Does Invalidation of 340B Orphan Drug Rule Doom HRSA’s Guidance?

October 20, 2015  |  Blog  |  By Ellyn L. Sternfield

Our recent post on HRSA’s Omnibus Proposed Guidance for the 340B Drug Discount Program (Proposed Guidance) noted that since the DC District Court had yet to rule on the validity of HRSA’s “interpretive” 340B orphan drug rule, it was an open question as to whether certain provisions in the Proposed Guidance would even be enforceable.

One week later, the Court in fact invalidated the orphan drug “interpretive” rule. The Court’s reasoning may well provide fodder for challenges to the Proposed Guidance if and when it is finalized. We have to wonder whether, like HRSA’s predecessor Omnibus 340B rule of June 2014, the final 340B Guidance never sees the light of day.

**How Did We Get Here?**

Since those who don’t learn from their history are doomed to repeat it, a recap of the history of the orphan drug rule is in order.

As we wrote in July 2013, “orphan” drugs, designated as such by the FDA under the Orphan Drug Act, are used to treat specific rare conditions such as ALS or Huntington’s disease. The Orphan Drug Act provides incentives for manufacturers of such drugs and, through a specific provision in the Affordable Care Act (ACA), Congress exempted orphan drugs from 340B drug discounts.

In a rule intended to implement the ACA orphan drug exception, HRSA adopted provisions limiting application of the ACA exception to situations where the drug was being used for the rare condition or disease for which it was designated as orphan by the FDA. So, for example, if drug X is designated as orphan for treatment of ALS, but is also FDA-approved to treat anorexia, manufacturers would have to make the drug available to covered entities at 340B discounted prices if the entity intended to dispense the drug to anorexia patients.

The Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit to enjoin enforcement of the orphan drug rule, arguing in part that HRSA was not authorized to issue rules interpreting the legislatively adopted orphan drug exception to 340B pricing. In May 2014, U.S. District Judge Rudolph Contreras ruled that HRSA lacked regulatory authority to promulgate regulations “interpreting” the breadth of the statutory orphan drug exception, finding that “[w]here Congress prescribes the form in which an agency may exercise its authority…[the court] cannot elevate the goals of an agency’s action, however reasonable, over that prescribed form.”

As an immediate result of the court ruling, HRSA took two actions. First, HRSA pulled its promised 340B Omnibus rule, then pending review at OMB, and never issued the rule. Then HRSA reissued its intended orphan drug rule as a statutory interpretation. In response, PhRMA filed a new lawsuit seeking to enjoin any implementation or enforcement of HRSA’s statutory “interpretation” as beyond its authority. HRSA argued that because the rule was an “interpretation,” it was not a final agency action subject to challenge. HRSA’s position was that manufacturers had to wait until HRSA actually attempted to enforce the interpretive rule before bringing a challenge to the rule.

In the meantime, HRSA issued its 340B Proposed Guidance, with the comment period closing at the end of this month.

**The Orphan Drug Ruling**

The sum and substance of the orphan drug ruling is that there is no orphan drug rule.

Judge Contreras was unimpressed with HRSA’s argument that the interpretive rule was not a final agency action subject to challenge. Contreras found that the interpretive rule was in essence an agency pronouncement setting forth its view of the law and imposing duties and obligations on the manufacturers and covered entities in the name of compliance. Thus, the interpretive rule met the criteria for judicial review. And in that review Judge Contreras found that the ACA’s statutory exemption for orphan drugs was plain on its face: the exemption was for drugs designated as orphan, and was not
dependent on how the drugs were used. Therefore, the interpretive rule was not consistent with the statute and could not stand.

What it Means?

So the open question we referenced in our earlier post is answered. And the answer clearly has the potential to affect the future of the Proposed Guidance.

The orphan drug ruling may well impact HRSA’s willingness to proceed on the Proposed Guidance given that a number of the provisions in the Proposed Guidance impose duties in the name of compliance that go beyond statutory requirements, such as the expanded definition of a 340B patient, the audit requirements for Contract Pharmacy arrangements, and mandatory notice of Limited Distribution Agreements. So just like its predecessor, the 2014 Omnibus 340B Rule, HRSA may decide to pull the Proposed Guidance and spare itself the attacks that are sure to come.

If HRSA does decide to go ahead with the Proposed Guidance, all impacted parties now have a blueprint on how to initiate affirmative litigation to enjoin the Proposed Guidance. Every provision that imposes duties or obligations on a manufacturer, covered entity, or contract pharmacy, not authorized by the 340B statute, can potentially be challenged.

As previously noted, this year there has been increasing Congressional attention to the 340B Program, with a March 2015 hearing in the House Energy and Commerce Subcommittee and requests for Senate hearings. The orphan drug ruling may further fuel congressional interest in a legislative fix to our 340B problems.

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