GOVERNANCE THOUGHT LEADERSHIP SERIES

Texas Healthcare Trustees

340B Program Transparency - is it "Trans-fair-ency"?

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Written by Lisa Scholz

When you look at the developments and debates surrounding the 340B program in recent years, it reads like a microcosm of the larger healthcare landscape. Politics, economics, social factors and technology are at play within 340B, and the program can sometimes serve as a scapegoat for issues such as drug prices, political polarization, and general social discontent with healthcare delivery.

In order to truly understand the nuances of what's been happening in the 340B program in recent years and the rationale behind the increased call for transparency, it's necessary to first set the backdrop of where we are with healthcare overall.

WHAT IS THE 340B PROGRAM?

Through the 340B program, pharmaceutical manufacturers sell drugs used in eligible safety net hospitals' outpatient settings at discounted prices, meaning participating entities can achieve savings of 25 to 50% on pharmaceutical purchases. Hospitals reinvest 340B savings for a wide range of purposes, including providing low-cost or free prescriptions for uninsured and low-income populations, expanding services offered to patients and providing services to more patients. The 340B program involves no federal spending. Currently, one in four Texas hospitals participate in the program.

More new bills aimed at curtailing and regulating the 340B program have been introduced in the past two years than at any time in the program's 27-year history. Below are some factors that contribute to the current volatility of the 340B program:

- **Multiple contract pharmacy arrangements** – Covered entities can now have relationships with multiple contract pharmacies, complicating the nature of tracking and reporting program savings, yet improving patient access through online accessibility and specialty pharmacy.
- **Community health center expansion** – As the number of federally qualified health centers (FQHCs,

community-based healthcare providers that receive funds from the Health Resources and Services Administration Health Center Program to provide primary care services in underserved areas) in the country continue to grow, use of the 340B program is increasing.

- **Increased government and manufacturer oversight** – Audits of 340B covered entities by both HRSA and pharma companies have increased in recent years, aligning with the administration's call for increased transparency and reduced healthcare costs.
- **Congressional interest** – Mention of the 340B program in congressional hearings and committee meetings, on both the House and the Senate side, have also increased in the past few years.
- **Stretched resources** – Hospitals' margins are getting slimmer, and resources are getting scarcer. Yet as complexity around 340B reporting and compliance increases, covered entities will need more resources, not fewer, in order to effectively optimize and manage the program.
- **Consulting and technology options broadening** As companies see the program's complexity increase, more consultants and more technology choices become available, and the cost for those services and technologies must be factored into the overall cost of managing the 340B program.
- **PBM reimbursement changes** – Pharmacy benefit managers (PBMs) are increasingly changing the way they reimburse pharmacies, and there have been efforts recently to deny pharmacies that contract with 340B providers rebates for drugs in the program.
- **Vertical integration and M&A activity** – As health systems continue to acquire independent hospitals or practices, retail pharmacy giants acquire payers, and tech companies and retailers from Google to Amazon to Uber begin growing roots in the healthcare space, the 340B program will inevitably be impacted.

With all of this volatility, it's no surprise that 340B seems to have reached a boiling point. That's why it's more important than ever for covered entities to be aware of the current healthcare landscape and work with partners that can offer both cutting-edge technology and industry expertise to help optimize 340B program participation; it's too easy for potential channel partners and conflicts of interest to go unnoticed against this backdrop, as the lines between public and private sector involvement continue to blur.

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THE CALL FOR TRANSPARENCY

Hand-in-hand with the government's current focus on drug prices has come an overarching call for transparency. On the surface, this seems advisable – covered entities, pharma manufacturers, and federal governing bodies should all be able to see with ease how and why the 340B program is working, and to identify areas that need improvement. However, in practice, some of the demands for transparency (including new bills aimed at curtailing the program and reimbursement cuts that have since been ruled unlawful) have crossed the line from practical to burdensome, and in some cases, even harmful to the patients for whom the program was intended.

Yet transparency is possible without undoing all the good the program has achieved these past 27 years. Here are some practical standards for transparency that covered entities could deliver while still maintaining the integrity of the program and serving vulnerable populations. Organizations may want to discuss internal processes at a high level with senior leadership and the board to ensure regulatory alignment with reporting requirements:

- Review of all appropriate data points that reflect the covered entities' true cost burden and benefit received
- Equal reporting by other involved parties (including manufacturers)
- Protection of proprietary and confidential information
- Elimination of anti-competitive behavior

With a little bit of common sense and a dash of empathy for vulnerable patients, it's possible that the government, pharma companies, and covered entities could reach a

compromise around transparency in which no stakeholder would be made to feel like the "losing" side.

WHAT IS TRANS-FAIR-ENCY ?

While the government and pharma manufacturers are calling for increased transparency and reporting from covered entities, we've seen very little transparency on the part of manufacturers thus far. This is where "fair" comes into play.

For example, consider the Civil Monetary Penalties ruling, in which the online posting of 340B ceiling prices—or maximum amount drug manufacturers are allowed to charge—was delayed five times over the course of 10 years before the information was finally made public.

