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**Practice Groups:****Healthcare****FDA**

## HRSA Issues 340B Program Omnibus Guidance

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On August 28, 2015, the Health Resources and Services Administration (“HRSA”) published proposed Omnibus Guidance (the “Proposed Guidance”) governing policies related to section 340B of the Public Health Service Act (“PHSA”), commonly referred to as the “340B Drug Pricing Program” (the “340B Program”).<sup>1</sup> HRSA is accepting public comments on the wide-ranging changes outlined in its Proposed Guidance through October 27, 2015.

The Proposed Guidance introduces significant changes that would reduce the 340B Program’s scope as a result of revisions to the definition of an eligible patient and other proposed changes. HRSA proposes covered entities participating in the 340B Program would now have to judge patient eligibility to use a drug purchased at 340B discounted pricing on a “prescription-by-prescription or order-by-order basis,” subject to new standards related to where the prescription is ordered, the prescriber’s relationship to the covered entity, the scope of services provided to the patient, and whether the patient is considered inpatient or outpatient at the time the drug is prescribed or ordered.

The Proposed Guidance also addresses a number of practical and operational considerations for 340B Program participants that will present new challenges to 340B covered entities, including changes related to the definition of covered outpatient drugs eligible for purchase through the 340B Program; preventing duplicate discounts for Medicaid MCO beneficiaries; compliance with the group purchasing organization prohibition; oversight and compliance of contract pharmacies; and repayments, termination, and re-enrollment of covered entities and manufacturers as a result of compliance reviews and eligibility changes.

This Client Alert contains a summary of the Proposed Guidance, and highlights significant changes and their potential impact on 340B Program participants.

### Background

In April 2014, HRSA sent the Office of Management and Budget comprehensive 340B Drug Pricing Program requirements as a draft “mega-regulation.” Though never publicly released, observers widely expected these regulations would provide greater clarity about key 340B Program compliance elements. However, after a federal district court concluded in May 2014 that HRSA lacked statutory authority to issue regulations related to the treatment of orphan drugs under the 340B Program, HRSA withdrew its draft “mega-regulation.”<sup>2</sup>

In response, HRSA reissued the orphan drug regulations as an “interpretive rule,” now the subject of pending litigation regarding HRSA’s interpretation of the orphan drug rule, as well as its authority under the Administrative Procedure Act to issue the orphan drug guidance.<sup>3</sup> HRSA is now proposing that its “mega-regulation” be adopted as agency guidance, rather

<sup>1</sup> 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).

<sup>2</sup> *Pharmaceutical Res. & Mfrs. of Am. v. U.S. Dep’t of Health and Human Servs.*, No. 13-1501 (D.D.C. May 23, 2014); see also <http://www.reginfo.gov/public/do/eoDetails?rrid=123970>, visited September 01, 2015, regarding withdrawal of the 2014 Proposed 340B Drug Pricing Program Regulations.

<sup>3</sup> *PhRMA v. HHS*, Docket No. 1:14-CV-01685-RC (D.D.C. Oct. 9, 2014).

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than a rule. If finalized,<sup>4</sup> HRSA's authority to issue such guidance may be similarly challenged. Of further note, as a result of the change from a regulation to agency guidance, despite the breadth of the potential changes, HRSA did not provide an economic analysis of the impact of these changes, which could be significant for some 340B stakeholders.

In the Proposed Guidance, HRSA did not address whether current arrangements established under existing HRSA guidance would be grandfathered or to what extent 340B stakeholders would be provided a window of time, if any, to come into compliance with the new requirements when finalized. Given the broad nature of the changes, and the likelihood that they will require arrangements to be restructured and drug tracking processes to be modified, HRSA likely will need to provide some period of time for 340B stakeholders to come into compliance, as it ultimately did with its 2013 Program Notice related to the GPO Prohibition.<sup>5</sup>

HRSA issued the Proposed Guidance subject to notice and comments, which are due October 27, 2015.<sup>6</sup>

### Individuals Eligible to Receive 340B Program Drugs

*The Eligible Patient Definition.* Under Section 340B of the PHSA, a covered entity participating in the 340B Program may only use such drugs for a "patient of the entity." The term "patient," as used therein, is not further defined in the statute; rather, the term is further defined in HRSA guidance published in 1996.<sup>7</sup> Under the 1996 guidance, an individual is deemed to be a "patient" of the covered entity if:

1. the covered entity has an established relationship with the individual,
2. the individual receives a health care service or range of services from the covered entity consistent with the service for which grant funding or look-alike status has been provided to the entity,<sup>8</sup> and
3. the health care professional providing the services is employed by or provides health care under contractual or other arrangements with the covered entity, but responsibility for care remains with the entity.

