Senate Health, Education, Labor and Pensions Committee hearing:
Examining Oversight Reports of the 340B Drug Pricing Program
May 15, 2018

On May 15, the Senate Health, Education, Labor and Pensions (HELP) Committee held hearing titled "Examining Oversight Reports of the 340B Drug Pricing Program." The two witnesses were:

- Ann Maxwell: Assistant Inspector General, Department of Health and Human Services
- Debra Draper, PhD: Director of Health Care Team, Government Accountability Office

This memo summarizes the discussion of the hearing. Witness statements are available here.

OPENING STATEMENTS:

Chairman Lamar Alexander (R-TN)

- Last week's blueprint to reduce drug prices was a sweeping, comprehensive plan which puts taxpayers and patients first. We will be hearing more about the plan in the coming weeks.
- Many elements of the drug plan fall under HELP's jurisdiction. We will have hearings, roundtables, and other briefings on the proposal as it unfolds.
- Congress needs an independent examination of the 340B program. We must establish what the purpose of the program is, whether it is achieving its goals, and what Congress must do to help it succeed.
- The lack of agreement on simple facts such as participation, eligibility, and pricing under the program underscores much of the complexity to solving the issue.

Ranking Member Patty Murray (D-WA):

- 340B program helps hospitals better serve their communities and is a critical safety net.
- The program requires transparency and clarity so taxpayers can rest assured participants are using the program properly and violators are held accountable.
- The Affordable Care Act authorized HRSA to provide regulatory oversight of the program, but the Trump Administration has abandoned that effort.
- President Trump's speeches and tweets about cracking down on drug companies are empty promises compared to the concrete steps he has taken to weaken oversight of drug makers.
- The 340B program should be strong and accountable going forward.

Maxwell:

- OIG conducts oversight of the 340B program to ensure it meets the needs of low income patients.
- OIG has made several recommendation to improve clarity of mission and integrity.
- OIG recommends HRSA share ceiling price data with states and providers to ensure they are not being overcharged. Self-policing alone has been ineffective. Congress authorized HRSA to share that data, but cannot begin until a secure sharing system is online.
- Even if we can bring clarity to pricing claims, it is still unclear which claims are subject to 340B. This means double discounting threatens program integrity.
- We must also better understand what prescriptions are eligible for 340B.
- Finally, we must better understand how the savings help uninsured patients.

Draper:

- Since its creation in 1992, 340B's intent has been for covered entities (hospitals or community health centers) to reach more patients with more services. This entails discounts ranging from 20% to 50%.
- As a result, participation has seen exponential growth in participation. There were 400 participating hospitals in 1993, and there are over 12,000 in 2017.
- GAO has recommendations to help HRSA to improve oversight.
    - Allow for audits of covered entities. Current self-policing policy and 2% rate of auditing is inadequate.
    - Provide more specific guidance to entities regarding patient eligibility.
    - Provide more specific guidance regarding provider eligibility.
- HRSA began to issue a rule on these matters, but pursuant to White House directive, HRSA withdrew the rulemaking.

QUESTIONS AND ANSWERS:

Senator Johnny Isakson (R-GA):

- What was the original intent of the program? Isn't it to lower drug costs?
    - Draper: The intent in the enacting statute was to "enable participating entities to stretch scare resources," which requires clarification for the market.
- Does the program involve middlemen and insurance companies when determining pricing?
    - Draper: Rules of the program limit how covered entities purchase their drugs.

Murray:

- Did ACA require regulations on drug manufacturers to list prices and hold them accountable?
    - Maxwell: Yes, however the administration has delayed the effective date of that rule to 2019.
- Has HRSA's regulatory authority impacted the market?
    - Maxwell: Though OIG has been given authority to take enforcement actions, HRSA has not referred any enforcement actions to us until the regulation takes effect.
- So by delaying the rule four times, the Trump Administration has delayed the one tool it has to substantially go after high drug prices. That is sabotage!
- We want hospitals to improve care for patients with 340B savings. How to we develop the metrics to determine that?
    - Maxwell: We want to preserve program integrity, but need responsible measures which do not overly burden hospitals.