After a very long road, on April 1 of this year HRSA finally made available online a way for covered entities to view the ceiling prices for drugs under the 340B program. The requirement for such a website was passed into law in 2010, and the final regulation implementing the changes was issued in January 2017.

This is just one example in which stakeholders are not exercising "trans-fair-ency" – the open sharing of information on all sides. Some additional information that would be beneficial to covered entities in the interest of trans-fair-ency include:

- **Good faith inquiries** – Manufacturers often contact covered entities to inquire why purchasing on certain drugs in the 340B space may have gone up. Covered entities are encouraged by HRSA to respond to these "good faith" inquiries, yet may have no idea how often they're occurring among their peers. Are there certain manufacturers who look for this information more than others? Do they send out 200 such inquiries a year, or 2,000?

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go both ways.

- **Number of manufacturer audits** – Covered entities have no insight into how often manufacturer audits occur. Although manufacturers must notify the Office of Pharmacy Affairs (OPA) when they conduct an audit, covered entities have no way to know how their frequency of audits compares with their peers, or which manufacturers tend to conduct such audits more frequently.
- **Specialty drugs** – Many manufacturers have been limiting access to certain drugs by distributing them only through specialty pharmacies. When this happens, it becomes more difficult for covered entities to access these drugs, and when they do access them, it may not be at the 340B price We know that the number of drugs being put into this limited-distribution, specialty pharmacy category has been increasing over the years, as noted by the OPA's online posting of letters from manufacturers. What we don't know is how many drugs actually fall into that category at any given time; there's no requirement for pharma manufacturers to provide a list.
- **Penny pricing** – Whenever a manufacturer increases the price of a 340B drug more quickly than the rate of inflation, the manufacturer is subject to a "penny pricing" penalty – that is, the manufacturer is then required to sell that drug to covered entities the following quarter at a price of one penny. Manufacturers claim this happens frequently, which is one reason they say the 340B program is costing them money, yet we have no way to know how often this really occurs, as there are limitations in the recently developed online reporting tool from HRSA. There is not a publicly available report to demonstrate the frequency of this penalty.
- **PBM rebates** – On July 1, OIG released a report in which they found that in 2014, PBMs missed out on potential rebates of up to $74.7 million on Medicare Part D prescriptions because those drugs were filled through the 340B program. PBMs, or "sponsors," typically receive rebates from drug manufacturers in exchange for offering those drugs on their formularies and playing middleman between manufacturers and insurance companies. However, when Medicare Part D drugs are filled through the 340B program, manufacturers are required to sell those 340B drugs to covered entities at a deep discount and – in an effort to avoid paying out double or stacked rebates – the manufacturers therefore do not offer rebates on those 340B drugs to the PBMs. Yet covered entities can't know for certain how many rebates manufacturers

are refusing to pay out in circumstances like these, because, again, no transparency or reporting requirements exist on the manufacturer side.

These examples serve to illustrate that transparency can—and should—go both ways. When calling for more transparency and more reporting, it's important that pharma manufacturers, government entities, and other stakeholders think about the limits of what is fair, what is practical, and what is burdensome.

CHOOSING A 340B PARTNER

As the push for transparency around 340B continues, health care organizations must be prepared. It will be imperative to keep track of what their 340B savings are, how they're being used (whether to provide prescriptions at discounts or to build new oncology clinics), and how they can prove compliance. In order to execute on these responsibilities with confidence, covered entities should engage with a partner that has not only the right technology, but the right level of 340B program expertise. When choosing a 340B partner, trustees and hospital leaders should:

- Understand the current marketplace.
- Be aware of potential conflicts and manage them accordingly.
- Develop a reporting infrastructure to match the needs of the future.
- Integrate and centralize information to create efficiencies and protect sensitive data.
- Engage with stakeholders on the health system's behalf.

With the right partners in your corner, maintaining 340B program integrity and compliance is possible, regardless of the changes we face. Trans-fair-ency is a team effort.

Trans-fair-ency is a ***team effort.***

RESOURCES

Human Resources & Services Administration. Federally Qualified Health Centers. Date Last Reviewed: May 2018. **https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html**

Sentry Data Systems. Industry comes together at 340B Winter Conference. February 2019. **https://www.sentryds.com/february-340buzz-industry-comes-together-at-340b-winter-conference/**

Sentry Data Systems. HHS continues to pursue Medicare Part B cuts. August 2019. **https://www.sentryds.com/august-340buzz-hhs-continues-to-pursue-medicare-part-b-cuts/**

Human Resources & Services Administration. Office of Pharmacy Affairs: 340B OPAIS. **https://340bopais.hrsa.gov/**

U.S. Department of Health and Human Services: Office of Inspector General. Medicare Part D Rebates for Prescriptions Filled at 340B Contract Pharmacies. July 2019. **https://oig.hhs.gov/oas/reports/region3/31600002.asp**

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