearing is to review the functionality of the program to understand how it is impacting patients, providers, manufacturers, and other stakeholders. This memo includes a list of witnesses, general background on the program, a review of changes made to the program by the Patient Protection and Affordable Care Act (PPACA), and a summary of findings made by Government Accountability Office (GAO) and U.S. Department of Health and Human Service's Office of Inspector General (HHS OIG) in reports on the program.

II. WITNESSES

- Diana Espinosa, MPP, Deputy Administrator, Health Resources and Services Administration, U.S. Department of Health and Human Services;

  Accompanied by Krista M. Pedley, PharmD, MS, CDR, USPHS, Director, Office of Pharmacy Affairs Health Resources and Services Administration, U.S. Department of Health and Human Services;

- Debbie Draper, Director, Health Care, Government Accountability Office; and,

- Anne Maxwell, Assistant Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services.

III. BACKGROUND

A. Overview of the 340B Program

The 340B drug discount program was created by Congress in 1992. Under section 340B of the Public Health Service Act (PHSA), in order to receive Medicaid reimbursement for their drugs, pharmaceutical drug manufacturers must enter into pharmaceutical pricing agreements

that provide discounts on covered outpatient drugs purchased by certain public health facilities (known as "covered entities"). In 2011, a third of all hospitals participated in the 340B program, with more being eligible and not participating. More have become eligible to participate as Medicaid expands through PPACA. As of May 31, 2013, 10,510 covered entities were participating in the 340B Program, including 1,103 community health centers and 1,039 disproportionate share hospitals (DSH).[1] Some 800 pharmaceutical manufacturers participate in the program.[2]

Participation in the 340B program is voluntary for covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities are eligible to receive discounts on outpatient prescription drugs from participating manufacturers. Covered entities include hospitals owned or operated by State or local government that serve a higher percentage of Medicaid beneficiaries, as well as Federal grantees such as Federally qualified health centers (FQHC), FQHC look-alikes, family planning clinics, State-operated AIDS drug assistance programs, Ryan White CARE Act grantees, family planning and sexually transmitted disease clinics, and others, as identified in the PHSA.

Covered entities do not receive discounts on *inpatient* drugs under the 340B program, but can realize substantial savings through 340B price discounts and generate 340B revenue. Moreover, while covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet Health Resources and Services Administration's (HRSA) current definition of a patient,[3] these entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

The 340B price for a drug paid by covered entities—sometimes referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities.[4] Manufacturers are permitted to audit covered entity records if they suspect product diversion or multiple discounts are taking place. Occasionally, the formula results in a negative price for a 340B drug. In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.

Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on a hospital's most recently filed Medicare cost report. In March 2010, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies.

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[1] http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf
[2] Number from the 2011 GAO report. Updated number has been requested from HRSA.
[3] For current definition of a patient, see HRSA's website: http://www.hrsa.gov/opa/eligibilityandregistration/index.html
[4] Manufacturers may sell a drug at a price that is lower than the ceiling price, so covered entities may negotiate prices below the ceiling price. The discount is determined by dividing the average total Medicaid rebate percentage of 15.1% for single source and innovator multiple source drugs, and 11% for non-innovator multiple source drugs by the average manufacturer price (AMP) for each dose and strength. Medicaid statute defines AMP as the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers are required to report AMP and their best price to the Secretary, but subject to verification, manufacturers calculate the maximum price ("ceiling price") they may charge 340B entities.

The growth and oversight of contract pharmacies has been identified as an issue of concern by HHS OIG.

Hospitals' participation in the 340B program also has grown markedly in recent years. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005, according to GAO.[5] Hospitals' participation in the 340B program has grown faster than that of Federal grantees, increasing almost three-fold in the number of participants from 2005 to 2011.[6] DSH hospitals alone represent about 75 percent of all 340B drug purchases.[7]

B. Changes PPACA Made to the 340B Program

Enacted in 2010, PPACA made a number of notable changes to the 340B program, some of which have yet to be fully implemented.

- *Expanded Participation in 340B Program*:[8] PPACA added the following to the list of covered entities entitled to discounted drug prices under the 340B program: (1) certain children's and free-standing cancer hospitals excluded from the Medicare prospective payment system; (2) critical access hospitals; and (3) certain rural referral centers and sole community hospitals. These 340B-eligible facilities also must meet other specified 340B participation requirements.

