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Can We Use 340B Drugs for…? New Answers on the Horizon

By: Christine M. Morse

The issue of who can be included under the definition of "patient" for purposes of dispensing 340B drugs is a critical one for many covered entities enrolled in the 340B Drug Discount Program, particularly disproportional share hospitals (DSHs). Four years after publishing proposed guidance on the definition of "patient" in January 2007, the Health Resources and Services Administration (HRSA), the agency tasked with administering the popular, and often controversial, 340B Drug Discount Program, has now forwarded new guidance to the Office of Management and Budget for approval. The content of the new guidance is not yet known and many covered entities are anxious to learn whether the new guidance will expand the definition of patient in a manner that will permit them to provide more discounted drugs to the indigent and under insured population that they service.

The 340B Drug Discount Program was established in 1992, when section 340B was added to the Public Health Services Act. The program requires drug manufacturers to sell drugs at a statutorily-set discounted rate to certain health care providers (designated in the statute as "covered entities") that serve indigent populations, including DSHs, Federally Qualified Health Centers (FQHCs), and other federal grantees. The 340B discount is one of the deepest discounts in the industry. There are, however, certain restrictions under the 340B program. For example, the statute protects manufacturers from being required to provide — for the same drugs — both a front-end discount (given to covered entities enrolled in the 340B program) as well as back-end rebates (given to state Medicaid agencies). Therefore, covered entities either must "carve-out" drugs for Medicaid patients (i.e., not dispense 340B drugs to Medicaid patients), or must bill Medicaid at acquisition cost for 340B drugs dispensed to Medicaid patients. In addition, for DSH covered entities, 340B drugs are not available for inpatients and may be dispensed only to outpatients of the covered entity.

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The extent to which covered entities can utilize the 340B program is dependent on how the agency interprets the definition of "patient." The previously published proposed guidance on the definition of patient, which has been largely interpreted by covered entities as unnecessarily restrictive, will likely be relaxed somewhat with the publication of the new guidance. The Office of Pharmacy Affairs (OPA), the office within HRSA that oversees the 340B program, recently posted a new FAQ on its website that appears to change a previously-posted FAQ that indicated that a DSH covered entity could not dispense 340B drugs to patients upon discharge from inpatient care. Under the newly-posted answer, however, OPA now states that 340B drugs "***can*** be used for discharge prescriptions to the extent that the drugs are for outpatient use. Whether a drug qualifies as outpatient and the individual meets the definition of patient depends upon the factual circumstances surrounding the care of that particular individual" (emphasis added).

Ober|Kaler's Comments

Although it is clear now that discharge prescriptions can be filled with 340B drugs, the new FAQ still leaves open a fair number of questions regarding the circumstances under which a covered entity may dispense 340B drugs to patients upon discharge. For instance, is the patient required to be a registered "outpatient" of the covered entity or is it simply sufficient that the patient is no longer an "inpatient?" To what extent must the covered entity be responsible for the ongoing care of the patient as it relates to the 340B drugs dispensed to that patient? Despite these ambiguities, the appearance of this new FAQ suggests there will likely be substantive changes to the previously proposed guidance. Hopefully, the new patient definition will provide the much-needed clarification.

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