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

July 3, 2018

TO: Members of the Subcommittee on Health

FROM: Majority Staff

RE: Hearing entitled "Opportunities to Improve the 340B Drug Pricing Program"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, July 11, 2018, at 10:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled "Opportunities to Improve the 340B Drug Pricing Program."

II. WITNESSES

The hearing will consist of two panels of witnesses.

Panel 1

- Debra Draper, Director, Health Care Team, U.S. Government Accountability Office.

Panel 2

- Frederick Cerise, President and CEO, Parkland Hospital;
- Debra Patt, M.D., MPH, MBA, Texas Oncology; and
- Charles Daniels, PhD, Pharmacist-In-Chief and Associate Dean, University of California, San Diego.

III. BACKGROUND

Creation of Program

The 340B Drug Pricing program was enacted in 1992 as part of the Veterans Heath Care Act (section 340B of the Public Health Service Act). The 340B program gives certain health care providers access to discounted drugs, similar to the 1990 Medicaid Drug Rebate program. The Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs is responsible for administering and overseeing the program.

Covered Entities Participating in the Program

The 340B program has two primary stakeholders: covered entities and pharmaceutical manufacturers. Under federal Medicaid law, pharmaceutical manufacturers that want to have their drugs covered by Medicaid must enter into pharmaceutical pricing agreements (PPAs) under which manufacturers agree to provide discounts on covered outpatient drugs purchased by certain covered entities. Covered entities include certain hospitals that either are non-profit organizations or owned or operated by State or local governments and serve higher percentages of low-income beneficiaries as well as federal grantees such as health centers, Ryan White Program grantees, and other specialized clinics. There are numerous types of covered entities that can participate in the program including:

Health Centers

- Federally Qualified Health Centers
- Federally Qualified Health Center Look-alikes
- Native Hawaiian Health Centers
- Tribal/Urban Indian Health Centers

Ryan White HIV/AIDS Program grantees

Hospitals

- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free-standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

Specialized Clinics

- Black Lung Clinics
- Comprehensive Hemophilia Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics.

Covered entities are entitled to purchase outpatient, but not inpatient, drugs for patients of their facilities at substantial discounts. Covered entities may then provide these drugs to their patients and bill patients' insurers or patients directly when they do not have insurance. Covered entities that have a positive return on 340B drug transactions are not restricted in how they may use the 340B revenue.

Requirements for Covered Entities

Each year covered entities must register with HRSA, certify that they meet the program requirements, and verify their information in the 340B database. Covered entities may have multiple or affiliate locations that they designate as child sites. HRSA allows child sites to participate in the 340B program. Examples of child sites are outpatient clinics that are not

located at the hospital or satellite clinics. Registered covered entities may purchase 340B drugs at or below the 340B ceiling price. In general, the statutory formula to calculate the ceiling price is the Average Wholesale Price minus the Unit Rebate Amount (as established by the Medicaid Drug Rebate program). However, it is difficult for States and covered entities to verify the accuracy of the drug prices because HRSA has yet to finalize the secure data system which would make the ceiling prices available to covered entities.[1]

Covered entities must ensure that they do not violate the duplicate discount and diversion prohibitions in the statute.[2] Duplicate discounts occur when a Medicaid beneficiary is provided a drug that was purchased by the covered entity at the 340B discounted price and the State Medicaid agency also receives a rebate from the Medicaid Drug Rebate program for the same prescription, which results in the manufacturer providing multiple discounts on the same drugs. This duplication in the 340B program is prohibited by law. Diversion refers to a scenario where a drug purchased at the 340B discounted price is dispensed to an individual who is not a patient, as defined in HRSA guidance, of the covered entity.[3] Both the Government Accountability Office (GAO) and the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) have identified the lack of clarity in the patient definition as an issue.[4]

