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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

July 9, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Opportunities to Improve the 340B Drug Pricing Program"

On **Wednesday, July 11th, at 10:00 a.m. in room 2123 of the Rayburn House Office Building**, the Subcommittee will hold a legislative hearing titled "Opportunities to Improve the 340B Drug Pricing Program." This hearing will examine a newly-released Government Accountability Office (GAO) study on 340B contract pharmacy arrangements as well as the following seven legislative measures, and eight discussion drafts:

- H.R. 2889, Closing Loopholes for Orphan Drugs Act
- H.R. 4392, To provide that the provision of the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final regulation
- H.R. 4710, 340B Protecting Access for the Underserved and Safety-Net Entities (340B PAUSE) Act
- H.R. 5598, 340B Optimization Act
- H.R. 6071, Stretching Entity Resources for Vulnerable (SERV) Communities Act
- H.R. 6240, To amend the Public Health Service Act to provide for certain user fees under the 340B drug discount program
- H.R. 6273, To amend the Public Health Service Act to ensure appropriate care by certain 340B covered entities for victims of sexual assault, and for other purposes
- H.R. __, Protecting Safety-Net 340B Hospitals Act
- H.R. __, Bettering Operations and Oversight through Senate-process Transparency (BOOST) in 340B Act
- H.R. __, To amend the Public Health Service Act to define the term patient for purposes of the 340B drug discount program
- H.R. __, To require the Secretary of Health and Human Services to implement the Government Accountability Office recommendations

- H.R. __, To amend the Public Health Service Act to require under the 340B drug discount program reports by covered entities
- H.R. __, To amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits
- H.R. __, To amend the Public Health Service Act to require certain covered entities under the 340B drug discount program
- H.R. __, To amend the Public Health Service Act to allow the Secretary of Health and Human Services to prescribe regulation

Additional background information on the 340B program can be found in recent committee hearing memos on the 340B program, held on October 11, 2017, July 18, 2017, and March 24, 2015.

I. CONTRACT PHARMACY ARRANGEMENTS IN THE 340B PROGRAM

A. Background

Some 340B covered entities choose to dispense 340B drugs to patients in part or in full through contracted pharmacy services; meaning the covered entity has a contractual arrangement with an outside pharmacy to dispense 340B discounted drugs on the covered entity's behalf and provide pharmacy services.[1] Covered entities may be better able to reach eligible patients through contracted pharmacy services, particularly in rural areas, or to offer certain patients more convenience than hospital pharmacies. For instance, hospitals or other 340B covered entities may use contracted pharmacy services to improve a covered entity's access to drugs, such as specialty products that are limited in distribution that otherwise may be difficult to obtain, if at all, through the covered entity's own pharmacies or some other means. These are not hypothetical scenarios given HRSA's publication of notices from manufacturers limiting distribution of specialty drugs, thereby making them unavailable, or no longer available from hospital pharmacies.[2]

HRSA has also published guidance governing contract pharmacies.[3] In brief, contract pharmacies must register for the 340B program, and 340B covered entities are made responsible for ensuring that all contract pharmacy arrangements comply with all standard 340B program requirements. Contract pharmacies also must ensure that 340B discounted drugs are not diverted to non-340B eligible patients. Further, all covered entities are required to provide oversight of the contract pharmacy, maintain auditable records and conduct annual independent audits of their contract pharmacies. Any violations by contract pharmacies of any of the 340B program requirements must be disclosed to HRSA by the covered entity, along with a plan to address the

[1] Health Resources and Services Administration (HRSA), *Contract Pharmacy Services* (May 2018) (https://www.hrsa.gov/opa/implementation/contract/index.html)

[2] HRSA, *Manufacturer Notices to Covered Entities* (June 2018) (https://www.hrsa.gov/opa/manufacturer-notices/index.html).

[3] Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services (March 5, 2010) 75 Fed. Reg. 10272.

violation. Importantly, contract pharmacies must carve-out Medicaid patients (i.e. not use 340B drugs for Medicaid patients) unless the covered entity has an arrangement in place with the state Medicaid agency to prevent duplicate discounts and that arrangement has been reported to HRSA.

B. GAO Report

On June 28, 2018, GAO released a report entitled, "Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement."[4] This report focused specifically on contract pharmacy arrangements in the 340B program.

According to GAO, in 2017 there were more than 12,000 covered entities and more than 38,000 total sites (including so-called "child sites") participating in the 340B program, along with roughly 20,000 contract pharmacies. GAO estimates in its review that roughly one-third of all covered entities use contract pharmacies. Overall, a higher percentage of hospitals (69.3 percent) had at least one contract pharmacy compared to federal grantees (22.8 percent). Among the six types of hospitals, the percentage that had at least one contract pharmacy ranged from 39.2 percent of children's hospitals to 74.1 percent of critical access hospitals. Among the 10 types of federal grantees, the percentage with at least one contract pharmacy ranged from 3.9 percent of family planning clinics to 75.2 percent of federally qualified health centers (FQHCs).

