



Health Reform Expands 340B Drug Program Eligibility and Compliance Measurers

CLIENT ADVISORY

The 340B Program enables a limited class of healthcare providers to receive significant discounts on pharmaceuticals purchased for their outpatients. The Patient Protection and Affordable Care Act (the "Health Reform Act"), which became law on March 23, 2010, included significant changes to the 340B Program. Some of these changes involved an expansion of the list of eligible "covered entities," an expansion of integrity and enforcement provisions and a requirement for the Health Resources and Services Administration ("HRSA"), which administers the 340B Program, to develop a complaint and dispute resolution process.

Eligibility

Section 602 of the Veterans Health Care Act of 1992 (Public Law 102-585) enacted Section 340B of the Public Health Service Act to create the 340B Program. In order for manufacturers of prescription drugs to receive Medicaid reimbursement for covered outpatient drugs, the 340B Program requires them to enter into pricing agreements with the Secretary of Health and Human Services. Through a statutory formula, the manufacturer agreements fix the prices that may be charged to "covered entities" for outpatient drugs.

Covered entities were limited to a narrow field of healthcare providers that included federal-qualified health centers and non-profit or governmental disproportionate share hospitals ("DSH") with a DSH

adjustment percentage of 11.75% or higher. The Health Reform Act expanded the list of covered entities to include:

- Children's hospitals with a DSH adjustment percentage of at least 11.75% (as if they were reimbursed under the prospective payments systems);
- Freestanding cancer hospitals with a DSH adjustment percentage of at least 11.75% (as if they were reimbursed under the prospective payments systems);
- Critical access hospitals;
- Rural referral centers with a DSH adjustment percentage of at least 8%; and
- Sole community hospitals with a DSH adjustment percentage of at least 8%.

This new class of covered entities will not be eligible to receive 340 Program discounts on certain "orphan drugs," as identified by the Food and Drug Administration. These drugs are generally used for the treatment of a rare disease or condition. The 340B Program prevents DSH hospitals that are covered entities from also participating in a group purchasing organization ("GPO") for 340 Program drugs. This same GPO limitation will also apply to children's hospital and cancer centers, but not to critical access hospitals, rural referral centers or sole community hospitals.



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The final Health Reform Act did not implement a few changes proposed in prior bills. For instance, the 340B Program was not expanded to the inpatient setting. Also, the list of new covered entities does not include substance abuse clinics, maternal and child health centers or comprehensive mental health centers.

Program Integrity

The Health Reform Act includes new compliance measures that affect drug manufacturers and 340B Program covered entities. Specifically, HRSA has been charged with developing a system to verify and account for manufacturer ceiling prices charged to covered entities, creating standards to be utilized by manufacturers in making such calculations, and auditing and policing the process. HRSA was also granted the authority to impose civil monetary penalties of up to \$5,000 per instance of a manufacturer knowingly and intentionally overcharging a covered entity. For covered entities, the Health Reform Law requires HRSA to develop:

- a system for covered entities to update information to HRSA and for HRSA to verify that such information is correct;
- more detailed guidance describing billing methodologies and options available to covered entities for billing drugs to Medicaid agencies in a manner that avoids duplicate discounts; and
- a single, universal and standardized system by which each covered entity site can be identified by manufacturers, distributors, covered entities and HRSA for purposes of facilitating drug delivery and the processing of chargebacks for covered drugs.

Covered entities will be subject to penalties for 340B Program violations.

This includes payments to manufacturers for the amount equal to the reduction in the price of the diverted drug and the amount of interest due. If the covered entity engages in systematic and egregious behavior, the covered entity may be suspended from participation in the 340B Program for a reasonable period of time determined by HRSA.

Finally, the Health Reform Act requires HRSA to develop a process for covered entities to resolve disputes with manufacturers concerning pricing issues, and for manufacturers to resolve claims against covered entities related to violations of the 340B Program limitations. The resolution of a claim submitted through this process would be binding upon the parties unless it is invalidated by a court of competent jurisdiction. Therefore, judicial review would be available.

Effective Date

The changes to the 340B Program took effective on January 1, 2010. HRSA will need to determine the most appropriate way to enroll new covered entities in compliance with this date. HRSA generally has 180 days to promulgate regulations to implement the new integrity and dispute resolution provisions.

The expansion of the 340B Program will create new opportunities for many healthcare providers. HDJN can help with explaining these changes in more detail, determining the impact of these requirements on your organization and developing a plan to implement any necessary changes. If you have any questions or if we can be of assistance, please contact Mike Newby (mnewby@hdjn.com) or Emily Towey (etowey@hdjn.com) at 804-967-9604.



HDJN is one of the largest Virginia law firms primarily focusing its practice on the needs of the healthcare industry.

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