In the Proposed Guidance, HRSA proposes to limit the definition of an eligible patient by expanding these three criteria to six and requiring assessment of whether an individual is a "patient" on a per-prescription or per-order basis. Specifically, the Proposed Guidance states as follows:

Section 340B(a)(5)(B) of the PHSA prohibits covered entities from reselling or otherwise transferring a 340B drug to a person who is not a patient of the entity. HHS interprets this

<sup>4</sup> In 2007, HRSA issued proposed guidance on the definition of an eligible patient that also proposed to narrow the current definition. However, those changes were never issued as final guidance. 72 Fed. Reg. 1543 (January 12, 2007).

<sup>5</sup> HRSA, Statutory Prohibition on Group Purchasing Organization Participation, Release No. 2013-1 (Feb. 7, 2013), available at <http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf>. While originally released in February 2013, HRSA ultimately granted 340B covered entities six months to come into compliance with the Program Notice's clarified standards, given the significant practical and operational impacts on covered entities.

<sup>6</sup> 80 Fed. Reg. at 52300.

<sup>7</sup> Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

<sup>8</sup> A covered entity participating in the 340B Program in one of the hospital covered entity categories is not subject to this limitation, unless enrolled in the 340B Program only on the basis of a federal grant, contract, or project.

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section to include all patients that meet all of the following criteria on a prescription-by-prescription or order-by-order basis:

1. The individual receives a health care service at a covered entity site which is registered for the 340B Program and 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 the 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 (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.<sup>9</sup>
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.
6. The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate 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 is met for each 340B drug.

This new definition of patient is considerably narrower than both the current definition and HRSA's 2007 proposed definition (never implemented),<sup>10</sup> and includes the following new restrictions:

- *Eligible Prescriber.* HRSA notes that having privileges or credentials at a covered entity is not sufficient to create the required covered entity-patient relationship and, most notably, limits a covered entity's ability to utilize 340B drugs to prescriptions by employed and contracted physicians for whom the covered entity "may bill." Under the current definition of an eligible patient and other HRSA guidance, a covered entity was permitted to use 340B drugs to fill prescriptions from health care providers under consultation and referral arrangements with a covered entity, which covered entities sometimes establish with non-employed or contracted specialist physicians in the community.<sup>11</sup>

<sup>9</sup> As with the current eligible patient definition, a covered entity participating in the 340B Program in one of the hospital covered entity categories is not subject to this limitation, unless enrolled in the 340B Program only on the basis of a federal grant, contract, or project. Under the Proposed Guidance, HRSA clarifies that this requirement extends to each child site of a covered entity.

<sup>10</sup> Notice Regarding Section 602 of the Veteran's Health Care Act of 1992 Definition of "Patient," 72 Fed. Reg. 1543 (Jan. 12, 2007).

<sup>11</sup> Until recently, Apexus, HRSA's 340B Program exclusive prime vendor, posted published guidance on its website related to establishing compliant referral relationships, which included a sample Referral Letter Agreement between covered entities and community providers. Such arrangements also were explicitly contemplated in the so-called Morford

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In addition, while it is not clear whether the covered entity must actually bill as a condition precedent based on HRSA's use of the term "may bill," it appears that HRSA may require a covered entity to meet a billing requirement for an eligible prescriber. If so, this would have the consequence—potentially unintended—of preventing contracted physician groups from being treated as eligible prescribers under the 340B Program, even though they work exclusively in a hospital's outpatient department under contract, if such groups bill and collect their own professional fees under a subsidy or guarantee model (e.g., emergency department providers).

