

340B Omnibus Guidance Would Significantly Narrow the Pool of Eligible Patients

By Kristi V. Kung

New guidance from the Health Resources Services Administration (HRSA) clarifying certain definitions integral to the 340B Drug Pricing Program (“340B Program”) will significantly limit the number of patients eligible to receive 340B drugs, resulting in substantial increases in prescription drug costs for many 340B-participating health care providers.¹ The guidance contains a 6-part test for “eligible patient,” substantially more onerous to meet than HRSA’s previous 3-part test and directly conflicting with previous guidance issued by HRSA. If this new “patient” definition is finalized, we expect that many 340B covered entities will be significantly affected and see a material reduction in the number of patients eligible to receive 340B discounted drugs. This decrease will result in higher pharmaceutical drug costs for these covered entities and potentially significant economic consequences. Additionally, the “clarifying” nature of the new guidance indicates that 340B hospitals may be subject to retroactive audits from both manufacturers and HRSA, applying the narrowed patient definition to prior time periods and resulting in hospital refunds to drug manufacturers. Covered entities will likely need to revise their 340B Program compliance and prepare for audits. Comments to the proposed guidance are due no later than October 27, 2015.



¹ In addition to the change to the eligible patient definition, the Omnibus Guidance addressed hospital eligibility criteria, eligibility of off-campus facilities, and compliance requirements for contract pharmacy arrangements, amongst others. 340B covered entities are encouraged to carefully review the Omnibus Guidance and evaluate the impact of these new interpretations on the entity’s 340B Program. See 80 Fed. Reg. 52300 (Aug. 28, 2015).

History of the Omnibus Guidance

The 340B Drug Pricing Program Omnibus Guidance (“340B Omnibus Guidance”) was published in the Federal Register on August 28, 2015.² This guidance comes approximately 18 months after HRSA announced that it would be issuing a proposed regulation to address the following areas of the 340B Program: the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and the eligibility of off-campus facilities. However, HRSA’s plan to release this so-called “Mega Rule” was halted following the D.C. Circuit Court’s ruling in favor of Pharmaceutical Research and Manufacturers of America’s (PhRMA) in its lawsuit against HRSA challenging the agency’s rulemaking authority with respect to HRSA’s orphan drug regulation.³ Rather than pursuing formal rulemaking, HRSA pursued the issuance of interpretative guidance—similar to HRSA’s former guidance concerning the 340B Program. The 340B Omnibus Guidance was submitted to the Office of Management and Budget (OMB) in May of 2015 and was published in the Federal Register on August 28, 2015.

The Omnibus Guidance also follows a Government Accountability Office (GAO) report citing substantially higher per beneficiary Medicare Part B drug spending, including oncology drug spending, at 340B hospitals than at non-340B hospitals.⁴ According to the report, approximately 40% of U.S. hospitals participate in the 340B Program and 12% of these hospitals were among the lowest in the country in the provision of charity care. “Stakeholders have questioned the increase in hospital participation in the 340B program, and the implications for Medicare and its beneficiaries, especially regarding cancer care; and whether certain of the program’s hospital eligibility criteria target hospitals appropriately.”⁵ The GAO recommended that “Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs than necessary to treat Medicare Part B beneficiaries at 340B hospitals.”⁶

History of the 340B Program

The 340B Program was established in 1992 pursuant to Section 340B of the Public Health Service Act to establish discounted prescription drug pricing for certain eligible covered entities that provide a substantial amount of charity care. This federal program requires drug manufacturers participating in the Medicaid drug rebate program to provide outpatient drugs to enrolled covered entities at or below statutorily defined ceiling prices.⁷ The purpose of the 340B Program is to permit covered entities “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”⁸ Meaning, the covered entities financially benefit from the reduced prescription drug costs and are able to pocket these savings in order to fund other operations and programs, conceivably expanding the range of services and programs offered to patients.

Historically, oversight over the 340B Program and enforcement activities by HRSA was minimal and primarily relied upon participant self-policing to ensure program compliance. Oversight increased following

² 80 Fed. Reg. 52300 (Aug. 28, 2015).

³ HRSA promulgated the orphan drug regulation to implement a statutory provision added by the Affordable Care Act that would have permitted covered entities to obtain 340B prices on orphan drugs, even if the orphan drug was used for a different, non-orphan indication. PhRMA’s lawsuit alleged that HRSA violated the Administrative Procedure Act (APA) because it did not have the authority to promulgate the final rule and alternatively, even if HRSA did have rulemaking authority, the final regulation conflicted with the plain language of the statute. The D.C. Circuit court found in favor of PhRMA, holding that HRSA had exceeded its rulemaking authority. *PhRMA v. HHS*, Docket No. 1:14-cv-01685-RC (D.D.C. Oct. 9, 2014). HRSA withdrew the 340B Mega Rule on November 13, 2014 (see <http://www.reginfo.gov/public/Forward?SearchTarget=RegReview&textfield=0906-AB04>).

⁴ GAO Report, [GAO-15-442](#), “Medicare Part B Drugs: Action needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals” (July 6, 2015).