GAO's review of contracted pharmacy arrangements included the following components:

- **The extent to which covered entities contract with pharmacies to distribute 340B drugs, and the characteristics of those pharmacies.** GAO analyzed certain basic standardized characteristics of HRSA's 340B program database to identify the covered entities registered to participate in the 340B program and the contract pharmacies registered to dispense 340B drugs for each entity, as of July 1, 2017.

- **Financial arrangements certain covered entities have with contract pharmacies and Third-Party Administrators (TPA) related to the administration and dispensing of 340B drugs.** GAO reviewed a sample of contracts between entities and pharmacies and collected information from certain entities and TPAs.

- **The extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low- income, uninsured patients.** GAO sent a questionnaire to 60 covered entities, and conducted follow-up conversations with representatives at ten of the 60 entities.

- **An evaluation of HRSA's work to ensure compliance with 340B program requirements at contract pharmacies.** GAO broadly reviewed all relevant HRSA policies, procedures and guidances, including HRSA's 2010 guidance on contract

[4] Government Accountability Office (GAO), *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 28, 2018) (https://www.gao.gov/products/GAO-18-480).

pharmacy services and documentation of the agency's audit procedures. Additionally, the agency also analyzed summaries of HRSA's audits of covered entities over the past five years and performed a randomized review of 20 specific audits.

GAO made seven recommendations related to this report. However, HRSA agreed with only four of the seven. HRSA also raised concerns with some of the information in GAO's report overall and noted in comments to GAO on the report that "HHS also has significant concerns regarding many of the findings in the draft report." The following are GAO's recommendations to HRSA:

- **The Administrator of HRSA should require covered entities to register contract pharmacies for each site (both the main parent site and any so-called "child site" or satellite site) of the entity for which a contract exists.** HRSA did not agree with this recommendation, citing their existing contract pharmacy registration requirements and detailing in their comments on the report that registering every single child site would be unnecessarily burdensome without measurably improving contract pharmacy compliance.

- **The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with the Centers for Medicare and Medicaid Services (CMS) as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs.** While HRSA concurred with this recommendation, HRSA noted the critical role that CMS would have to play in implementing this recommendation. Historically, coordination between Medicaid and the 340B program has been difficult. With respect to duplicate discounts specifically, there are a number of complicating factors. Under federal rules, states (as opposed to 340B providers) are the regulated entities responsible for managed care organizations (MCO) duplicate discount prevention. Moreover, some confusion has resulted because the 340B statute governs duplicate discounts that apply only to fee-for-service Medicaid claims, and not to MCO claims. MCO duplicate discounts are governed by the Medicaid rebate statute.

- **The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.** With the caveats noted above, HRSA concurred with this recommendation.

- **The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit.** HRSA concurred with this recommendation, while again noting the agency's lack of ability to issue any binding regulatory guidance without statutory authority.

- **The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the**

methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance. HRSA did not concur with this recommendation. Specifically, there is already a risk-based audit system that incorporates this recommendation in a way that far more effectively uses resources. The agency noted that this would add significant burden for all parties—both manufacturers and covered entities—with little gained.

- **The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit.** HRSA did not concur with this recommendation, citing again their preference for an alternative, more effective methodology to accomplish the same goal.

- **The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.** HRSA supports this recommendation but noted that binding regulatory guidance is not possible within current authority.

II. 340B LEGISLATION AND DISCUSSION DRAFTS

A. H.R. 2889, Closing Loopholes for Orphan Drugs Act

H.R. 2889, introduced by Reps. Welch (D-VT) and Harper (R-MS) would allow rural and cancer hospitals to access discounted prices on orphan drugs when they use the drugs for non-orphan diseases or conditions. Orphan drugs are often used for non-orphan purposes. Since orphan drugs are among the most expensive drugs on the market, this bill would significantly reduce costs for these hospitals, helping them keep their doors open and enabling patients to access affordable medications and services. Under the proposed legislation, 340B pricing would be available in these instances for these hospitals.

B. H.R. 4392, To provide that the provision of the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final regulation relating to changes in the payment amount for certain drugs and biologicals purchased under the 340B drug discount program shall have no force or effect, and for other purposes

H.R. 4392, introduced by Rep. McKinley (R-WV) would provide relief to 340B hospitals subject to a nearly 30 percent reduction in Medicare Part B drug payments that went into effect January 1, 2018, as part of the 2018 Outpatient Prospective Payment System (OPPS) payment rates.

C. H.R. 4710, 340B Protecting Access for the Underserved and Safety-Net Entities (340B PAUSE) Act

H.R. 4710, introduced by Reps. Bucshon (R-IN) and Peters (D-CA) would issue a two-year moratorium on certain hospitals in the 340B program as well as additional extensive reporting requirements on such hospitals in the program. For instance, H.R. 4710 would collect information on patient mix disaggregated by insurance status, including uninsured status and charity care provided.

D. H.R. 5598, 340B Optimization Act

H.R. 5598, introduced by Rep. Carter (R-GA) would collect information to demonstrate an outpatient low-income patient utilization rate for hospitals. The bill would also call for HRSA to submit a report to Congress on the outpatient utilization information.

