CliftonLarsonAllen

Regulatory Advisor Volume Four

340B Program Looks to the Future With New Updates

A Guide to **Regulation and Legislation**

WEALTH ADVISORY | OUTSOURCING | AUDIT, TAX, AND CONSULTING

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Like many health care programs, the 340B program, created in 1992, continues to receive many updates as the landscape evolves. As many covered entities struggle to fully comprehend the program's complex rules and updates, it is important to gain a full understanding of all program developments to properly comply with requirements. This volume of the Regulatory Advisor will discuss some of the recent updates that have been seen in the program.

Health Resources and Services Administration (HRSA) regulatory updates

The HRSA is still in the process of reviewing the 1,264 comments received from covered entities, manufacturers, and other stakeholders concerning the 340B Drug Pricing Program Omnibus Guidance, or the "mega-guidance." Despite the many stakeholder requests for meetings, the HRSA is unable to discuss the implications of the proposed guidance as they proceed with drafting the final guidance. While the target publication date is December 2016, there is no deadline by which HRSA has to publish its final guidance, if at all. Until the guidance is finalized, covered entities need to ensure that the controls they have in place are compliant with the current 340B regulations.

In the Affordable Care Act (ACA), the HRSA was granted regulatory authority over certain areas of the 340B program. On June 17, 2015, the HRSA published the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, which defines the 340B ceiling prices that can be charged to covered entities for covered outpatient drugs by manufacturers. In addition, the regulation sets monetary penalties for manufacturers that knowingly and intentionally overcharge covered entities for 340B drugs. The HRSA received 35 comments during the initial comment period, which spanned from June 17 – August 17, 2015. In April 2016, the comment period was reopened and the HRSA received an additional 70 comments. The HRSA is in the final stages of drafting the final regulation and expects that it will be published in November 2016. Additionally, the HRSA has been continually working to develop a secure database for covered entities to access 340B ceiling prices.

The HRSA was also granted regulatory authority in the dispute resolution process, which will assist covered entities that feel that they have been overcharged for a 340B covered outpatient drug by a manufacturer. A draft notice of proposed rulemaking has been submitted to the Office of Management and Budget (OMB). After approval by the OMB, the regulation will be published with a 60-day comment period. September 2016 is the expected publication date. Until the regulation is finalized, the HRSA recommends that covered entities and manufacturers enter into good faith negotiations to settle concerns.

HRSA program integrity updates

The HRSA continues to perform randomized, risk-based audits, along with targeted audits of 340B covered entities. HRSA feels that they have made improvements to the processes and protocols, including the addition of desk audits. Since the audits began in 2012, over 1,000 covered entities and 13,000 contract pharmacies have been audited. All audit results from fiscal years 2012 through 2015 have been posted on the HRSA website. The HRSA has found issues with registration, diversion, duplicate discounts, and contract pharmacy oversight. Covered entity penalties have included repayments to manufacturers, corrective action plans, and removal of child sites and contract pharmacies from the 340B program. The HRSA is optimistic about an increased trend in fewer audit findings in 2016, and is hopeful that this will continue throughout the year and into 2017. Covered entities are encouraged to continue to work diligently to implement innovative and effective strategies to mitigate 340B liabilities and risk, and run successful 340B programs.

The HRSA has added a 340B evaluation process to specific grantee site visits. During HRSA primary health care and HIV/AIDS program site visits, auditors review a questionnaire focused on establishing that the grantees are maintaining policies and procedures and have processes in place to avoid duplicate discounts and 340B diversion. The results of the audits are reported to the OPA, who follow up with targeted audits if concerns are identified. The HRSA plans to add additional grantees to this process later in 2016.

The National Association of Community Health Centers (NACHC) has made a 340B manual available on their website. The manual is intended to assist Federally Qualified Health Centers in establishing a compliant 340B program by guiding them through program requirements and advising them on best practices.

The HRSA has statutory authority and has initiated manufacturer audits. To date, one audit has been completed and five more are scheduled to be performed before the end of 2016. The audits are intended to establish compliance among manufacturers and ascertain accuracy of 340B ceiling prices. The HRSA will conduct additional spot checks of manufacturer sales information to assess compliance.

A proposal has been submitted in the fiscal year 2017 budget that would grant the HRSA explicit regulatory authority over the audit process. The change would allow the HRSA to create efficiencies in the process and better oversee the program. This change would be aligned under the OPA and should not have any impact on the covered entities.

Presidential and congressional elections

The consensus maintains that a Clinton administration would be similar to a third Obama term and would likely build on the ACA, with a focus on affordable health care. A Trump administration would potentially attempt to repeal and replace the ACA. Most believe that any administration would have difficultly repealing any of the ACA legislation. Both candidates have expressed concern over prescription drug pricing and would be expected to support pricing negotiations or legislation. In the Congressional branch, the Senate has 34 seats up for election, and every seat in the House of Representatives is up for election; the current balance of power in the Senate and House could possibly change in January, shifting power back to the Democrats.

