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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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March 20, 2015
MEMORANDUM

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Commerce on Energy and Commerce Democratic Staff

Re: Subcommittee on Health Hearing on "Examining the 340B Drug Pricing Program"

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."

I. BACKGROUND

The 340B Drug Pricing Program was signed into law in 1992 as part of the Veterans Health Care Act.[1] The 340B Program requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety net health care providers specified in statute, known as covered entities. Covered entities include Federally Qualified Health Centers, family planning clinics, Black Lung clinics, hemophilia clinics, AIDS Drug Assistance Programs, and certain disproportionate share hospitals.

Drug manufacturers must provide these discounts to covered entities in order to have their drugs covered by state Medicaid programs. Drugs included in the 340B program generally consist of outpatient prescription drugs and drugs administered by physicians in an outpatient setting, excluding vaccines. Drug spending under the 340B Program represents approximately two percent of the overall U.S. drug market.[2]

According to the Health Resources and Services Administration (HRSA), 340B price discounts average anywhere from 25 to 50 percent off the drug's standard price. The 340B ceiling price, which is the maximum amount a drug manufacturer can charge a covered entity for a given drug – is equal to the Average Manufacturer Price (AMP) minus the Unit Rebate Amount (URA), both of which are set by the Center for Medicare and Medicaid Services (CMS).

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[1] *See, e.g.*, Section 602 of the Veterans Health Care Act of 1992 (Pub. L. 102-585).

[2] *See, e.g.*, U.S. Department of Health and Human Services, *Health Resources and Recourses and Services Administration FY 2016 Justification of Estimates for Appropriations Committees* (online at http://hrsa.gov/about/budget/budgetjustification2016.pdf).

Covered entities purchase at least 23.1 percent below AMP for brand name drugs; 13 percent below AMP for generic drugs; and 17.1 percent below AMP for clotting factor and pediatric drugs.[3] According to the Government Accountability Office (GAO), in FY 2013, 340B purchases totaled $7.5 billion and covered entity participation has increased 30 percent since 2008.[4]

As of January 1, 2015, 11,530 covered entities and 18,176 associated sites participate in the 340B program, for a total of 29,706 registered sites.[5] Of the 11,530 unique 340B sites ("Parent sites") 80 percent are not hospitals. Still, the 340B program is often portrayed as a hospital discount because the largest volume of 340B drugs occurs in the hospital setting. Twenty-seven percent of 340B sites have contract pharmacy arrangements, which have resulted in the registration of approximately 15,600 unique pharmacy locations in the 340B database.[6]

II. AFFORDABLE CARE ACT

The Affordable Care Act (ACA) expanded the types of entities eligible for participation in the 340B program to include certain children's and freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.[7] The ACA also explicitly provided rulemaking authority for HRSA in three areas: ceiling price transparency, dispute resolution and civil monetary penalties. These provisions have helped to address many longstanding program integrity issues. For instance, development of a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintenance of a centralized list of 340B prices will help to ensure HRSA has the tools in place to identify and resolve suspected violations.

The ACA also mandated a GAO report that resulted in recommendations for HRSA to conduct more direct oversight of manufacturers. Such oversight is to include selective audits to determine whether covered entities are being charged the correct 340B price, and audits of covered entities to ensure that they are in full compliance with program guidance.[8] HRSA has conducted more than 200 risk-based audits since 2012.[9] Such activities were made possible, however, by additional appropriations provided by Congress over the past two budget cycles,

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[3] *Id.*

[4] These numbers reflect the latest figures given by the Government Accountability Office to Committee staff on March 2, 2015.

[5] *Id.*

[6] *See, e.g.*, U.S. Department of Health and Human Services, *Health Resources and Recourses and Services Administration FY 2016 Justification of Estimates for Appropriations Committees* (online at http://hrsa.gov/about/budget/budgetjustification2016.pdf).

[7] *See, e.g.*, Section 7101 of the Affordable Care Act.

[8] *See, e.g.*, Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* (Sept. 23, 2011) (online at http://www.gao.gov/products/GAO-11-836).

[9] U.S. Department of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY12 Audit Results* (online at http://www.hrsa.gov/opa/programintegrity/auditresults/fy12results.html).

which increased HRSA's operating budget from approximately $4 million to a total of $10.2 million.[10]

III. PROGRAM INTEGRITY

There are several major outstanding concerns with respect to program integrity in the 340B program. The main issues that are generally raised are summarized below:

A. Rulemaking Authority

In the summer of 2013, HRSA issued the first final regulation in the history of the program to clarify the treatment of orphan drugs for purposes of 340B pricing. Orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act and are drugs or biological products known to treat a rare disease or condition. Specifically, HRSA's final rule would permit covered entities to purchase orphan drugs at 340B discounted prices, provided that the drugs are used for non-orphan drug indications.