- *Eligible Site.* Similar to the restriction on eligible providers, HRSA appears to intend requiring that the eligible prescriber must also be practicing within the parent covered entity or from an enrolled 340B-eligible child site at the time of the writing of the prescription.<sup>12</sup> HRSA clarifies in commentary, however, that the use of telemedicine, telepharmacy, remote and other health care service arrangements, such as medication therapy management, are permitted where a covered entity prescribes the drug, provided the practice is authorized under state and federal law and the drug purchase otherwise complies with the 340B Program.
- *No Eligibility for Infusions Only.* The Proposed Guidance clarifies that infusion of a drug alone, in the absence of a provider-patient encounter, does not render a patient eligible to receive a 340B drug. While many covered entities would otherwise have had an employed or contracted physician review and rewrite these prescriptions from outside providers, it may be difficult for covered entities to meet each element of the new six part test.
- *Inpatient/Outpatient Status Changes.* HRSA proposes that a patient's status as inpatient or outpatient for 340B Program eligibility purposes must be determined by how the claim for health care services is billed to the patient's insurance or third-party payor. This new guidance appears to prohibit prescriptions written at the time of an inpatient discharge to be filled with a 340B drug, even if the prescription is filled after the patient is no longer an inpatient. This also appears to preclude 340B drugs for outpatient services where the patient's payor requires the hospital to bill such services as part of the patient's inpatient stay. For example, a Medicare billing requirement known as the "72-hour Rule" requires certain outpatient services performed within 72 hours of an inpatient stay to be billed as part of the inpatient service. Both outcomes are contrary to current guidance, which does not instruct covered entities to rely on how a claim is billed to classify a patient, but rather, permits a covered entity to rely on the status of the patient as an outpatient at the time the prescription is filled.<sup>13</sup>

*Exceptions to the Proposed Eligible Patient Definition.* In the Proposed Guidance, HRSA proposes two exceptions to the new six part test: (1) an individual enrolled in a Ryan White

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Letter issued in 2001 by HRSA to lawyers representing 340BHealth (formerly "Safety Net Hospitals for Pharmaceutical Access" or "SNHPA"). See [www.340bhealth.org/files/Morford-Letter-1.26.01.pdf](http://www.340bhealth.org/files/Morford-Letter-1.26.01.pdf). Likewise, the 2007 proposed eligible patient definition also contemplated "health care under contractual or other arrangements (e.g., referral for consultation)."

<sup>12</sup> While commentary implies that the script must be written at the eligible site, it is noteworthy that in the six-part eligibility test, criterion (3) only refers back to criterion (2) as to the prescription itself. In this regard, it may be possible to read criterion (1) to be required only at some point prior to the writing of the prescription, although commentary would suggest that was not HRSA's intent.

<sup>13</sup> See, e.g., the HRSA website at Eligibility & Registration: Eligible Drugs, available at <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

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HIV/AIDS AIDS Drug Assistance Program will be considered an eligible patient and (2) in recognition of the “unique circumstances” that exist, HRSA proposes to “allow certain flexibilities” for demonstrating eligible patient status during declared public health emergencies (such as limited medical record documentation or the use of 340B drugs at a site not listed in the 340B database).<sup>14</sup>

### 340B Eligibility Standards

Among other eligibility criteria and types, Section 340B of the PHS Act outlines three types of hospitals that may participate in the 340B Program:

- A hospital that is owned or operated by a state or local government.
- A hospital that is a public or private non-profit corporation that is formally granted governmental powers by a unit of state or local government.
- A hospital that is a private non-profit hospital that has a contract with a state or local government to provide health care services to low-income individuals who are not entitled to Medicare or Medicaid benefits.<sup>15</sup>

HRSA clarifies that it will only enroll hospitals under the first category that are wholly owned by a state or local government and recognized as such by the Internal Revenue Service or other federal entity documentation, or that are operated through an arrangement under which the state or local government is the hospital's sole operating authority.

Under the second category, HRSA proposes that a hospital must be formally granted a power typically exercised by the state or local government (such as the power to tax, issue government bonds and act on behalf of the government) through state or local statute or regulation, creation of a public corporation or development of a hospital authority or district to provide health care to a community on behalf of the government. HRSA further clarifies that it will exclude hospitals granted powers generally granted to private persons or corporations upon meeting licensure requirements, such as a license to practice medicine or provide health care services commercially.

With regard to the last category, HRSA has been criticized in prior reviews of the 340B Program for failing to better define what constitutes a “qualifying contract.”<sup>16</sup> However, HRSA's Proposed Guidance does not make major changes to this criterion, though it does clarify that a qualifying contract “should create enforceable expectations for the hospital for the provision of health care services, including the provision of direct medical care.”<sup>17</sup>

### Duplicate Discounts and Medicaid MCOs

Pharmaceutical manufacturers that want to participate in the Medicaid program and have their drug reimbursed by state Medicaid agencies must participate in both the Medicaid Drug Rebate Program (which allows states to collect a rebate on drugs provided to Medicaid patients) and the 340B Program (which requires manufacturers to sell covered outpatient

<sup>14</sup> 80 Fed. Reg. at 52307.