It is expected that the only legislative actions that will occur in 2016 will include noncontroversial or "must pass" bills, which do not include any health care legislation. The 21st Century Cures Bill may move forward in 2017 in some format. If it moves forward, it is predicted that it will include an FDA user fee to fund all medical product reviews. Other legislation that may move forward in 2017 includes antibiotic incentives, generic priority review, REMS reform, opioid training mandate, 340B reform, and Part B Demonstration Project.

Medicaid and Medicare

In February 2016, the Centers for Medicare and Medicaid Services (CMS) published the average manufacturer price (AMP) final rule for covered outpatient drugs, effective April 1, 2016. The rule directs state Medicaid programs to develop and include a 340B reimbursement policy for all fee-for-service (FFS) covered outpatient drugs in its Medicaid State Plan Amendment. States have been directed to reimburse on an actual acquisition cost (AAC) basis.

CMS offers states some flexibility in how to set the AAC pricing; they can use a state-wide pharmacy survey, a nationally set AAC, or other benchmarks. For 340B-covered entities, a cap will be set at the 340B ceiling price. These entities have expressed concern that the reimbursement will not take into consideration the purchases made at wholesaler acquisition cost (WAC) pricing, the consequences of excluding the 340B prices from the calculation of "best price," and the implications on duplicate discounts. Covered entities are encouraged to talk with their state Medicaid agency about the reimbursement policy.

The final AMP rule also speaks to the states' need to address 340B duplicate discounts for both FFS and Medicaid managed care organizations (MMCO) claims. Current regulations only apply to duplicate discounts in the Medicaid FFS program. CMS has directed MMCO states to work with covered entities, pharmacies, and the MCCOs to identify processes to classify 340B claims at either the point of sale or retrospectively. Many states are moving towards requiring covered entities to carve-out Medicaid claims at both in-house and contract pharmacies, and collect rebates from the manufacturers. This would force hospitals subject to the group purchasing organization exclusion to purchase all drugs at WAC pricing, significantly increasing drug spend. Again, covered entities need to engage in an open dialogue and voice concerns to the state Medicaid Agency.

Finally, Medicare spending for 340B covered entity Part B drugs has grown from $0.5 billion in 2004 to $3.5 billion in 2014. Medicare patients and Medicare pay the same rate for drugs purchased at 340B and non-340B hospitals, despite the fact that 340B covered entities are able to purchase the drugs at a discounted rate. Congress/CMS engaged the Medication Payment Advisory Commission (MedPAC) to review and make recommendations to Medicare about Part B payment rates for 340B qualified hospitals. MedPAC recommended that Medicare reduce payment rates to covered entities, sharing in the 340B savings. MedPAC provided numerous policy options on how to redistribute the 340B savings, and 340B covered entities need to keep a close eye on proposed policy changes that will affect their reimbursement.

How we can help

Our compliance services can be powerful tools to help improve operations, reduce waste, tighten internal controls, identify risks, and lead to proactive collaboration on your business strategies. Many of our professionals have firsthand experience working in a variety of health care organizations, and our pharmacy team has thoroughly reviewed the 340B program rules and regulations on a federal and state level, and will keep you apprised of regulatory changes and updates.

We can provide you with insights on future opportunities and risks that will ultimately translate into ideas and recommendations beyond just the typical compliance-related comments. Our approach to serving you is always shaped by this greater goal. We can also help you assess your program controls, identify risk areas, and proactively implement effective strategies to mitigate your risks. There is some ambiguity about complying with the 340B Program; let CLA help you clarify and strengthen your position.

In addition to assisting you in developing policies, procedures, and self-audit programs, our team can provide annual independent audits of contract pharmacy arrangements and focus on the areas of your organization with the greatest risk.

Author

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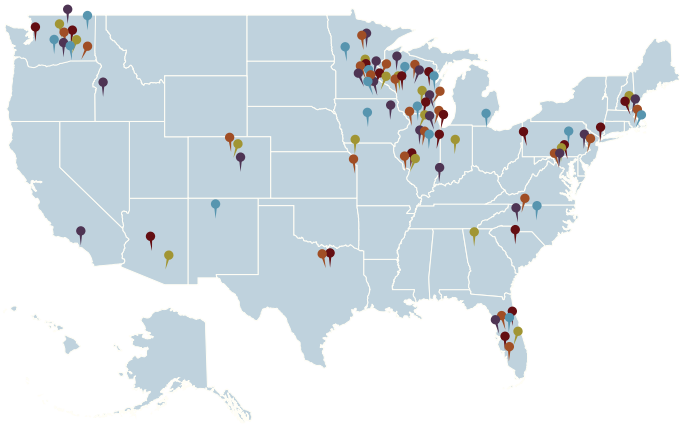

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