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Healthcare Reform Law Leads to Significant Changes to the 340B Program

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The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law, or Law), provides for a number of significant revisions to the existing 340B Drug Discount Program. It expands the types of entities qualifying for participation in the 340B Program, requires an expansion of integrity and enforcement provisions (including civil monetary penalties (CMPs)), and mandates development of regulations to address complaints and dispute resolution. The legislation took effect on January 1, 2010 and applies, retroactively, to drugs purchased on or after January 1, 2010.

Although the legislation does grant the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS) 180 days to develop certain regulations, including assessment standards for CMPs and an administrative process for the resolution of claims raised by manufacturers and covered entities, other provisions of the Healthcare Reform Law, including development of certain processes to achieve improvements in 340B Program compliance by both manufacturers and covered entities, do not have as clear a timeline.

In a March 19 web posting, HRSA stated that such tasks will need to be "implemented by or require input from OPA [Office of Pharmacy Affairs (within HRSA)] to occur," but it has not yet provided additional detail or guidance on when OPA will address such issues. Given the potential impact on both manufacturers and covered entities, involved parties will want to stay apprised of and involved in HRSA/OPA's efforts as it works to put processes in place to satisfy the Law's requirements.

Expansion of the 340B Program

The "340B Program" was established by Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585), which put Section 340B of the Public Health Service Act into place. The 340B Drug Pricing Program, which is administered by the HRSA, requires drug manufacturers to provide outpatient drugs to certain "covered entities," as defined by the relevant statute provisions, at a reduced price.

The Healthcare Reform Law expands the types of entities (covered entities) eligible, assuming other statutory requirements are satisfied, to participate in the 340B Program to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. For the new types of covered entities, the term "covered outpatient drug" does *not* include orphan drugs (drugs designated for rare conditions by the Secretary under section 256 of the Food, Drug, and Cosmetic Act). Although the expansion of the definition of covered entities is expected

to expand participation in the 340B Program, the impact on manufacturers will be somewhat tempered by the fact that the 340B statute mandates that if a manufacturer provides a 340B drug discount, then it does not also have to pay a Medicaid rebate on that same drug.

340B Program Integrity[1]

Manufacturer Implications

Existing 340B laws offer only limited guidance on both operational and compliance aspects of the 340B Program. The Healthcare Reform Law has sought to rectify this by tasking the HHS Secretary, likely through HRSA, with improving compliance by manufacturers. This will be accomplished by creating a system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities by (1) developing and publishing standards and a methodology for calculating ceiling prices; (2) comparing the ceiling prices as calculated by HRSA with the **quarterly** pricing data reported by manufacturers; (3) performing spot checks of sales transactions by covered entities; and (4) inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies. Additionally, in the event that there is an overcharge, the manufacturer involved will be required to issue refunds to impacted covered entities and will be obligated to explain to HRSA why and how the overcharge occurred, how the refunds will be calculated and to whom the refunds will be issued. HRSA must ensure that the refunds are issued accurately and within a reasonable time.

In addition, HRSA is also charged with developing a mechanism enabling manufacturers to (1) report rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of 340B drugs to covered entities and (2) issue appropriate credits and refunds to covered entities if the discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter. To ensure compliance with the integrity provisions, HRSA will engage in selective auditing of manufacturers and wholesalers.

The Healthcare Reform Law also grants HRSA the authority to impose CMPs not to exceed $5,000 for each instance of a manufacturer knowingly and intentionally overcharging a covered entity. The Healthcare Reform Law mandates that regulations addressing standards for the imposition of sanctions in the form of CMPs must be drafted within 180 days. It remains unclear how soon other integrity provisions required under the Healthcare Reform Law will be addressed by HRSA/OPA.

Covered Entity Compliance

The Healthcare Reform Law not only addresses enhanced integrity responsibilities for manufacturers, it also requires HRSA to improve compliance by covered entities. Specifically, HRSA must develop the following: (1) procedures to enable and require covered entities to regularly update (at least annually) their information in the HRSA covered entities database; (2) a system for HRSA to verify the accuracy of information in the covered entities database; (3) more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to state Medicaid agencies in a manner that avoids duplicate discounts; and (4) a single, universal, standardized system by which each

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[1] See the Morgan Lewis March 31, 2010 LawFlash, "Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions" (available at http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf), for additional guidance on integrity provisions contained in the Healthcare Reform Law.

covered entity can be identified by manufacturers, distributors, covered entities, and HRSA for purposes of facilitating the ordering, purchasing, and delivery of covered drugs, including the processing of chargeback for such drugs.

The Healthcare Reform Law provides for penalties that can be levied against a covered entity that violates the statutory prohibition against diverting 340B drugs to individuals who are not patients of the covered entity. Specifically, the covered entity would be liable to the manufacturer for the amount equal to the reduction in the price of the diverted drug and the amount of interest due, depending on the circumstances. In instances of systematic and egregious conduct, HRSA will be required to remove the covered entity from the 340B Program for a reasonable period of time.

Administrative Dispute Resolution Process

The Healthcare Reform Law also imposes new requirements for handling of complaints raised by both manufacturers and covered entities and for dispute resolution. Specifically, HRSA must, within 180 days of the enactment of the Healthcare Reform Law, promulgate regulations to develop an administrative process to (1) resolve claims by covered entities that they have been charged prices for covered drugs in excess of agreements and the statute, and (2) resolve claims by manufacturers that covered entities have violated certain provisions of the 340B Program. The process must provide for procedures to obtain/discover the necessary information from the other parties and allow for jointly asserted claims. Decisions reached through the dispute resolution process will be final and binding on the parties.

The revisions to the 340B Program, as specified in the Healthcare Reform Law, reflect the most significant changes related to the 340B Program since its inception for manufacturers, covered entities, and HRSA alike. Although the 340B provisions in the Healthcare Reform Law are fairly prescriptive, HRSA will have discretion in developing the specific language for the implementing regulations.

Morgan Lewis's FDA and Healthcare Practice has been directly involved in representing entities, including manufacturers and covered entities, in the requirements of the 340B Program. We will continue to monitor the development of HRSA's 340B requirements and provisions. In the upcoming days, we will be releasing additional LawFlashes on the implications of the Healthcare Reform Law to manufacturers, hospitals, and other providers. Additionally, we will be releasing LawFlashes on the compliance program requirements contained in the Healthcare Reform Law.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, Betsy McCubrey (202.739.5465; bmccubrey@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

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