Pharmaceutical manufacturers who participate in the 340B program sell outpatient drugs to the covered entities at the ceiling price. Manufacturers must calculate the ceiling price every quarter and submit this information to HRSA. If the calculation results in negative prices, manufacturers set the price at $0.01 for that quarter, referred to as "penny pricing."[5] Penny pricing is not in statute, but allowed by HRSA guidance. Covered entities may negotiate with manufacturers for deeper discounts. Negotiation can be done by the covered entity itself, through HRSA's prime vendor program (PVP), or for some types of covered entities, through a group purchasing organization (GPO).[6] Both GPOs and PVP seek to negotiate on brand-name and generic outpatient 340B drugs.[7]

Role of Pharmacies in the Program

Pharmacies sell and dispense 340B drugs on behalf of the covered entity. These pharmacies may be in-house, or covered entities may contract with outside pharmacies to dispense 340B drugs on its behalf. HRSA initially limited the use of contract pharmacies to covered entities that did not have an in-house pharmacy and only allowed these entities to

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[1] https://www.hrsa.gov/opa/updates/2016/april.html
[2] https://www.hrsa.gov/opa/program-requirements/index.html
[3] Federal Register, Vol 67, No. 207, Noticed October 24, 1996. Available at https://www.hrsa.gov/sites/default/files/hrsa/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf
[4] U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement". September 2011. Available at https://www.gao.gov/assets/330/323702.pdf https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf
[5] https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf
[6] DSH, Children's, and Freestanding Cancer hospitals that participate in 340B cannot use a GPO for the purchase of outpatient drugs.
[7] The current PVP vendor is Apexus. Vendor details can be found at https://www.340bpvp.com/controller.html

contract with a single outside pharmacy. However, guidance issued by HRSA in 2010 lifted this restriction and allowed any covered entity, even those with an in-house pharmacy, to contract with an unlimited number of outside pharmacies. Contract pharmacies include community, mail order, and specialty pharmacies. Additionally, many contract pharmacies are chain pharmacies. For example, covered entities may contract with a chain pharmacy, such as Walgreens, or an independent community pharmacy, to dispense 340B drugs.

Covered entities must inform HRSA of the pharmacies they contract with. If a covered entity contracts with a pharmacy, the duplicate discount and diversion prohibitions still apply. To ease the management of 340B pharmacy transactions and to assist in the prevention of diversion and duplicate discounts, some covered entities use a third-party administrator (TPA).

Trends in Program Growth and Concerns with Oversight

In 2010, the Patient Protection and Affordable Care Act (PPACA)[8] broadened the definition of covered entities that could participate in the 340B program.[9] As a result, the number of covered entities increased dramatically. From 2001 to 2017, the number of covered entities increased from 8,605 to 12,722.[10]

The PPACA also expanded the Medicaid Drug Rebate program to require rebates for drugs covered by managed care organizations. Prior to 2010, the Medicaid Drug Rebate program was primarily utilized by beneficiaries in a fee-for-service arrangement. Operating under a fee-for-service arrangement allows for better transparency in 340B claims, as States work to reduce duplicate discounts. States can use the Medicaid Exclusion File (MEF) provided by HRSA to determine which covered entities are participating in the 340B program. That list is cross-referenced with the Medicaid Drug Rebate program to ensure that duplicate discounts are not provided. Although some issues with the MEF exist, such as a lack of up-to-date information, it still is a valuable tool for States to prevent duplicate discounts.

Covered entities are legally responsible for ensuring that duplicate discounts do not occur for Medicaid beneficiaries enrolled in managed care. There are several ways in which duplicate discounts can be avoided, such as using a TPA to identify and reconcile duplications, using a 340B indicator on claims and using special health plan or provider identifiers. However, these methods can be costly and complex. For example, TPAs may receive either a flat fee or a percentage of the 340B revenue for this de-duplication. Evidence from a 2016 HHS OIG report indicates that States need better guidance from HRSA on how to prevent duplicate discounts within managed care organizations. The report also indicated that some States might not be using any methods to prevent these duplications from taking place.[11]

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[8] Public Law 111-148
[9] Allowed for four new hospital types and one new health clinic type to participate.
[10] U.S. House of Representatives, Energy and Commerce Committee, "Review of the 340B Drug Pricing Program". Available at https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf
[11] U.S. Department of Health and Human Services Office of Inspector General, "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016. Available at: https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf

Following HRSA's 2010 guidance allowing covered entities to dispense 340B drugs at more than one contract pharmacy, the number of contract pharmacies increased significantly from approximately 1,300 to more than 20,000.[12] Additionally, according to HRSA data, in 2017 there were more than 46,000 contract pharmacy arrangements. However, this number is likely underestimated as HRSA does not require covered entities to report on arrangements between pharmacies and child sites.