Senator Susan Collins (R-ME):

- There are 25 hospitals in Maine participating in 340B. 14 of the 25 have negative operating margins. The other 11 have very slim margins. Indeed, the 340B program IS the margin.
- There has been a 30% increase in 340B costs in the past four years.
- How do we ensure overpayments are not occurring?
    - Maxwell: The best way is for HRSA to share ceiling price data with providers and states. HRSA intends to do that, but is waiting for a secure data system to come online.

Senator Tim Kaine (D-VA):

- Virginia's academic medical centers have been harmed by the cuts to 340B. In looking at the program, did OIG look at how the cuts will affect the communities these hospitals serve?

    - Maxwell: We did not look at that element, but were aware those discussions we being had. Further, big policy changes could result in hospitals dropping out of the program altogether.
- You stated that HRSA audited 200 participating hospitals. How many participating drugmakers did HRSA audit? I believe if we audit hospitals, we should also audit drug manufacturers.
    - Draper: HRSA audited five pharmaceutical manufacturers in 2016 and five more in 2017. But those are not as thorough examinations due to statutory requirements. GAO has a forthcoming report examining third party administrators, contract pharmacies, and how discounts are passed along.

Senator Bill Cassidy (R-LA):

- If 340B is being used as intended, that is a good thing. However, NYU researchers have found that cancer centers participating in 340B have treated fewer low income patients under the program. This is a brutal indictment of the 340B program.
- I worry hospitals are using more expensive because the raw savings from the discount is greater. Is that the case?
    - Draper: We examined that dynamic regarding DSH hospitals and 340B hospitals. We found that the current structure for outpatient services used more expensive services.
- Larger hospitals participating in 340B have monopolies in their communities. Figures show they are charging 12% higher than competitive hospitals. Does 340B incentive consolidation?
    - Draper: We did not examine that issue.

Senator Tina Smith (D-MN):

- It is very hard to understand who is paying whom and how much. I believe 340B allows rural hospitals to stay open.
- Transparency starts with how much a drug costs.
    - Maxwell: That has been a problem with 340B since its inception. We found in 2005 14% of purchases were above ceiling price.

Chairman Alexander:

- In 2015, the domestic prescription drug sales were $457 billion. Of that, $12 billion were for 340B, and it saved $6 billion to hospitals. Should we ask facilities to describe how they used that $6 billion in savings?
    - Draper: That requirement isn't a mandated part of the program, which has long been a problem for program integrity.

Senator Elizabeth Warren (D-MA):

- 340B has only one requirement, that drug makers give discounts to certain categories of patients. That program can only work if the ceiling price is accurate. But the formula to establish the ceiling price is determined by the drug manufacturers. No one can check their work. Why is it a problem for drug makers to establish the ceiling price?
    - Draper: Because it is not available to covered entities currently.
- The ACA included provisions to verify the ceiling prices and impose penalties for over-charging. How many enforcement actions has the OIG taken?
    - Maxwell: HRSA has sent zero referrals since the rule is not yet effective.
- So by delaying the rule four times, pharmaceutical companies have avoided any penalties for overcharging taxpayers.

- If Donald Trump wants to reduce drug prices, he should enforce the law on the books that allows HRSA to penalize drug companies who overcharge taxpayers.

Senator Tammy Baldwin (D-WI):

- President Trump has unfairly targeted hospitals by claiming 340B increases the price of drugs.
- The pharmaceutical industry can provide pricing data to hospitals, but has chosen not to. What penalties can OIG take when drug makers deny information to hospitals about their drugs?
    - Draper: That is a HRSA matter.
- When HRSA undertakes audits, there is an uneven playing field between hospitals and drug companies.