Insight Into The 340B Drug Discount Program

An ESI Healthcare Business Solutions White Paper

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Summary

The 340B Prescription Drug Discount Program originated from good intentions to help safety-net providers in the provision of services to the indigent. But the program lowers drug prices for all of a covered entities eligible patients, not just the uninsured. Additionally, a major change in 2010 resulted in unanticipated growth in the volume of discounts provided by drug manufacturers which has not set well with the industry. By allowing covered entities to contract with multiple pharmacies, this significantly expanded the number of patients receiving discounted drugs, many of whom have insurance. It was this change which initiated significant expansion of the program as well as the increased vocalization of program opponents that covered entities were reaping unintended profits from the program.

Both sides of the controversy have valid points. It is unlikely that the 340B program will be eliminated. However, additional changes are certain in the areas of regulation, auditing, and restrictions. Covered entities can count on HRSA releasing new regulations on patient eligibility, hospital eligibility, and contract pharmacy monitoring. While these changes could limit the program, it is much more likely that it will simply slow the expansion rate of additional discounts. Most importantly, as with many regulations, technology will become more important in both the efficient application of inventory maintenance as well as maintenance of covered entity auditing program.

Background

The 340B Prescription Drug Discount Program was designed to correct an unintended consequence of the 1990 Medicaid prescription drug rebate program that resulted in higher drug prices for the Department of Veterans Affairs and safety-net providers. Congress intended for 340B to provide financial support to covered entities so they use scarce resources to reach more eligible patients and provide more comprehensive services. However, 340B was designed to focus on covered entities rather than uninsured or other patient populations, with the hope that covered entities would use 340B savings to improve and expand care in general, benefiting uninsured, indigent, and other patients. This is similar to other government safety-net policies and programs, including Medicare and Medicaid DSH payments and HRSA Section 330 grants in that they provide general resources to clinics and hospitals with the goal of improving and expanding health care in the safety net and in general.

The 340B program is restricted to outpatient prescription drugs. The program excludes drugs that are part of bundled payments to hospitals for inpatient care as well as drugs used to treat rare diseases. The ‘orphan drug’ exclusion was introduced as part of the ACA expansion. Drug manufacturers are not required to participate in the 340B program, however participation is required for Medicaid coverage and for inclusion in the U.S. Department of Defense and Veterans Affairs contracting programs.

Current State

Only individuals who have an established relationship with the covered entity, receive care from a provider associated with the covered entity, and receive a range of health care services beyond prescription drugs are eligible to receive 340B-purchased drugs. Many patients with private or public health insurance will meet these eligibility requirements. There are no eligibility requirements based on financial need. If a patient meets the HRSA definition and has insurance, the entity can then bill insurers for payment. Thus, covered entities can generate revenue related to 340B drugs in excess of purchase and distribution costs.

The amount of potential revenue a covered entity can generate is proportional to the size of the contract pharmacy network. The more contract pharmacies within the service area, the more eligible prescriptions that can be captured for the network to generate revenue. The fact that some covered entities are reaping millions of dollars in revenue has not set well with the drug manufacturers and some members of Congress.

Future Considerations

The ACA's reductions in Medicare and Medicaid DSH payments to hospitals may increase the importance of 340B savings for some safety-net providers. The combined effects of Medicaid expansion in some states, health insurance marketplaces, and the individual mandate will reduce the number of uninsured Americans and, in some states, increase the number of Medicaid-insured individuals. The likely net result of the coverage expansion on the 340B program is not immediately clear. Not all aspects of the ACA have been fully implemented or enforced. The demand for health care in general and for prescription drugs may increase among covered entity patients as well as non-covered entity patients. In terms of eligibility, more hospitals will become eligible for 340B as Medicaid expansion in some states pushes DSH adjustment percentages over the eligibility threshold.

Conclusion

The 340B program has always generated controversy, and never as much as it does currently. Drug manufacturers and safety-net providers are using a wide array of tools and outlets to lobby for their distinct perspectives on the purpose and appropriate role of 340B. Meanwhile, HRSA is implementing changes in program administration and oversight in response to internal and external calls for transparency and accountability. It plans to release new regulation for comment that will address issues including patient eligibility, hospital eligibility, and contract pharmacy monitoring.

While it is certain the program will undergo regulatory change, the long-term impact of the ACA on the program is the uncertainty. While Medicaid percentages are sure to rise, which will impact DSH calculations, it is unsure how much ACA will go towards eliminating uninsured patients as many provisions of the act have been postponed and the individual mandate has yet to be enforced. What is certain, is that changes to the 340B program will necessitate better management of the program by covered entities through the use of technology and auditing tools.

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