The Medicaid and CHIP Payment and Access Commission (MACPAC), HHS OIG, and GAO have highlighted concerns about the 340B program, including HRSA's ability to oversee the program.[13] While the number of covered entities and contract pharmacies has grown, the number of full time equivalent HRSA staff has not grown proportionately. Although HRSA has increased the number of annual audits from 51 to 200, this represents less than two percent of all covered entities.[14] There has been debate over the number of audits performed annually, lack of parity between audits of covered entities versus audits of pharmaceutical manufacturers, and audit follow up.

Additionally, questions have arisen about how covered entities use the revenue generated through the 340B program. Covered entities may generate revenue by selling 340B drugs to individuals with insurance. This revenue, which is the difference between a drug's 340B discounted price and the reimbursement received from insurance plans, has been used by covered entities in a variety of ways. Some covered entities pass this revenue along to activities that address the mission of serving low-income and uninsured patients. Some covered entities use this revenue for general operations or other activities not related to vulnerable populations. Further, OIG found that some covered entities do not offer discounts to low-income or uninsured patients, even though they participate in the 340B program.[15] There has been debate over the ability of covered entities to generate revenue, the use of that revenue, and HRSA's lack of statutory authority to regulate these activities.

Recent Oversight of the Program

From 2015 to 2017, the Oversight and Investigations Subcommittee examined the 340B program.[16] This examination included three hearings, letters to covered entities requesting information, a review of a sample of audits, and more than 50 interviews with stakeholders.

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[12] U.S. Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Need Improvement", July 2018, Available https://www.gao.gov/products/GAO-18-480

[13] MACPAC, "The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact". May 2018. Available at https://www.macpac.gov/wp-content/uploads/2018/05/340B-Drug-Pricing-Program-and-Medicaid-Drug-Rebate-Program-How-They-Interact.pdf

[14] U.S. Government Accountability Office, "Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight", Statement of Debra Draper, Director, Health Care, at footnote 19 (July 18, 2017), Available at https://www.gao.gov/assets/690/685903.pdf

[15] https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

[16] U.S. House of Representatives, Energy and Commerce Committee, "Review of the 340B Drug Pricing Program". Available at https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

Results from this extensive examination culminated in 12 recommendations to HRSA and Congress to improve the oversight and operation of the program.[17]

In recent years, multiple HHS OIG and GAO audits examining the 340B program have been conducted. Almost every audit or review has identified challenges in HRSA's oversight and operation of the program and made recommendations to HRSA or Congress regarding ways to improve the program.

For example, one recent investigation from the HHS OIG is entitled "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates."[18] The study focused on how States identified 340B drug claims and the processes they used to avoid duplicate discounts and alternatively forgone rebates. Findings from the study indicate that States use provider-level or individual claims-level methods to identify and assess the eligibility of 340B drug claims. OIG made the following two recommendations: (1) the Centers for Medicaid and Medicare Services (CMS) should require the use of claims-levels methods to ensure accuracy of 340B claims (CMS did not agree with this recommendation); and (2) HRSA should clarify guidance on how covered entities and States can prevent duplicate discounts for beneficiaries enrolled in managed care organizations.

