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340B Program

340B Drug Pricing Program: The Withdrawal of Mega Guidance and the Future of Patient Definition

BY CHRISTINE M. MORSE

On January 30, 2017, the Department of Health and Human Services withdrew guidance that had been proposed by the Health Resources and Services Administration (HRSA) in August 2015. That proposed guidance (80 Fed. Reg. 52,300) was intended by HRSA to end a decades-long wait for clarification on the popular 340B Federal Drug Discount Program (340B Program). The Proposed Omnibus Guidelines—known throughout the industry as the ''Mega Guidance''—set forth the much-needed clarification regarding the most critical question for stakeholders in the 340B Program: who qualifies as a 340B patient? The withdrawal of the Proposed Omnibus Guidelines has now left the industry in a state of uncertainty—not only as to the status of the patient definition, but the future of the 340B Program more broadly.

The 340B Program is a federal drug discount program established in 1992 when section 340B was added to the Public Health Service Act. See 42 U.S.C. § 256b. The 340B 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. Generally, only certain grantees of federal agencies, federally-qualified health centers (FQHCs), and certain designated hospitals are eligible to participate in the 340B Program. 42 U.S.C. § 256b(a)(4). A covered entity may purchase drugs at a statutorily established ceiling price from drug manufacturers. The 340B Program is the ''flip side'' of the congressionally-mandated Medicaid rebate program, which requires manufacturers to provide rebates to state Medicaid programs as a precondition for coverage of their drugs. The 340B Program, which is administered by HRSA through its Office of Pharmacy Affairs (OPA), offers one of the deepest discounts in the industry.

Christine M. Morse is a shareholder in Baker Donelson's Baltimore office. She focuses her practice on general health care law and regulatory matters.

For covered entities participating in the 340B Program, the threshold question in any analysis of 340B Program patient eligibility has always been whether the recipient of the 340B drugs meets the definition of a ''patient of a covered entity.'' There has been a long history of fits and starts with respect to any formal guidance from HRSA regarding who is considered a ''patient'' of a covered entity for purposes of receiving 340B drugs. The only definitive guidance relating to the patient definition was issued as a ''final notice'' (61 Fed. Reg. 55,156) by HRSA in October 1996 (1996 Patient Definition). This is the earliest, and currently the only *official*, guidance on the patient definition, despite multiple attempts by HRSA to promulgate meaningful guidance.

The 1996 Patient Definition indicates that an individual will be considered a ''patient'' of the covered entity if: (1) the covered entity has established a relation-

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ship with the individual, such that it maintains records of the individual's health care; and (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under a contractual or other arrangement (*e.g.*, referral for consultation), such that responsibility for the care provided remains with the covered entity. This definition has been largely criticized for being overly broad and difficult to interpret. In fact, the organization and operations of the health care and drug industries have evolved so significantly over the past 20 years that the 1996 Patient Definition has been rendered outdated and, in the views of many, largely unworkable—particularly in light of ongoing HRSA enforcement efforts, including audits of covered entities.

The Proposed Omnibus Guidelines had been the most detailed guidance on the patient definition ever offered by HRSA. Even though it was officially withdrawn by HRSA before it could be adopted—as drafted or with revisions—and despite the fact that stakeholders have once again been redirected to the 20-year-old guidance, covered entities should nevertheless consider the guidance as instructive because it is likely that HRSA will seek to apply at least some of the components of the new patient definition as it continues to monitor compliance by covered entities and contract pharmacies with 340B Program requirements.

The basic premise of the six-prong definition of ''patient,'' as described in the Proposed Omnibus Guidelines, is that there must be a very strong nexus between the covered entity, the nature and location of the service provided to the patient, the health care professional who provides the care and the drug that is ultimately prescribed by the health care professional.

Specifically, as set forth in the Proposed Omnibus Guidelines, an individual would not be considered by HRSA to be a patient of a covered entity unless the following criteria are met:

1. The individual receives a health care service at a covered entity site which is registered for the 340B Program and is listed on the public 340B database;

2. The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity, such that the covered entity may bill for services on behalf of that provider;

3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in item 2. An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug;

4. The individual receives a health care service that is consistent with the covered entity's scope of grant, project or contract. [Note: this does not apply to hospital covered entities];

5. The individual is classified as an outpatient when the drug is ordered or prescribed. The patient's classification status is determined by how the services for the patient are billed to the insurer (*e.g.*, Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently; and

6. The individual has a relationship with the covered entity such that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity and that each element of this patient definition in this section is met for each 340B drug.

While HRSA had in the past taken positions during audits of covered entities that are consistent with several aspects of the Proposed Omnibus Guidelines, including the site-of-service requirement, some of the more restrictive interpretations included in the Proposed Guidelines were not anticipated, and caught the industry somewhat off guard. These include the second prong—requiring that the covered entity be able to bill on behalf of the health care professional—and the fifth prong—that the patient must be classified as an outpatient—which effectively precludes the use of 340B drugs for discharge prescriptions. The withdrawal of the Proposed Guidelines, and the reversion to the 1996 Patient Definition, leaves open the question as to what standards HRSA will apply to covered entities on a going-forward basis.

Covered entities considering changes to their 340B operations should proceed with caution before applying the more liberal standards potentially afforded by the 1996 Patient Definition however. While it is possible HRSA will forego applying some of the more restrictive elements of the proposed patient definition in conducting audits of covered entities, it is likely that HRSA will continue to interpret the patient definition in a manner that is largely consistent with its audits to date, which in many respects reflects the guidance set forth in the Proposed Omnibus Guidelines.

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