

E-ALERT | Life Sciences & Government Contracts

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WHAT DRUG MANUFACTURERS NEED TO KNOW ABOUT 340B IN 2013

The 340B Drug Pricing Program may not be as well-known as other pharmaceutical pricing programs, but the impact and scope of this drug discount program in pharmaceutical sales continues to grow. In 2011, the Government Accountability Office (GAO) estimated that covered entities purchased over \$6 billion worth of deeply discounted drugs,¹ making up approximately two percent of all US pharmaceutical sales. Drug sales under the 340B program have now grown to about \$6.9 billion per year and are expected to grow to \$12 billion by 2016.² The program includes one third of the nation's hospitals, which is triple the number of participating hospitals in 2005.³ Rapid growth of this program has been fueled in part by the Affordable Care Act (ACA), which expanded eligibility to an additional 3,000 340B providers, approximately 1,600 of which have already registered for the program according to the Health Resources and Services Administration (HRSA).⁴ More hospitals may continue to become eligible for the program by increasing the number of Medicaid patients they treat, even as the ACA should result in fewer people being uninsured.

Throughout the program's 20 year history, it has been plagued with compliance and enforcement concerns, but in recent months, HRSA has significantly ramped up its integrity and oversight efforts through a number of new initiatives. It is expected that these efforts will continue in the year ahead,⁵ and potential legislative and regulatory changes are on the horizon. This article summarizes the key issues that stakeholders should be aware of heading into what is likely to be an eventful year for 340B.

AUDITS

Last year, HRSA conducted its first ever covered entity audits in the history of the 340B program. The 51 covered entity audits conducted were both random and targeted, with the targeted audit subjects chosen based on risk assessments and allegations of drug diversion, duplicate discounts, or entity ineligibility.⁶ Earlier this month, HRSA released a report on 18 of the completed audits, with

¹ GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11,836, (Washington, D.C. September 2011), at <http://www.gao.gov/new.items/d11836.pdf>.

² Andrew Pollack, *Dispute Develops Over Drug Discount Program*, The New York Times (February 12, 2013), http://www.nytimes.com/2013/02/13/business/dispute-develops-over-340b-discount-drug-program.html?nl=todaysheadlines&emc=edit_th_20130213&r=0 (last visited February 17, 2013).

³ *Id.*

⁴ Bruce Buckley, *340B Program a \$6 Billion Market Force*, Specialty Pharmacy Continuum, http://www.specialtypharmacycontinuum.com/ViewArticle.aspx?d=Policy&d_id=498&i=August+2012&i_id=878&a_id=21477.

⁵ HRSA, Letter to 340B Participants (February 10, 2012), at <http://www.hrsa.gov/opa/programrequirements/policyreleases/programintegrity021012.pdf>.

⁶ HRSA, Clarification of HRSA Audits of 340B Covered Entities (March 5, 2012), at <http://www.hrsa.gov/opa/programrequirements/policyreleases/auditclarification030512.pdf>.

no adverse findings for 16 of the 18, and an inaccurate database entry for two of the audits.⁷ In some cases, the audited entities have already alerted manufacturers that the entity may have been ineligible for discounts and offered repayment, which may have consequences for manufacturers' price reporting obligations under other drug pricing programs.

In addition to HRSA audits, manufacturers began exercising their authority under the statute to audit covered entities last year and may increasingly do so in 2013. Six audit work plans have been submitted to HRSA, and four of those are proceeding to audit, with no findings publicly available yet.

Finally, industry experts believe that manufacturers will potentially be audited by HRSA in this coming year. Audits for manufacturers likely would focus on whether manufacturers are inappropriately withholding 340B drugs from covered entities or charging the correct discounted price for 340B drugs.

RECERTIFICATION

In 2012, HRSA engaged in its first ever systematic recertification initiative. HRSA's February 2012 policy letter stated that HRSA will do yearly qualifications to make sure that 340B entities qualify and meet statutory requirements and will verify on a quarterly basis.⁸ As a result of this recertification effort, HRSA reviewed the eligibility of over 6,300 non-hospital sites and 3,800 hospitals in 2012, and decertified 269 entities. On December 3, 2012, HRSA notified community health centers that recertification for their eligibility for 340B drug discounts will begin in January of 2013.⁹ HRSA is now running weekly reports showing changes to the covered entity list, signaling that increased monitoring by manufacturers may be prudent to avoid offering discounts to newly decertified entities.