As noted, GAO has also conducted several studies on the 340B program. In 2011, GAO published "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight

[17] The recommendations are as follows: (1) HRSA should soon finalize and begin enforcing regulations in each of the three areas in which it currently has regulatory authority, including the 340B Alternative Dispute Resolution process, the imposition of civil monetary penalties against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug, and the calculation of ceiling prices; (2) Congress should give HRSA sufficient regulatory authority to adequately administer and oversee the 340B program, including the ability to improve program integrity, clarify program requirements, monitor and track program use, and ensure that low-income and uninsured patients directly benefit from the 340B program; (3) Congress should require certain covered entities to conduct independent audits of program compliance, and should determine what such audits should assess and evaluate; (4) All covered entities should perform independent audits of their contract pharmacies at regular intervals to ensure 340B program compliance; (5) Congress should equip HRSA with more resources and staff to conduct more rigorous oversight and more effective management of the 340B program; (6) Congress (and HHS to the degree possible) should take steps to identify and reduce duplicate discounts for drugs paid for under Medicaid managed care; (7) Congress should evaluate whether the permissible scope of HRSA's audits should be expanded to cover other features of the program; (8) HRSA should work toward ensuring that it audits covered entities and manufacturers at the same rate; (9) Congress should clarify the intent of the 340B program to ensure that HRSA administers and oversees the 340B program in a way that is consistent with that intent. In doing so, Congress also should evaluate how developments in the health care landscape over the past 25 years have affected, if at all, the structure and goals of the 340B program; (10) Congress (or HRSA where HRSA already has authority to make such changes) should promote transparency in the 340B program, including ensuring that covered entities and other relevant stakeholders have access to ceiling prices and requiring covered entities to disclose information about annual 340B program savings and/or revenue; (11) Congress should establish a mechanism to monitor the level of charity care provided by covered entities. This should include a clear definition of charity care such that the data can be used to fairly compare care provided across entities; (12) Congress should reassess whether DSH is an appropriate measure for program eligibility, or whether a metric based on outpatient population would be more appropriate.

[18] U.S. Department of Health and Human Services Office of Inspector General, "State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016. Available at: https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf

Needs Improvement."[19] In that report, GAO made the following four recommendations for HRSA:

1. Provide more guidance on the patient definition;
2. Conduct audits to reduce diversion;
3. Provide guidance on criteria that non-public hospitals must meet to participate; and
4. Provide more specificity on nondiscrimination guidance.

IV. GAO REPORT

The GAO's most recent 340B report focuses on several major issues associated with contract pharmacies in the 340B program. According to GAO's analysis, approximately one-third of the over 12,000 covered entities contract with outside pharmacies. While all types of covered entities contract with outside pharmacies, GAO found that federally qualified health centers and critical access hospitals were the most likely to have a contract pharmacy. GAO's report also states that the average number of contract pharmacies per covered entity was 12, with Disproportionate Share Hospitals (DSH) having the most and critical access hospitals having the least. GAO found that 75 percent of contract pharmacies were chain pharmacies, even though only around one-half of all U.S. pharmacies are chain pharmacies. Although the median distance between a covered entity and its contract pharmacy was 4.2 miles, 45 percent of DSH hospitals had at least one contract pharmacy farther than 1,000 miles away.

The report states that financial arrangements varied, but primarily required the covered entity to pay the contract pharmacy a flat fee for each 340B prescription. This flat fee generally ranged from $6 to $15.[20] Flat fees were typically higher for hospitals than for federal grantees, as well as higher for brand name and specialty drugs than generics. GAO found that some contracts completely excluded generic drugs from the program. In addition to the flat fee, some contracts required covered entities to pay an additional fee based on a percentage of the 340B revenue for a specific prescription.

The report states that a little over one-half of the covered entities reviewed provided low-income or uninsured patients discounts on 340B drugs dispensed at contract pharmacies, with federal grantees more likely than hospitals to do so. Around two-thirds of these covered entities passed on the full 340B discount, using varying methods to determine a patient's eligibility for discounts, such as providing discounts for all patients, basing eligibility on patient's income level, or determining eligibility for discounts on a case-by-case basis. Some covered entities (more often hospitals) reported providing a discount to patients on dispensing or administrative fees.