⁵ *Id.*

⁶ *Id.*

⁷ 42 U.S.C. § 256b.

⁸ H.R. Rep. No. 102-384(II), at 12 (1992).

statutory enactments under the Affordable Care Act expanding enforcement powers and increasing funding to HRSA for 340B Program activities, as well as an earlier GAO report admonishing HRSA for failing to properly oversee and enforce program compliance.⁹

Enforcement efforts and audits by HRSA have been increasing annually since 2010, and renewed efforts at clarifying ambiguous provisions in former interpretative guidance have been pursued.

The Evolving Eligible Patient Definition

Up until the release of the Omnibus Guidance, HRSA's eligible patient definition required that to be eligible to receive 340B purchased drugs, patients must receive health care services other than the provision of such drugs from the 340B covered entity.¹⁰ HRSA required the satisfaction of three elements for an individual to be considered an eligible patient:

- 1) The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
- 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 contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
- 3) The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally Qualified Health Center look-alike status has been provided to the entity. Disproportionate Share Hospitals are exempt from this requirement.¹¹

Since 1994, commenters have complained about the limitations of, or ambiguity inherent in, the HRSA patient definition. In the October 1996 Final Notice, HRSA considered several comments regarding the "eligible patient" definition. One commenter asserted that "[p]rivate patients of a physician who is under a contract to provide services to a covered entity should be considered patients of the entity."¹² HRSA agreed that "[a] physician, under contract with a covered entity, may see an individual and provide care for a medical indication," but noted that *"if care is provided outside of the contractual arrangement with the covered entity, the individual would not be considered a patient of the entity"* (emphasis added). *Id.* Further, HRSA emphasized that entity health record documentation and responsibility for care provided *must* remain with the covered entity.¹³

On January 26, 2001, Thomas Morford, Deputy Administrator for HRSA, responded to a request by the Public Hospital Pharmacy Coalition clarifying the definition of an eligible patient for 340B Program Disproportionate Share Hospitals (DSH). In this letter (the "Morford Letter"), HRSA acknowledged that "where the dispensing pharmacy is included on the covered entity's Medicare cost report but the physician's services are not, there are circumstances where it would be permissible for the pharmacy to dispense drugs purchased at a 340B discount." Where a patient initiates care at an eligible hospital and pursues additional care through non-cost report clinics, the patient is eligible to receive 340B drugs so long as the continuing non-cost report care bears

⁹ See GAO Report, GAO-11-836 (Sept. 23, 2011).

¹⁰ An individual will not be considered a patient of the Hospital if the only health care service received by the individual from the Hospital is the dispensing of a drug for subsequent self-administration or administration in the home setting. 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).

¹¹ 42 U.S.C. § 256b(a)(5)(B); 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996) (emphasis added).

¹² 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).

¹³ *Id.*

a proximate relationship to the hospital care in both type and time, and the patient fills the prescription at the hospital's cost report pharmacy. The Morford Letter provides the following example:

"A [covered entity] hospital pharmacy on the hospital's Medicare cost report may dispense 340B drugs, for example, to a diabetic who seeks [covered entity] hospital emergency room care for a diabetes crisis, and then receives a prescription as a result of follow up diabetes care from a non-cost report clinic. If the same individual returned to the clinic two years later with an unrelated complaint, for example, HRSA would view the medical relationship as sufficiently attenuated to not classify the individual as a 340B patient."

The Morford Letter concludes with "we certainly hope that this clarification of policy regarding [covered entity] hospital patient eligibility will assist you in advising the Coalition on appropriate procedures for complying with 340B Drug Discount Program guidelines."

340B Program covered entities relied upon the publicly available guidance on the patient definition issued by HRSA, including the 2001 clarification of its Deputy Administrator.

In 2007, HRSA issued a Notice to clarify the definition of "eligible patient" under the 340B Program; however, never finalized or formally adopted this guidance.¹⁴

While the industry anticipated that the new guidance might narrow the eligible patient definition, the definition as it currently exists in the Omnibus Guidance directly conflicts with prior guidance and substantially narrows the category of patients eligible to receive 340B drugs. Under the new definition, an individual would be considered a patient of a covered entity if the individual, on a prescription-by-prescription basis, meets the following six conditions:

- 1) The individual receives a healthcare service at a 340B-eligible facility or registered clinic site;
- 2) The individual receives a healthcare service provided by a covered entity provider who is either employed by or who is an independent contractor for the covered entity, such that the covered entity may bill for the services provided;
- 3) The individual receives a drug that is ordered or prescribed by the covered entity as a result of the services described in #2 above;
- 4) The individual receives services consistent with the designated federal grant, project designation or contract;
- 5) The drug that is ordered or prescribed pursuant to an outpatient hospital service; and
- 6) The individual's records are accessible by the covered entity that is responsible for care.