REGULATORY DEVELOPMENTS

In addition, after much delay, significant regulatory changes affecting the 340B program could potentially occur within the coming year.

- A final version of the rule implementing a restriction on purchase of orphan drugs by certain 340B entities is pending at the Office of Management and Budget (OMB) and may be released this year.
- HRSA may provide better clarity regarding the definition of "patient" in light of pressure from Congress and industry groups.
- HRSA may move forward with rulemaking for dispute resolution and civil monetary penalties (CMPs).
- The Centers for Medicaid and Medicare Services (CMS) may finalize a rule on the Medicaid Drug Rebate Program that addresses the effect of sales to 340B entities on "best price" calculations.
- Finally, HRSA may release guidance on 340B price calculations and adjustments, including the process for and impact of covered entity refunds and manufacturer true ups.

⁷ HRSA, Fiscal Year 2012 340B Completed Program Audits (February 8, 2013), at <http://www.hrsa.gov/opa/programintegrity/auditresults/340bauditreport02082013.pdf>.

⁸ HRSA, Letter to 340B Participants (February 10, 2012), at <http://www.hrsa.gov/opa/programrequirements/policyreleases/programintegrity021012.pdf>.

⁹ Drug Discount Monitor, HRSA Notifies 340B Health Centers About Upcoming Recertification, <http://drugdiscountmonitor.com/2012/12/hrsa-notifies-340b-health-centers-about-upcoming-recertification/>.

These long-awaited regulations will likely have a significant impact on the 340B program, ranging from determining who is eligible for 340B discounts to how this program affects government pricing under other programs.

LEGISLATIVE INTEREST

Congress has recently shown increased interest in the 340B program. Following a trend begun in March 2012 when members of Congress expressed concern about oversight in the 340B program, on January 31, 2013, six members of Congress sent a letter to HRSA demanding greater transparency regarding the recent audit and recertification process.¹⁰ Stakeholders also may see new versions of legislation introduced in the last Congress, such as the 340B Improvement Act of 2011 (H.R. 2674). In addition, states increasingly are looking to 340B as a mechanism of obtaining cost savings for state Medicaid programs. For example, California requires covered entities to purchase drugs under the 340B rather than Medicaid if the option is available.¹¹ Illinois recently passed a law that requires all entities that would be eligible for the 340B program to enroll in the program and purchase drugs for eligible patients under the 340B program rather than bill Medicaid.¹² Massachusetts is considering similar legislation.¹³ This trend may continue as states seek for ways to keep their Medicaid programs financially sustainable.

CONCLUSION

The 340B program has undergone significant changes during 2012 and likely will continue to do so throughout 2013. Stakeholders should monitor developments carefully to ensure that they are able to deal with uncertainties presented by audits and recertification, as well as to maintain compliance even as potential new legislation, regulations, and guidance come into effect.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our life sciences and government contracts groups:

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¹⁰ Lamar Alexander, U.S. Senator, Joe Pitts, Member of Congress, Michael Enzi, U.S. Senator, Orrin G. Hatch, U.S. Senator, Charles E. Grassley, U.S. Senator, Bill Cassidy, Member of Congress, Letter from Members of Congress (January 31, 2013), at <http://www.grassley.senate.gov/about/upload/2013-01-31-CEG-to-HRSA-Drug-Pricing-Program.pdf>.

¹¹ Kate Traynor, *Medicaid Reform Causes Major 340B Program Changes in Illinois*, Pharmacy News (September 1, 2012), <http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=3762> (last visited February 17, 2013).

¹² *Id.*

¹³ National Conference of State Legislatures, States and the 340B Drug Pricing Program, <http://www.ncsl.org/issues-research/health/340b-drug-pricing-program-and-states.aspx> (last visited February 17, 2013).