GAO found several weaknesses in HRSA's oversight of compliance with 340B requirements at contract pharmacies. For example, HRSA's audits fail to fully assess

[19] U.S. Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement". September 2011. Available at https://www.gao.gov/assets/330/323702.pdf
[20] U.S. Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Need Improvement", July 2018, Available https://www.gao.gov/products/GAO-18-480

compliance with the prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries, specifically in managed care. HRSA allows covered entities to self-report on corrective action that was taken as a result of audit findings. No further action is taken by HRSA to validate that the corrective action issues were adequately addressed and corrected.

V. LEGISLATION

The Subcommittee will discuss introduced or draft legislation to improve the 340B program's oversight or operation. The 340B bills and discussion drafts that will be discussed include the following:

1. **H.R. 2889, Closing Loopholes for Orphan Drugs Act (Welch, D-VT; Harper, R-MS).** The bill amends the Public Health Service Act to revise the 340B Drug Pricing Program, which currently requires drug manufacturers to discount orphan drugs (drugs for rare conditions) for certain entities covered by the program. The bill discounts orphan drugs that are not being used to treat rare conditions for all entities covered by the program.

2. **H.R. 4392, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (McKinley, R-WV; Thompson, D-CA; Johnson, R-OH; Kustoff, R-TN; Courtney, D-CT; Castor, D-FL).** The bill nullifies the CY2018 Medicare hospital outpatient reimbursement change that was finalized by HHS in a November 13, 2017 regulation. The reimbursement policy change decreased reimbursement for outpatient drugs under Medicare that certain hospitals purchased under the 340B program – reducing the reimbursement from the average sales price (ASP) plus six percent to ASP minus 22.5 percent.

3. **H.R. 4710, 340B PAUSE Act (Bucshon, R-IN; Peters, D-CA).** The bill prohibits the registration of any new 340B covered entities into the program for two years, effective upon enactment. This moratorium includes DSH hospitals and their potentially new child sites. To improve transparency, 14 months after the enactment of the bill covered entities shall begin to report on:
    - the number and percentage of individuals dispensed 340B drugs,
    - total cost incurred at each site,
    - total charity care as defined by line S-10 on the Medicare cost report,
    - aggregate amount of gross reimbursement, and
    - name of all 340B vendors who have entered into contractual arrangements with child sites (this information is already collected by HRSA on parent sites).

    The bill calls for a series of reports by GAO, OIG, and the Comptroller about the level of charity care, an analysis of contracts between covered entities (parent and child sites) and vendors, and a comparison of 340B reimbursements to costs.

4. **H.R. 5598, 340B Optimization Act (Carter, R-GA; Collins, R-NY).** The bill requires certain DSH covered entities under the 340B program to submit reports to the Secretary

of HHS on the low-income utilization rates of outpatient hospital services furnished by such entities, including both parent and child sites.

5. **H.R. 6071, Strengthening Entity Resources for Vulnerable Communities Act (SERV Act) (Matsui, D-CA).** The bill seeks to codify the 340B definition of a patient as described in the 1996 Federal Register. Under the bill, covered entities may not discriminate against a patient's choice of drugs received and pharmacies may not discriminate against covered entities in the reimbursement for drugs. The bill directs HHS to publish 340B ceiling prices – no later than 90 days from enactment – so that covered entities can verify that they are being charged the correct amount. If there is a discrepancy between the price paid by the covered entity and the 340B published ceiling price, then HRSA shall enforce civil monetary penalties on manufacturers in the amount of $5,000 or 200 percent of the overcharged amount. The bill also requires parity in HRSA's audits of hospitals and pharmaceutical manufacturers; formalizes penny pricing; and prevents HHS from making the Medicare hospital outpatient payment change as described in the November 2017 HHS regulation. Within one year of enactment, the bill requires the GAO to report on HRSA's progress toward enacting these changes.

