MINTZ

The Increasingly Murky World of 340B: What's Next?

September 02, 2014 | Blog | By **Theresa C. Carnegie**

VIEWPOINT TOPICS

- Health Care

RELATED PRACTICES

RELATED INDUSTRIES

Written by: **Ellyn L. Sternfield**

For the past 18 months, health care providers and the pharmaceutical industry have been hoping for some clarity regarding 340B Drug Discount Program operations. But things just keep getting murkier.

In a March 2013 article describing the history of the 340B Program, I wrote that "Twenty years after the 340B Program was created, there are competing views of its purpose. And those competing views frame the current pressures for 340B Program reform." And in a July 2013 **post**, I wrote that the heart of the controversy over the 340B Program operations comes down to purpose – Is the 340B Program intended to provide uninsured safety net patients with access to outpatient drugs, or is it intended to provide safety net providers with enhanced revenue to increase patient access to health services? It is hard to bring clarity to 340B Program operations when there is intense disagreement as to the end the 340B Program is meant to achieve.

In January 2014, I **predicted** that the year 2014 would be a game-changer for the 340B Program, in part because of an on-going challenge by PhRMA to HRSA rules intended to implement the statutory Orphan Drug exception to 340B pricing, and in part because HRSA publicly declared its intent to issue an omnibus rule governing many aspects of 340B Program operations by the end of June 2014.

In fact, to date in 2014:

- In February I **wrote** that OIG was adding its voice to the mix, criticizing the inconsistent operations and oversight of 340B contract pharmacies and the failure of those contract pharmacies to extend 340B discount pricing to uninsured patients.
- In April, it was widely reported that HRSA's omnibus 340B rule had been submitted to OMB, and was on track for a June 2014 release.
- In May, I **posted** that U.S. District Judge Rudolph Contreras had invalidated HRSA's 340B Orphan Drug Rule, **holding** that HRSA lacked regulatory authority to promulgate regulations implementing the Orphan Drug exception enacted by Congress. The Court enjoined HRSA from implementing the rule, but offered the parties an opportunity to further brief the question of whether the rule could stand under HRSA's interpretive authority. HRSA declined further briefing. Industry commenters, including me, predicted that the ruling would cause HRSA to pull back its omnibus rule.
- In June, I **wrote** that HRSA announced its intention to "interpret" its 340B Orphan Drug rule into effect.
- In July, HRSA in fact reissued the exact same Orphan Drug Rule, this time as an interpretive rule. PhRMA immediately requested that Judge Contreras either order additional briefing on HRSA's authority to issue the rule as interpretative, or enter a judgment vacating the new rule as outside HRSA's authority.
- On August 27th, Judge Contreras ruled that PhRMA's challenge to the new rule was beyond the scope of the pending lawsuit: the interpretive rule, while identical in language, was not properly before the Court. Judge Contreras finalized his order vacating the original rule, but held that PhRMA would need to file a new lawsuit to challenge the interpretive rule.
- June, July and now August have passed without HRSA's issuance of its omnibus 340B rule.

There are still four months left in 2014. While I don't have a crystal ball, I do have three predictions for the remainder of 2014.

1. PhRMA will, if it has not already, file a new lawsuit challenging the "interpretive" Orphan Drug Rule.
2. HRSA will not issue its omnibus rule, but may issue parts of the rule. Existing statutory provisions do authorize HRSA to promulgate regulations implementing its monetary-sanction authority for compliance violations by both manufacturers and covered entities, so HRSA could issue rules

implementing those provisions. But given the uncertain state of its regulatory authority, HRSA may be reluctant to promulgate rules on the more controversial aspects of 340B Program operations, such as defining what constitutes a 340B "patient"; addressing the dispensation of 340B drugs to fully insured individuals; or regulating how covered entities can use revenue derived from billing insurers for 340B drugs.

3. Neither HRSA, nor Congress, will answer the key question: Is the 340B Program intended to provide uninsured safety-net patients with access to outpatient drugs, or is it intended to provide safety-net providers with enhanced revenue to increase patient access to health services? And without an answer to those questions, the public relations wars on all sides will continue.

So for all of you who deal with the 340B Program, tread carefully and keep your eyes peeled for further developments.

Authors

Theresa C. Carnegie, Member

Theresa advises clients on all aspects of the pharmaceutical supply chain, including counseling industry stakeholders on a range of business, legal, transactional, and compliance matters. She provides clients with strategic counseling and creative business modeling that considers legal restrictions and regulatory risk in light of innovation and business goals.