You and Your 340B Program: Are You Compliant or Confused?

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What is the 340B program?
The 340B program is a means through which providers, known as "covered entities," can offer pharmaceuticals to a greater amount of eligible patients than they could at traditional manufacturer pricing. This is because the program requires that manufacturers sell the drugs to the eligible providers at a discount, thereby enabling a larger number of those in need to get the assistance they need with purchasing their prescriptions. The 340B program is very popular for this very reason; covered entities are able to purchase drug supplies at the 340B discounted price, and then bill the patient's insurance company the traditional rate. This "margin" generates much needed profit for some of the more income-challenged providers, while having minimal impact on the Medicare and Medicaid program costs. The patient wins, the provider wins, and the government programs win. Providers understand the upside, and annual 340B drug spending by covered entities exceeds six billion dollars and approximately one-third of U.S. hospitals participate in the program. The spending and number of participating providers is forecast to increase significantly during the coming years.

In 1992, Congress created the 340B program via Public Law 102-585, the Veterans Health Care Act of 1992, which is otherwise known as Section 340B of the Public Health Service Act. The law requires drug manufacturers that participate in the Medicaid program to agree to provide discounts on covered outpatient drugs purchased by government-supported facilities, or "covered entities." Examples of "covered entities" include disproportionate share hospitals, sole community hospitals, rural referral centers, critical access hospitals, and children's hospitals and cancer hospitals exempt from the Medicare prospective payment system. Enrollment periods for those providers seeking to participate in the program are open on a quarterly basis. Administration of the 340B program is performed by the Office of Pharmacy Affairs (OPA) of the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services.

Achieving Compliance with 340B Program Guidelines
Compliance pertaining to a 340B program is relative. A provider may consider themselves in compliance with the guidelines of the program based on their understanding of these guidelines, whereas HRSA and the OPA may consider the provider to be noncompliant based on their interpretation of these same guidelines. These divergent opinions are a result of a set of rules that are written in a somewhat general manner, excluding the detailed implementation regulations that are common to other HHS programs. HRSA recognizes the need for more clarity on the part of the covered entities and is actively working to close the interpretation "gap" and to achieve more compliance within the program.

HRSA has heard the rumblings from the industry and Congress over the past several years regarding the 340B program and the need for more detailed directions to minimize both unintentional violations of the program as well as intentional efforts to take advantage of the interpretation "gap" to prosper to an extent not anticipated by the authors of the program. Audits

in recent years by HRSA and the Office of the Inspector General (OIG) of HHS have confirmed the fact that covered entities are having challenges meeting full compliance with guidelines, particularly in the areas of diversion and duplicate discounts. Another key factor in meeting compliance requirements identified through the audits is the degree to which providers utilize contract pharmacies and their oversight of such. The use of contract pharmacies, while occurring in the minority of covered entities at this point, is growing and there is a wide disparity in their treatment and oversight. HRSA has strongly recommended the use of independent audits of contract pharmacies to address compliance.

Increased Focus on Integrity and Compliance

So where does one go from here? Good question and one that the HHS OIG and HRSA intend to address in the immediate future. They are both being very active in publishing clarifying documents and preparing to conduct more extensive audits of 340B programs. The HHS OIG 2014 Work Plan contains initiatives pertaining to the 340B program, including a focus on contract pharmacy compliance by covered entities. In February, 2014, the OPA issued a program update that addressed contract pharmacy compliance and the continued focus on the program's integrity. In its June, 2014 program update, HRSA discussed an additional six million dollars that Congress had set aside for the 340B program. The additional funding is being used to establish a new branch of HRSA – Program Performance and Quality – which is tasked with overseeing program integrity. HRSA stressed that program integrity has always been a focal point of their staff, but that the new branch will now enable them to devote even more emphasis on this topic. And in its July, 2014 program update, HRSA further clarified its audit process, reaffirming its focus on increased audits and the intent to no longer issue preliminary audit reports but to only issue final reports. The commitment to a renewed attention to compliance through increased audits is evident through these updates and publications and covered entities would be advised to prepare for the inevitability of an increase in 340B program audits and that they may soon fall within HRSA's radar.

"Mega-Reg" to provide clarification Many facilities may be feeling somewhat alarmed by this enhanced focus on program integrity in that they believe they may need more guidance to ensure that their program is truly compliant. As discussed before, heretofore, detailed implementation guidance on the 340B program has been found to be somewhat lacking, and compliance became an "interpretation of the rules" exercise. Now, with more expected of them, the covered entities are in need of specific clarification of the rules and HRSA is preparing to provide such guidance. The much discussed "mega-reg" that HRSA is expecting to issue will provide specific guidance on issues such as the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and the eligibility of off-site hospital facilities.

Throwing a potential curve into HRSA's plans is the recent (May, 2014) decision by the United States District Court for the District of Columbia (USDCDC), which held that HRSA lacked the ability to issue the regulation regarding orphan drugs. HRSA had attempted to promulgate limitations on the use of orphan drugs by certain covered entities; however, the USDCDC found that the 340B regulation itself limited HRSA's ability to promulgate regulations to only those areas dealing with the administrative dispute resolution process, calculation of ceiling prices, and civil monetary penalties. Furthermore, orphan drugs were not deemed to be included in the

definition of any of these three areas, therefore, HRSA was found to not have the authority to issue any regulations pertaining to them.

Covered entities may wonder why this is important if orphan drugs are not a large part of their 340B program. The importance lies in the ability of HRSA to issue and enforce the "mega-reg." HRSA has so far chosen not to appeal the USDCDC finding, and it must decide, before proceeding, whether the issues covered by the "mega-reg" would survive a likely court challenge in light of the USDCDC decision, and whether a further "tweaking" of the regulation should occur prior to its actual issuance. At this point, HRSA has indicated that they continue to look to move forward with the "mega-reg."

Conclusion

It is very clear that the history of the 340B program being loosely regulated and enforced is just that – history. HRSA, the OPA and the HHS OIG all have the 340B program high on their list of priorities and they are committed to ensuring a more consistent implementation of the program and to strengthening its integrity. Through audits and publication of clarifying guidance, they are working with covered entities to achieve those goals. Covered entities should be proactive in assessing the compliance of their 340B programs and taking steps to document compliance and/or perform corrective efforts to become compliant. Steps may include performing internal assessments of policies and procedures or partnering with external agents to assist with these assessments, performing audits of the program components, obtaining independent audits of contract pharmacy arrangements, and developing a routine process of monitoring new HRSA program updates and their impacts, including the new "mega-reg." By taking these steps, covered entities can begin to move the gauge from "confusion" to "compliance."

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