- *Made Changes to 340B Program Integrity*: PPACA required the Secretary of HHS to develop systems to improve manufacturer and covered entity compliance and program integrity activities, as well as administrative procedures to resolve disputes. The compliance and program integrity systems were to include a number of specifications to increase transparency and strengthen monitoring, oversight, and investigation of the prices that manufacturers charge covered entities, as well as additional improvements to ensure covered entities do not divert drugs or obtain multiple discounts. The Secretary was required to establish a new administrative dispute resolution process to mediate and resolve covered entity overpayment claims and manufacturer claims against covered entities for drug diversion or multiple discounts. Civil money penalty (CMP) sanctions up to $5,000 per instance for manufacturer overcharges were authorized. The Secretary was required to establish standards and issue regulations for assessing CMPs on drug manufacturers for overcharge violations and was required to issue regulations to implement a dispute resolution process by which covered entities can report instances where they suspect they have been overcharged.

- *Required Manufacturers Communicate Prices to HHS*: PPACA required that pricing agreements stipulate that drug makers will report to the Secretary quarterly ceiling prices for each covered drug and to offer these drugs to covered entities at or below these prices.

[5] http://gao.gov/assets/330/323702.pdf
[6] http://gao.gov/assets/330/323702.pdf
[7] http://gao.gov/assets/330/323702.pdf
[8] Section 7101, as amended by HCERA Sec. 2302, amended PHSA Sec. 340B.

C. GAO and HHS OIG Findings

- *GAO Findings*: In 2011, GAO issued a report, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement."[9] GAO found that the 340B program allows certain providers within the U.S. health care safety net to stretch Federal resources to reach more eligible patients and provide more comprehensive services. However, GAO cautioned that HRSA's then-current approach to oversight did not ensure 340B program integrity, and raised concerns that may be exacerbated by changes within the program. Among GAO's key findings:

    - According to HRSA, the agency largely relies on participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers.
    - HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements, so participants may be interpreting guidance in ways that are inconsistent with the agency's intent.
    - Participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance.
    - With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance are put in place.
    - PPACA outlined a number of provisions that, if fully implemented, would help improve many of the 340B program integrity issues identified.
    - GAO identified other program integrity issues that HRSA should also address: (1) HRSA is not required to audit covered entities or further specify the agency's definition of a 340B patient; (2) HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance; (3) HRSA guidance may allow some entities to be eligible for the program that should not be.
    - Finally, GAO noted that while HRSA would benefit from more resources, limited resources could be prioritized to address areas of greatest risk to the program.

HRSA has addressed some of the concerns raised by GAO. For example, HRSA began conducting audits of covered entities and issued more specific nondiscrimination guidance for cases in which distribution of drugs is restricted.

- *HHS OIG Findings:* Covered entities participating in the 340B Program may contract with pharmacies to dispense drugs purchased through the program on their behalf.[10] Such pharmacies are referred to as "contract pharmacies." In a 2014 report examining "Contract Pharmacy Arrangements in the 340B program," HHS OIG noted that in 2010, the percentage of all covered entities that use contract pharmacies had risen from 10 percent to 22 percent.[11] Moreover, the number of unique pharmacies serving as 340B contract pharmacies has grown

[9] http://www.gao.gov/products/GAO-11-836
[10] http://www.hrsa.gov/opa/implementation/contract/index.html
[11] http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent. Amongst HHS OIG's key findings from the contract pharmacy arrangements they examined:

- HHS OIG found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways.
- In some cases, HHS OIG explained that different methods lead to differing determinations of 340B eligibility across covered entities. That is, two covered entities may categorize similar types of prescriptions differently. As a result, HHS OIG concluded "there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible."
- Several covered entities did not offer the discounted 340B price to uninsured patients at their contract pharmacies.
- Most covered entities examined did not conduct all of the oversight activities recommended by HRSA. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.
- Contract pharmacy administrators reported difficulties in identifying beneficiaries covered by managed care organization Medicaid, and some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts.