<sup>15</sup> 42 U.S.C. 256b(a)(4)(L)(i).

<sup>16</sup> See, e.g., Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program* at 14–15 (May 2015), available at <http://www.medpac.gov/documents/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>.

<sup>17</sup> 80 Fed. Reg. at 52301.

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drugs to 340B covered entities at no greater than the 340B ceiling price). However, the 340B statute prohibits “duplicate discounts” where a state receives a rebate on a drug provided to a Medicaid patient, and that same drug was discounted under the 340B Program.<sup>18</sup> Initially limited to Medicaid fee-for-service (“FFS”) patients, the Affordable Care Act extended Medicaid drug rebate eligibility to certain Medicaid Managed Care covered outpatient drugs and, in turn, the prohibition on duplicate discounts was also extended to covered outpatient drugs dispensed by Medicaid Managed Care Organizations (“MCOs”).<sup>19</sup>

To prevent such duplicate discounts on drugs subject to Medicaid rebates for FFS patients, HRSA established a Medicaid Exclusion File,<sup>20</sup> where a covered entity must report its Medicaid billing number and/or National Provider Number (“NPI”) and whether it will “carve in” (use 340B Program pricing for Medicaid FFS patients) or “carve out” (not use 340B Program pricing for Medicaid FFS patients).

*Medicaid MCO Exclusion File.* As to Medicaid MCO beneficiaries, states have used a variety of methods to track such purchases, and HRSA had not to date developed a policy or mechanism to report carve-in or carve-out status for Medicaid MCOs. Under the Proposed Guidance, HRSA is proposing that covered entities may make carve-in/carve-out determinations for Medicaid MCO patients that are separate from similar determinations regarding Medicaid FFS patients, and separate carve-in/carve-out decisions by covered site and Medicaid MCO, and that such information “may be made available publicly through an Exclusion File or other mechanism.”<sup>21</sup>

*Contract Pharmacies & Medicaid MCOs.* In addition, HRSA is proposing that contract pharmacies be presumptively required to carve out Medicaid FFS (which is existing policy)<sup>22</sup> and Medicaid MCOs. HRSA further proposes, if the covered entity wishes its contract pharmacies to dispense 340B drugs to Medicaid beneficiaries, it must provide HRSA with a written agreement with its contract pharmacy and state Medicaid agency or Medicaid MCO describing a system to prevent duplicate discounts, which HRSA must approve prior to the contract pharmacy carving in Medicaid for either FFS or MCO patients. Once approved, the contract pharmacy would be listed on the 340B database as dispensing 340B drugs to Medicaid FFS and/or MCO patients.

The change is noteworthy as—notwithstanding HRSA guidance suggesting that managed care plans should not have a right to a portion of the 340B Program discount<sup>23</sup>—many managed care plans have sought such discounts on 340B Program drugs. By requiring an agreement with the Medicaid MCO regarding duplicate discounts, managed care plans may use the need for such agreement as leverage to request discounted pricing on all 340B Program drugs dispensed by the covered entity and/or contract pharmacy.

<sup>18</sup> 42 U.S.C. 256b(a)(5)(A)(i).

<sup>19</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501(c), 124 Stat. 119, 308 (2010).

<sup>20</sup> Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (June 23, 1993); see also HRSA, Release No. 2013-2, Clarification on Use of the Medicaid Exclusion File (Feb. 7, 2013).

<sup>21</sup> 80 Fed. Reg. at 52320.

<sup>22</sup> HRSA, Clarification on Use of the Medicaid Exclusion File, Release No. 2014-1 (Dec. 12, 2014), available at <http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf>.

<sup>23</sup> Apexus, 340B & Medicaid (May 7, 2015), available at [https://docs.340bvp.com/documents/public/resourcecenter/340B\\_Medicaid.pdf](https://docs.340bvp.com/documents/public/resourcecenter/340B_Medicaid.pdf) (warning regarding providers of discriminatory contracts with managed care plans offering lower reimbursement to 340B entities in an attempt to capture part of the 340B margin).