In October 2013, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit, alleging that HRSA did not have authority to promulgate the final rule. In May 2014, the U.S. District Court for the District of Columbia ruled in favor of PhRMA. In its opinion, the court interpreted HRSA's rulemaking authority very narrowly, circumscribing the agency's authority to only those areas specifically provided for in the ACA (highlighted above). The court's opinion stated that the U.S. Department of Health and Human Services (HHS) does not have the general authority to issue such regulations on the 340B program, as it does, for example, under the Medicare and Medicaid programs. HRSA responded by implementing the same policy as an interpretive rule rather than a regulation. As these issues continue to be litigated in the courts, they have had serious implications for implementing a 340B program having broader program integrity.[11]

HRSA has concurred with GAO and Office of Inspector General (OIG) recommendations that the 340B program needs additional oversight and regulation. In addition, HRSA has issued guidance, but not promulgated rules on a number of issues that GAO and OIG have raised over the past several years; these issues will be discussed in testimony offered at Thursday's hearing.

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[10] *See, e.g.,* U.S. Department of Health and Human Services, *Health Resources and Recourses and Services Administration FY 2016 Justification of Estimates for Appropriations Committees* (online at http://hrsa.gov/about/budget/budgetjustification2016.pdf).

[11] *See, e.g.,* Theresa C. Carnegie, Health Law and Policy Matters, *Court Invalidates 340B Orphan Drug Rule* (May 28, 2014) (online at http://www.healthlawpolicymatters.com/2014/05/28/court-invalidates-340b-orphan-drug-rule/); and *see, e.g.,* The National Law Review, *Judge Requires PhRMA to Initiate New 340B Orphan Drug Lawsuit to Challenge Interpretive Rule* (Sept. 13, 2014) (online at http://www.natlawreview.com/article/judge-requires-phrma-to-initiate-new-340b-orphan-drug-lawsuit-to-challenge-interpret).

Over the past two years, HRSA worked on and submitted an omnibus oversight regulation to the Office of Management and Budget (OMB) that would provide additional oversight in the remaining areas highlighted by GAO and OIG including: revising the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, and hospital eligibility criteria. This regulation was submitted to OMB in May 2014, but was withdrawn in November 2014 in light of the orphan drug court decision.[12]

On its website after withdrawing the broad oversight regulation, HRSA has stated:

> "In 2015, HRSA plans to issue a proposed guidance for notice and comment that will address key policy issues raised by various stakeholders committed to the integrity of the 340B program. HRSA is also planning to issue proposed rules pertaining to civil monetary penalties for manufacturers, calculation of the 340B ceiling price, and administrative dispute resolution."

B. Patient Definition

Critics contend that the 340B program, particularly after the ACA expansion, has extended beyond the original intent. Often, critics will highlight that the 340B discount can be used for insured patients, and argue for changes to the patient definition that would narrow the patient definition to only uninsured patients.[13] Such a narrowing would be inconsistent with Congress's intent, when it passed the 340B program, which was not to limit the program to uninsured patients exclusively. Rather, the legislative intent was to enable safety net entities to stretch scarce federal resources and provide expanded services through discounts on drugs purchased. In addition, discussions over the 340B "patient" definition continue: HRSA has not modified the definition since issuing guidance back in 1996.[14] HRSA has indicated that the "patient" definition will be an issue it intends to address in its Omnibus Guidance, planned for later on this year.

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[12] *See, e.g.*, Billy Wynne, Health Affairs Blog, *The Coming Storm Over The 340B Rx Drug Discount Program* (May 6, 2014) (online at http://healthaffairs.org/blog/2014/05/06/the-coming-storm-over-the-340b-rx-drug-discount-program/); and *see, e.g.*, U.S. Department of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program: Important Benefit, Significant Responsibility* (Jan. 9, 2014) (online at http://www.hrsa.gov/opa/update.html).

[13] *See, e.g.*, Health Affairs, *Health Policy Briefs, the 340B Drug Discount Program* (Nov. 17, 2014) (online at http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=130).

[14] The current patient definition can be found online at ftp://ftp.hrsa.gov/bphc/pdf/opa/FR10241996.pdf. Since issuing the 1996 guidance, HRSA has tried to update the Patient Definition on three subsequent occasions:

- in a 2007 guidance that was never finalized;
- in a 2010 guidance that was also never finalized: and
- in the 2014 "omnibus" regulation that was pulled back from OMB after HRSA's authority to issue regulatory guidance on anything not explicitly identified in statute was questioned in federal court.

