



**hfma**<sup>™</sup>

healthcare financial management association

HFMA would like to thank Susan Banks of King & Spalding LLP's for providing this executive summary of the Health Resources and Services Administration's (HRSA) proposed 340B "Mega-Guidance."

### ***340B Omnibus Guidance Packs a Punch*** – by Susan Banks

On August 27, 2015, the Health Resources and Services Administration ("HRSA") released its long-awaited, proposed Omnibus Guidance on the 340B Drug Pricing Program ("Proposed Guidance"). 80 Fed. Reg. 52300 (Aug. 28, 2015). The 340B Program provides significant discounts to various types of hospitals and non-hospital, nonprofit healthcare organizations that have certain Federal designations or receive certain Federal grants (collectively, "covered entities") on the purchase of "covered outpatient drugs" that are furnished to eligible patients. 42 U.S.C. § 256b.

The Proposed Guidance "clarifies many current 340B Program guidances," but also includes several significant changes that depart significantly from current policies. Because it is not a formal agency rulemaking, if finalized, the Proposed Guidance will not carry the force of regulation. Nevertheless, for practical purposes, HRSA's interpretive guidance sets the rules for 340B Program participants, and the stakes are high for noncompliance. HRSA is encouraging all stakeholders to provide comments on the Proposed Guidance. Comments are due by October 27, 2015. Some of HRSA's most significant proposals are summarized below.

#### **The "Patient" Definition (80 Fed. Reg. at 52306-08, 52319)**

Under the 340B Program, 340B drugs may be furnished only to patients of the covered entity. The statutory prohibition against diversion prohibits the resale or other transfer of 340B drugs to anyone who is not a "patient." 42 U.S.C. § 256b(a)(5)(B). In the Proposed Guidance, HRSA proposes to replace the current, three-part definition of "patient" (61 Fed. Reg. 55156, 55157-58 (Oct. 24, 1996)) with a six-part definition. HRSA proposes that an individual will qualify as a "patient" on a prescription-by-prescription, order-by-order basis if all of the following conditions are met:

1. *The individual receives healthcare services at a facility that is registered under the 340B Program and listed in the public 340B database.—Follow-up care furnished by a physician in his or her non-340B private practice would not qualify.*

2. *The individual receives healthcare services from a practitioner who is either employed by or is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the practitioner.*
3. *The individual receives a drug that is ordered or prescribed by the covered entity practitioner as a result of such services.*—HRSA states that if a covered entity’s “only relationship” to the individual is the “dispensing or infusion of a drug alone, without a covered entity provider-to-patient encounter,” then individual would not be considered a “patient.” This would mean that an individual receiving chemotherapy is only a “patient” of the entity at which the cancer was diagnosed and chemotherapy was prescribed. This is a significant change from current 340B policy.
4. *The individual receives healthcare services consistent with the range of services designated in the federal grant, project, or contract, if applicable, that qualifies the healthcare provider to participate in the 340B Program.*
5. *The individual receives the drug pursuant to a health care service classified as outpatient.*—Under the Proposed Guidance, the individual must be classified as an outpatient when the drug is ordered or described, as determined by how the health care services resulting in the prescription are billed to the individual’s health insurance. This is another significant change in current 340B policy, and would eliminate 340B eligibility of discharge prescriptions.
6. *The individual has patient records that are accessible by the covered entity and demonstrate that the covered entity is responsible for the patient’s care.*

HRSA reiterates its position that employees of covered entities are not eligible “patients” of the covered entity unless the employees also receive direct health care services from the covered entity such that they meet the definition of “patient.”

**“Covered Outpatient Drugs” (80 Fed. Reg. at 52305-06, 52319)**

Drug discounts under the 340B Program apply only to “covered outpatient drugs,” which term is defined through reference to the Medicaid statute. *See* 42 U.S.C. § 256b(b)(2); Social Security Act § 1927(k)(2)–(3). The Medicaid definition excludes drugs that are “provided as part of, or as incident to and in the same setting as” certain listed services and for which Medicaid bundles payment for the drug, rather than making payment “as direct reimbursement for the drug.” *Id.* at § 1927(k)(3). Thus, in the Proposed Guidance, HRSA proposes that drugs provided as part of or incident to a service for which Medicaid bundles payment for the drug would not be “covered outpatient drugs” for 340B purposes. Whereas, “a drug provided as part of a hospital outpatient service which is billed to any other third party or directly billed to Medicaid would still qualify as a covered outpatient drug.”