In June 2011, HHS OIG published a review of States' reimbursement policies and oversight related to 340B-purchased drugs. At the time, HHS OIG found that States lacked pricing information needed for oversight and that nearly half of States did not have written 340B policies.[12]

D. Current Issues

Covered entities are subject to audit by the manufacturer or the Federal government. Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts or cause the covered entity to be removed from the 340B Program. In its 2011 report, GAO noted that, "according to HRSA officials, since the program's inception, only two covered entities have been terminated from the program due to findings of program violations and no manufacturers has ever been terminated for this reason."[13] However, since the report was issued in 2011, HRSA has started conducting program integrity audits of covered entities. For the period fiscal year (FY) 2012 to today, HRSA's website lists 178 audits conducted.[14] These audits may help inform HRSA guidance and oversight activities.

In 2014, HRSA was preparing an omnibus regulation, which the agency said would have addressed a wide range of policy issues related to the program, including the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities.

[12] http://oig.hhs.gov/oei/reports/oei-05-09-00321.pdf
[13] http://www.gao.gov/products/GAO-11-836
[14] http://www.hrsa.gov/opa/

However, before the omnibus 340B regulation was released, HRSA found itself in litigation over a separate orphan drug regulation.[15] In May 2014, a ruling by the United States District Court for the District of Columbia vacated HRSA's orphan drug regulation in the 340B program on the grounds that HRSA lacks the statutory authority to engage in that form of rulemaking.

In June 2014, HHS/HRSA announced it continued to stand by it its interpretation described in its published final rule, and in July, HRSA issued an interpretive guidance pertaining to the statutory requirement for inclusion of drugs with orphan drug designations in the 340B drug pricing program.[16] These agency actions were met with further litigation. Accordingly, the legal issues regarding the orphan drug exclusion remain unresolved at this time.

In November 2014, with the ongoing litigation on the orphan drug regulation, HRSA withdrew its omnibus 340B regulation. On the topics that the statute is not definitive on, HRSA plans to release guidance sometime this summer to address those topics.

HRSA also plans to release additional regulations in coming months on two issues where the statute is more definitive.[17]

- One regulation would impose monetary sanctions (not to exceed $5000 per instance) on drug manufacturers who intentionally charge a covered entity a price above the ceiling price established under the procedures of the 340B Program and also define standards and methodology for the calculation of ceiling prices for purposes of the 340B Program.[18]

- The other regulation would implement an enhancement to the 340B Program by establishing a required and binding administrative dispute resolution process to resolve claims raised by covered entities that they have been overcharged for drugs purchased under the 340B Program. The administrative dispute resolution process also would be available to drug manufacturers.[19]

In late spring/early summer, GAO has said it plans to complete its work on an additional report on the 340B program.[20] Because GAO notes that "providers can generate revenue through their participation in the 340B program" and "the 340B statute does not specify how any revenues generated through the program should be used," in its new report, GAO will examine the following questions:

- How do 340B hospitals compare with non-340B hospitals in terms of characteristics such as sources of revenues and margins, and to what extent have these characteristics changed over time?

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[15] The orphan drug rule HRSA issued allowed 340B covered entities affected by the orphan drug exclusion (critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation.
[16] http://www.hrsa.gov/opa/programrequirements/interpretiverule/
[17] These regulations were required by PPACA and are in areas where HRSA has clear statutory authority.
[18] http://reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=0906-AA89
[19] http://reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=0906-AA90
[20] Based on a review of http://watchdog.gao.gov, a GAO intranet for Congressional staff

- To what extent do Medicare Part B outpatient drug payments to 340B hospitals vary by type of hospital, and to what extent have these payments changed over time relative to payments to non-340B hospitals?

The HHS OIG's "FY 2015 Work Plan" also outlines additional work the Inspector General's office is conducting related to the 340B program and expects to issue sometime in FY 2015. HHS OIG is examining Medicare Part B payments for drugs purchased under the 340B Program and "will determine how much Medicare Part B spending could be reduced if Medicare were able to share in the savings for 340B-purchased drugs."[21]

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Josh Trent of the Committee staff at (202) 225-2927.

[21] http://oig.hhs.gov/reports-and-publications/archives/workplan/2015/FY15-Work-Plan.pdf