In addition to these concerns, critics have expressed differences as to the original intent of the program: namely, that it was not intended to benefit the covered entities themselves but rather to benefit individual patients directly. To that end, many have asserted that the program should not allow covered entities to profit by receiving reimbursements from public and private payers at higher dollar amounts than what they paid for the 340B discounted drugs.

Importantly, the original 340B statute and subsequent HRSA guidance do not limit reimbursement for 340B-covered drugs nor place any restrictions on covered entities' use of that revenue.[15] HRSA has repeated its position that the benefit of the program is intended for 340B eligible institutions and that covered entities' administration of 340B discounted drugs is not connected to whether a patient is insured or uninsured. Covered entities view this as an essential aspect of the program, reporting that it allows them to recoup the costs of providing pharmacy and other services to uninsured or underinsured patients.[16]

C. Hospital Eligibility

Hospitals have also received attention by some for their use of the program. The largest volume of 340B drugs originates in these settings, while various organizational issues, such as ownership, funding, and oversight of hospitals, complicate the administration of the program. This includes the fact that unlike other covered entities, hospitals treat both outpatients and inpatients.[17] Hospital eligibility for the 340B program has more elements than that of federal grantees, because rather than qualifying for the program based on receipt of grant funding, hospital eligibility is determined by meeting specified Disproportionate Share Hospital adjustment percentages. Hospitals must also be either public or non-profit. 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 the hospitals most recently filed Medicare cost report, which provides additional complexities with administration of the program.

Hospitals have been the largest volume purchaser of drugs in the program, and participation has increased at a more rapid rate than other types of covered entities. For example, in GAO's 2011 report, the agency highlighted that in 2005, hospitals represented just 10 percent of program participants, and as of July 2011, they represented 27 percent. The complexities involved with hospital growth in the program have led GAO, OIG, and others to call for clarifications in rulemaking in this area.[18]

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[15] *Id.*

[16] *See, e.g.,* Safety Net Hospitals for Pharmaceutical Access, *SNHPA Responds to Health Affairs Article On 340B* (Oct. 6, 2014) (online at http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=130).

[17] *Id.*

[18] *See, e.g.,* Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* (Sept. 23, 2011) (online at http://www.gao.gov/products/GAO-11-836).

D. Contract Pharmacy Complexities

Additionally in 2010, HRSA allowed for 340B entities to sign agreements with more than one outside pharmacy—known as contract pharmacies—to provide the covered drugs. Specifically, a covered entity may contract with an outside pharmacy to dispense 340B drugs on its behalf. A hospital or community health center may undertake such an arrangement because it has no in-house pharmacy, because it wants to reduce the on-site pharmacy load, or for other reasons relating to patient service or management of the 340B program, including patient access and convenience or potential financial benefit.

Most covered entities do not engage in multiple contract pharmacy arrangements.[19] However, some have built large networks of contract pharmacies after HRSA's 2010 multiple contract pharmacy guidance. As contract pharmacy arrangements have proliferated, they have come under scrutiny.[20]

IV. GAO AND OIG REPORT HIGHLIGHTS

Three past reports that will be the focus of Tuesday's hearing:

- **Government Accountability Office, September 2011, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement**
    - GAO is expected to provide an update of recommendations since publishing its 2011 report. Of the four program integrity recommendations, two recommendations (a revised patient definition and hospital eligibility) remain outstanding. Specifically, the GAO recommended that HRSA issue guidance to further specific the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program, and finalize guidance with more clarity regarding the implementation of the definition of a 340B "patient". Both of these recommendations were included in HRSA's omnibus regulation attempt, however, and they are likely to be part of the guidance that HRSA issues later this year.

- **HHS-OIG, February 2014, Contract Pharmacy Arrangements in the 340B Program**;
    - HHS-OIG is expected to discuss recommendations related to tightening oversight of contracting pharmacies to prevent drug diversion to ineligible patients and duplicate discounts through state Medicaid programs.

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[19] *See, e.g.,* Health Affairs, *The 340B Discount Program: Outpatient Prescription Dispensing Patterns Through Contract Pharmacies In 2012, November 2014* (vol. 33no. 11 2012-2017) (online at http://content.healthaffairs.org/content/33/11/2012.abstract).

[20] *See, e.g.,* U.S. Department of Health and Human Services, Office of the Inspector General. *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-0043* (Feb. 2, 2014) (online at http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf).

- **HHS-OIG, June 2011, State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs**.

    - HHS-OIG recommended that CMS work with states to create written 340B policies, and share 340B policies with states to ensure that entities are not overpaying for drugs. OIG also recommended that HRSA work to improve the accuracy of the Medicaid exclusion file to help provide additional oversight of prohibited duplicate Medicaid discounts. HRSA issued some guidance on this issue for Fee-for-Service Medicaid programs last year, but Medicaid Managed Care guidance remains in flux at the agency at this time.

V. WITNESSES

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