Some in the manufacturer community argue that HRSA’s proposal would expand the scope of “covered outpatient drugs,” which currently excludes all drugs for which payment is bundled *by any payor*. Under HRSA’s proposed definition, a drug prescribed to a Medicare

outpatient who is subsequently admitted as an inpatient within the “3-Day Payment Window” (42 C.F.R. § 412.2(c)(5))—and for which drug Medicare would therefore bundle payment into payment for the inpatient admission—would presumably still qualify for 340B pricing.

### **Prohibition of Duplicate Discounts (80 Fed. Reg. at 52308-09, 52319-20)**

The 340B statute prohibits “duplicate discounts,” which means that a drug manufacturer cannot be required to discount the same prescription twice, under both the 340B Program and pursuant to a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A). Covered entities that dispense 340B drugs to Medicaid patients (*i.e.*, “carve in”) are listed in HRSA’s 340B Medicaid Exclusion File. Manufacturers are not required to provide Medicaid drug rebates with respect to any drugs purchased with Medicaid billing numbers or NPIs listed in the Exclusion File.

Section 2501(c) of the Affordable Care Act extended Medicaid drug rebate eligibility to covered outpatient drugs furnished to patients of Medicaid managed care organizations (“MCOs”). This Proposed Guidance is the first time HRSA has squarely addressed the issue of how to prevent duplicate discounts for outpatient drugs furnished to Medicaid MCO patients. HRSA proposes to expand the 340B Medicaid Exclusion File to include Medicaid MCOs. HRSA seeks comments on this proposal and on possible mechanisms for updating and supplementing the Exclusion File that could allow for greater purchasing flexibility.

### **Contract Pharmacy Arrangements (80 Fed. Reg. at 52310-11, 52320-21)**

Covered entities are permitted to enter into arrangements with one or more contract pharmacies to dispense 340B drugs to patients, instead of or in addition to dispensing such drugs through the covered entity’s own in-house pharmacy. In the Proposed Guidance, HRSA emphasizes the need for a written contract between the covered entity and the contract pharmacy that adequately addresses Program compliance issues, including, but not limited to, systems to prevent diversion and duplicate discounts. Covered entities that wish to “carve-in” Medicaid fee-for-service or MCO patients at their contract pharmacy sites must first submit a written agreement with their contract pharmacy *and* State Medicaid agency to HRSA for preapproval.

HRSA reiterates in the Proposed Guidance, consistent with its current guidance regarding contract pharmacy services (75 Fed. Reg. 10272 (March 5, 2010)), that covered entities should conduct annual audits of contract pharmacy arrangements through independent auditors. HRSA also reinforces its position that covered entities are “expected to” conduct quarterly reviews of contract pharmacies’ 340B dispensing records to ensure that there have been no diversions or duplicate discounts.

### **Concluding Thoughts**

Additional topics addressed in the Proposed Guidance include:

- Program eligibility and registration requirements for covered entities and “child sites,” including termination of enrollment (80 Fed. Reg. at 52301-05, 52316-19);
- Exceptions to the group purchasing organization (“GPO”) prohibition for certain covered entity types (80 Fed. Reg. at 52304-05, 52318-19);

- Manufacturer refunds to covered entities (80 Fed. Reg. at 52311-13, 52321-22);
- Establishment of a five-year records retention requirement for Program participants (80 Fed. Reg. at 52309-11, 52320-21);
- “Qualified payments” required under the rebate option for AIDS drug assistance programs (“ADAPs”) (80 Fed. Reg. at 52313-14, 52322); and
- Program integrity and audit requirements and procedures (80 Fed. Reg. at 52314-16, 52322-23).

HRSA’s Proposed Guidance provides some clarification and also proposes some significant changes to the 340B Program. Providers should keep in mind that at this point, the Proposed Guidance is only proposed—providers should not modify their business processes in reliance upon new policies articulated in the Proposed Guidance. To the extent, however, that the Proposed Guidance rearticulates many existing HRSA recommendations, covered entities should take notice and consider whether their systems can be tightened or tweaked to ensure more effective 340B compliance. Stakeholders are strongly encouraged to take advantage of this opportunity to submit comments to HRSA on this Proposed Guidance, which touches so many aspects of the 340B Program.

---

Susan Banks is an associate in the healthcare practice group in King & Spalding LLP’s Washington, D.C. office. She may be reached at [sbanks@kslaw.com](mailto:sbanks@kslaw.com) or (202) 626-2953.