E. H.R. 6071, Stretching Entity Resources for Vulnerable (SERV) Communities Act

H.R. 6071, introduced by Rep. Matsui (D-CA) would seek to require balanced auditing of compliance by manufacturers in the 340B program. The legislation would also require HHS to move forward with regulations enforcing civil monetary penalties to hold manufacturers accountable for program violations as well as rules clarifying how manufacturers should calculate 340B prices. Further, the bill requires HHS to share 340B ceiling prices with providers. Congress directed HHS to move forward with a ceiling price website for providers eight years ago, but the agency has yet to make prices available. This legislation would also codify the intent behind the 340B program, the definition of a "patient" in the program and reverse the Medicare Part B payment cut for 340B hospitals.

F. H.R. 6240, The Drug Discount Accountability Act

H.R. 6240, introduced by Rep. Collins (R-NY) would create a user fee program applicable to hospitals that would fund a variety of oversight activities and give HRSA direct hiring authority to cover ten additional staff. Currently, 340B program staff are limited and lack the resources needed to oversee the program. This policy was included in President Trump's 2018 Budget proposal and had been a President Obama budget proposal for many years.

G. H.R. 6273, To amend the Public Health Service Act to Ensure Appropriate Care by Certain 340B Covered Entities for Victims of Sexual Assault, and for other Purposes

H.R. 6273, introduced by Rep. Walters (R-CA) would require all 340B DSH hospitals to be "SAFE-ready" facilities within 12 months of enactment. The legislation allows for a full 24 months for those hospitals not meeting the deadline to come into compliance, during which time they must provide appropriate transfer of rape victims to a "SAFE-ready" facility unless the individual provides written consent to receive care. A "SAFE-ready" facility is a health care facility designated as a sexual assault forensic exam-ready facility.

H. H.R. __, Protecting Safety-Net 340B Hospitals Act

The discussion draft, proposed by Rep. Barton (R-TX) would raise the DSH eligibility threshold for the 340B program from 11.75 percent to 18 percent.

I. H.R. __, Bettering Operations and Oversight through Senate-Process Transparency (BOOST) in 340B Act

The discussion draft, proposed by Rep. Hudson (R-NC) would create a Presidentially-appointed and Senate-confirmed administrator of the 340B program.

J. H.R. __, To amend the Public Health Service Act to define the term patient for purposes of the 340B drug discount program

The discussion draft, proposed by Rep. Collins (R-NY) would make similar changes once proposed in the 340B HRSA-proposed "mega guidance" (later withdrawn) to the definition of an eligible 340B "patient" for DSH, children's, and cancer hospitals, including: 1) preventing the use of 340B for discharge prescription; 2) preventing the use of 340B for infusion orders written outside the hospital; 3) preventing the use of 340B for emergency room drugs; and 4) preventing the use of 340B if the patient, among other statuses, is an inmate.

K. H.R. __, To require the Secretary of Health and Human Services to implement the Government Accountability Office recommendations

The discussion draft would implement all seven of GAO's recommendations for contract pharmacies.

L. H.R. __, To amend the Public Health Service Act to require under the 340B drug discount program reports by covered entities

The discussion draft, proposed by Rep. Bucshon (R-IN) would require extensive reporting by 340B hospitals. Specifically, the draft would require reporting beyond the current 340B program requirements to include, for instance, the percentage of overall inpatient day charges and overall outpatient visit charges broken down by payor mix (including Medicare, Medicaid, CHIP, other federal health programs, individual market plans, and the uninsured) as well as information related to savings on drug purchases.

M. H.R. __, To amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits

The discussion draft would require the HHS Secretary to conduct audits under the 340B program for all parties—both manufacturers and covered entities—in accordance with generally accepted government auditing standards.

N. H.R. ___, To certain covered entities under the 340B drug discount program to establish certain fee amounts charged to certain low-income patients for 340B drugs

The discussion draft, proposed by Rep. Burgess (R-TX) would require 340B DSH, cancer and children's hospitals to provide discounted drugs directly to "low-income" patients as defined by the covered entity. Such a term does not include anyone covered under minimum essential coverage.

O. H.R. __, To amend the Public Health Service Act to allow the Secretary of Health and Human Services to prescribe regulation

The discussion draft, proposed by Rep. Mullin (R-OK) would grant HRSA broad regulatory authority over the program. Currently, HRSA does not have broad binding regulatory authority, and it can only issue regulations in three specific areas outlined in the Affordable Care Act (ACA). Notably, HRSA has not yet issued regulations in two of those areas: ceiling price and civil monetary penalties on manufacturers. HRSA has delayed issuing regulatory guidance in these areas multiple times.

III. WITNESSES

Panel I:

Debra A. Draper, PhD, MSHA
Director, Health Care
Government Accountability Office

Panel II:

Charles E. Daniels, BS Pharm, PhD
Pharmacist-In-Chief and Associate Dean
University of California, San Diego

Frederick Cerise, MD, MPH
President and Chief Executive Officer
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Debra Patt, MD, MPH, MBA
Vice President of Public Policy and Academic Affairs
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