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### GPO Prohibition Guidance

The so-called “GPO Prohibition” prohibits certain covered entities—disproportionate share hospitals (“DSH”), freestanding cancer hospitals and children’s hospitals—from purchasing covered outpatient drugs through a group purchasing organization (“GPO”), though they may purchase non-covered drugs, such as drugs dispensed to inpatients, through a GPO.<sup>24</sup> The GPO Prohibition has presented challenges to covered entities in tracking usage of 340B Program drugs in mixed-use clinical settings (particularly for inpatient/outpatient status changes) and drugs reimbursed under a bundled payment mechanism.

*GPO Prohibition Exceptions.* In the Proposed Guidance, HRSA proposes three specific exceptions in which a covered entity may purchase covered outpatient drugs under a GPO arrangement without violating the GPO Prohibition:

- For use at an off-site outpatient facility not participating in the 340B Program or listed on the 340B database, as long as (i) drugs for that off-site facility are purchased under a purchasing account separate from the covered entity parent site or any enrolled child site, and (ii) the GPO-purchased drugs are never used at the parent or any registered child site. This exception is not new, and appears in previously issued HRSA guidance.<sup>25</sup>
- For use with inpatients whose status is subsequently changed to outpatient by a third party, such as an insurer or Medicare Recovery Audit Contractor, or pursuant to hospital review, provided the covered entity maintains sufficient documentation of the status change. This change is related to HRSA’s proposed change (discussed above) to treat the manner in which the patient’s care is billed (inpatient or outpatient) as determinative of the patient’s eligibility status. A patient’s status as billed may be challenged by a payor or auditor and subsequently switched to outpatient, triggering the GPO Prohibition on a prescription for a patient who was deemed an inpatient at the time and whose drug usage was then accumulated to a GPO account.
- In cases in which a covered entity is not able to access a drug at the 340B price or at wholesale acquisition cost (“WAC”), and such inaccessibility would disrupt patient care, provided the covered entity maintains documentation of the facts surrounding the purchase and provides HRSA with the drug’s name, manufacturer, and a brief description of its attempts to purchase the drug at the 340B or WAC price prior to purchasing through the GPO. HRSA maintains a similar process for reporting such issues, but the proposed change would better clarify that usage in this context is not in violation of the GPO Prohibition.<sup>26</sup>

<sup>24</sup> See 42 U.S.C. § 256b(a)(4)(L)(iii).

<sup>25</sup> See footnote 5.

<sup>26</sup> Currently, HRSA states that if a covered entity subject to the GPO prohibition is unable to purchase a covered outpatient drug at the 340B price, it must provide written notification to OPA immediately detailing the drug(s) involved, the manufacturer, and the process by which the entity was notified that the purchase could not be made. In connection with such notification, HRSA advises covered entities that the agency “reviews all allegations brought to its attention to ensure compliance with program requirements.” See HRSA FAQs: 340B Implementation, available at <http://www.hrsa.gov/opa/faqs/>.

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### Definition of a Covered Outpatient Drug

Prior HRSA guidance suggested that a drug that might otherwise be considered a covered outpatient drug under the 340B Program could not be treated as such if reimbursed by Medicaid under a bundled payment mechanism.<sup>27</sup> 340B stakeholders understood this to apply to such drugs across the board, and, for example, some drug manufacturers took the position their drug was no longer subject to 340B Program Pricing and refused to sell at 340B pricing.<sup>28</sup>

In comments to the Proposed Guidance, HRSA appears to be limiting its prior approach and suggesting that the bundled payment rule only applies when a drug is reimbursed by Medicaid under a bundled payment methodology. As drafted, HRSA's comment suggests that a drug billed to any other third party would still qualify as a covered outpatient drug and be subject to the GPO Prohibition. Likewise, if billed to Medicaid under a bundled methodology, pursuant to the Proposed Guidance, a covered entity could not utilize 340B pricing.

### Contract Pharmacy Registration and Oversight Requirements

HRSA took no action in the Proposed Guidance to fundamentally limit the number or geographic scope of contract pharmacy arrangements a covered entity may maintain, and otherwise affirmed the ability to work with contract pharmacies to extend the benefits of the 340B Program. HRSA did, however, affirm its position that covered entities maintain responsibility for the compliance of their contract pharmacy partners and, as such, further strengthens covered entities' obligations regarding contract pharmacy oversight.

*Contract Pharmacy Registration.* HRSA proposes to restrict authority to manage contract pharmacy data on the 340B Database solely to the covered entity during registration and thereafter. Moreover, HRSA advises covered entities that they must have written contracts with contract pharmacies, and that such contracts must carefully comply with standards identified in the Proposed Guidance, and covered entities should be prepared to attest to these compliance standards upon registration.