6. **H.R. 6240, Amend the Public Health Service Act to provide for certain user fees under the 340B drug discount program (Collins, R-NY; Carter, R-GA).** The bill directs HRSA to assess and collect user fees from covered entities. The Secretary will have 180 days to determine the fee amount and the amount shall not exceed 0.1 percent of the total paid during the previous year by a covered entity to manufacturers. User fees shall be used to finance the administration and oversight of the program. The Secretary is given direct hire authority to hire, at a minimum, 10 more full time equivalent employees. Fees shall be collected upon certification or re-certification as appropriate. The bill also directs the OIG to submit a report to Congress on the enactment and implementation of user fees.

7. **H.R. 6273, Amend the Public Health Service Act to ensure appropriate care by certain 340B covered entities for victims of sexual assault, and for other purposes (Walters, R-CA; Walden, R-OR).** The bill applies only to 340B Disproportionate Share Hospitals that have an emergency department. Within one year of enactment, such hospitals must enact a plan to transfer victims of sexual assault to the nearest SAFE (Sexual Assault Forensic Examiner)-certified facility using official hospital transportation at no charge to the victim. Within two years of enactment, such hospitals must become SAFE-certified, meaning the entity employs or contracts with a SANE (Sexual Assault Nurse Examiner) program such that a SANE is available or on call 24 hours a day. HHS will publish a list of 340B SAFE-certified entities on the HHS website, and update such list annually.

8. **H.R. ____, To amend the Public Health Service Act to require under the 340B drug discount program reports by covered entities regarding certain information on savings to covered entities from discounted prices under the program and the relationship between such savings and charity care expenditures of such covered entities (Bucshon, R-IN).** The discussion draft requires covered entities to report to

HRSA every 12 months on 340B total savings, total amount of revenue generated from the sale of 340B outpatient drugs, payor mix, and total uncompensated costs (including charity care, net loss or income, bad debt, unreimbursed costs).

9. **H.R. ____, To amend the Public Health Service Act to allow the Secretary of Health and Human Services to prescribe regulations as necessary or appropriate to carry out the 340B drug discount program, and for other purposes (Mullin, R-OK).** The discussion draft gives HRSA the authority to enforce specific regulations regarding all aspects of the 340B program.

10. **H.R. ____, Protecting Safety-Net 340B Hospitals Act (Barton, R-TX).** The discussion draft will increase the required DSH percentage from 11.75 percent to 18 percent. This discussion draft also increases the 340B discount for all covered entity types, other than DSH hospitals and critical access hospitals, by five percent.

11. **H.R. ____, Bettering Operations and Oversight through Senate-Process Transparency (BOOST) 340B Act (Hudson, R-NC).** The discussion draft requires the administrator of the 340B program to be an Assistant Secretary and Senate-confirmed, with the goal of increasing the oversight of the program and accountability of the administrator.

12. **H.R. ____, To amend the Public Health Service Act to define the term patient for purposes of the 340B drug discount program (Collins, R-NY).** The discussion draft would establish a new definition of a patient for purposes of the 340B program. The draft requires HRSA to promulgate rulemaking on the new patient definition within 180 days.

13. **H.R. ____, To amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits under the 340B drug discount program in accordance with generally accepted government auditing standards, and for other purposes (Burgess, R-TX).** The discussion draft requires HRSA to perform audits utilizing auditing standards recognized by the Comptroller General of the United States.

14. **H.R. ____, To amend the Public Health Service Act to require certain covered entities under the 340B drug discount program to establish certain fee amounts charged to certain low-income patients for 340B drugs (Burgess, R-TX).** The discussion draft prohibits 340B covered entities from charging low-income and uninsured patients the full price for 340B drugs. The discussion draft does not mandate a specific discount for covered entities for such patients, but states that certain covered entities must pass on a discount (at or below the 340B ceiling price) and that covered entities have documentation of this process.

15. **H.R. ____, To require the Secretary of Health and Human Services to implement the Government Accountability Office recommendations for the Health Resources and Services Administration relating to 340B contract pharmacies (Burgess, R-TX).**

The discussion draft requires HRSA to implement all the recommendations in the 2018 GAO contract pharmacies report within three years.

VI. STAFF CONTACTS

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