Under the first criterion, HRSA stated, in contrast to prior guidance, that: "An individual who sees a physician in his or her private practice which is not listed on the public 340B database or any other non-340B site of the covered entity, even as follow-up to care at a registered site, would not be eligible to receive 340B drugs for the services provided at these non-340B sites."¹⁵ This new guidance is a direct retraction of the guidance contained in the Morford Letter and is contradictory to the 1996 guidance. Under

¹⁴ 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).

¹⁵ 80 Fed. Reg. 52300, 52306 (Aug. 28, 2015).

this new standard, only prescriptions written by physicians at the covered entity or a registered “provider-based” practice of a covered entity would be eligible. The use of telemedicine, however, where the covered entity prescribes the drug for a patient during a telehealth consultation at a physician’s private practice, would qualify as long as the practice is permitted under state and federal law. Additionally, HRSA stated that health care services provided by a health care organization that has an affiliation arrangement with the covered entity, even if the covered entity maintained access to the patient’s records, would not qualify.

Similar to the first criterion, under the second criterion HRSA elaborated: “If a patient is referred from the covered entity for care at an outside provider and receives a prescription from that provider, the drug in question would not be eligible for a 340B discount.”¹⁶ Again, this is a direct departure from the industry guidance contained in the Morford Letter.

The third criterion clarifies that in the case of OPICs (Outpatient Infusion Centers), “the infusion of a drug alone, without a covered entity provider-to-patient encounter, does not qualify an individual as a patient for purposes of the 340B Program.” The patient must have received the infusion as a result of a health care service provided at the covered entity, or a registered child site, and the prescription must have been written by the covered entity provider.

In relation to the fifth criterion, HRSA noted that an individual is only considered a patient of the covered entity if that patient received a health care service that was billed as outpatient. This means that when a patient receives an inpatient hospital service from a covered entity and is discharged with prescriptions for outpatient drugs and an order for outpatient follow up care, the patient is not eligible to receive 340B drugs because the health care service to which those prescription drugs relate was an inpatient, rather than an outpatient, hospital service.

This expanded 6-part test is substantially more onerous to meet than HRSA’s previous 3-part test and further, directly conflicts with previous guidance issued by HRSA. If this new patient definition is finalized, we expect that many 340B covered entities will be significantly impacted and see a significant decrease in the number of patients eligible to receive 340B discounted drugs. This decrease will result in higher pharmaceutical drug costs for these covered entities and potentially significant economic consequences.

Increased 340B Program Enforcement Expected

Perhaps even more troubling is HRSA’s repeated assertion throughout the Omnibus Guidance that it merely “clarified” current 340B Program guidances.”¹⁷ The 340B statute does not define what individuals qualify as eligible patients, and no regulations have ever been promulgated, leaving only reference to interpretative rulemakings. While the purpose of interpretative rules is to provide clarification for underlying statutes or regulations and generally, interpretative rules create no enforceable rights or obligations, the concern is that both the drug manufacturers and HRSA itself may view the Omnibus Guidance as merely clarifying, rather than changing, its historic interpretations. Typically, a change in a statute or regulation only applies that change prospectively, whereas clarifications to a statute or regulation retroactively apply the interpretation. The Omnibus Guidance provides:

“In its clarification of what constitutes a violation of Section 340B(a)(5)(B) of the PHS Act, HHS also is proposing its interpretation of Section 340B(a)(5)(D). Section 340B(1)(5)(D) states a covered entity violating [the section] shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug. *The sale or*

¹⁶ Id. at 52306-52307.

¹⁷ 80 Fed. Reg. 52300 (Aug. 28, 2015) (emphasis added).

transfer of 340B drugs to an individual not meeting the criteria in this section of the proposed guidance is considered diversion.”¹⁸

In the event that drug manufacturers, or HRSA, attempt to apply the new patient definition retroactively, 340B hospitals should challenge the lack of enforcement authority associated with interpretative rules and underscore the drastic change in position taken by HRSA compared to historic guidance.

In addition to the change to the eligible patient definition, the Omnibus Guidance addressed hospital eligibility criteria, eligibility of off-campus facilities, and compliance requirements for contract pharmacy arrangements, amongst other issues. 340B covered entities are encouraged to carefully review the Omnibus Guidance and evaluate the impact of these new interpretations on the entity's 340B Program. Public comments on the Omnibus Guidance may be submitted up to October 27, 2015. For covered entities that are members of 340B Health, a free webinar is being offered on key provisions of the guidance on Tuesday, September 1, 2015. There has been a ramping up of enforcement and audits under the 340B Program in recent years, and the release of this new guidance is likely to further intensify focus in this area. It will be critical for 340B covered entities to carefully review their 340B policies and procedures and prepare themselves for the inevitable HRSA or manufacturer audit. Pillsbury attorneys have experience with respect to the representation of 340B covered entities, both in terms of proactive compliance and post-conduct guidance.

If you have any questions about the Omnibus Guidance and its applicability, please contact Gerry Hinkley or Kristi Kung with Pillsbury's Health Care Practice Group.

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¹⁸ 80 Fed. Reg. 52300, 52306 (Aug. 28, 2015) (emphasis added).