*Contract Pharmacy Oversight.* Contract pharmacy guidance issued by HRSA in 2010 recommended annual audits of contract pharmacies.<sup>29</sup> In the Proposed Guidance, HRSA now "further clarifies the expectations of this recommendation," noting that covered entities should conduct annual audits *of each contract pharmacy location* using an independent auditor. Additionally, HRSA indicates its expectation that covered entities should conduct quarterly reviews of their 340B prescribing records, as compared to the contract pharmacy's 340B dispensing records, again for the purpose of preventing diversion as well as duplicate discounts. As a result of these reviews, HRSA reiterates its expectation that covered entities

<sup>27</sup> See Apexus 340B Prime Vendor Program FAQ ID 1355 (last modified February 25, 2015), available at <https://www.340bpvp.com/resourceCenter/faqSearch.html?N=8&No=60&Ntt&Num=0&category=content> (establishing that a hospital subject to the GPO Prohibition may use a GPO for drugs that are part of/incident to another service and payment is not made as direct reimbursement of the drug, as long as the covered entity interprets the definition of covered outpatient drug referenced in the 340B Statute and decides that drugs do not meet this definition, and further ensures that this decision is defensible, consistently applied in all areas of the entity, documented in policy/procedures and auditable).

<sup>28</sup> See 80 Fed. Reg. at 52306 (clarifying that manufacturers may not unilaterally refuse to sell at 340B prices under such circumstances).

<sup>29</sup> Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).



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are responsible for errors associated with contract pharmacies, should correct instances of diversion or duplicate discounts and report corrective action to HRSA.

### 340B Compliance Requirements

The Proposed Guidance contains numerous comments regarding termination and removal procedures for covered entities and contract pharmacies, some of which are summarized below. Likewise, the Proposed Guidance reiterates that, in certain circumstances, a covered entity may be required to repay manufacturers for the value of 340B discounts to which the covered entity was not entitled or the value of rebates paid to state Medicaid agencies as a result of duplicate discounts. In this regard, the overall tenor of the Proposed Guidance suggests an increased likelihood of future compliance enforcement activities.

*Records Retention.* HRSA is proposing a record retention standard for all 340B Program records for a period of not less than five years, including all child sites and contract pharmacies. Current guidance indicates a three-year retention period.

*Covered Entity Compliance Timelines.* In the Proposed Guidance, HRSA establishes an “expectation” that, within 90 days of identifying diversion, covered entities should notify HRSA and affected manufacturers of instances of diversion and, thereafter, “work with manufacturers” to effectuate repayment.

Similarly, with regard to the GPO Prohibition, HRSA encourages manufacturers and covered entities to continue to work together to identify and correct GPO purchasing errors. HRSA appears to establish an expectation that this would be completed within 30 days of purchase for routine credit/rebill corrections, raising the potential that HRSA may conclude the use of that process after 30 days must be reported.

*Notice and Hearing and Removal Procedures.* HRSA proposes to extend a notice and hearing process to allow covered entities to respond to adverse audit findings and other instances of noncompliance, or to respond to the proposed loss of 340B Program eligibility. For example, HRSA notes that violations of the GPO Prohibition may result in a notice and hearing in which the covered entity must demonstrate the violation was an isolated incident, as opposed to a systemic issue. HRSA then suggests covered entities for which a GPO violation is not an isolated incident may be deemed ineligible for the 340B Program and immediately removed.<sup>30</sup> Similarly, HRSA proposes a finding of systemic failure to maintain auditable records for the requisite five-year period<sup>31</sup> may lead to a finding of covered entity ineligibility, but would also first entitle such covered entity to notice and hearing prior to removal.

*Reenrollment after Termination.* The Proposed Guidance proposes that, when removed from the 340B Program for a violation of an eligibility requirement, including the GPO Prohibition requirement, the terminated covered entity may reenroll during the next regular enrollment period after it has satisfactorily demonstrated it will comply with all statutory requirements

<sup>30</sup> Notably, HRSA states in comments that, where a child site has violated the GPO Prohibition and is removed from the 340B Program, the parent site “may be able to remain in the 340B Program” if it can demonstrate that the GPO Prohibition violation was isolated to the child site and that the parent site did not violate the GPO Prohibition, suggesting that HRSA may allow a covered entity to isolate the compliance issue and remedy to the only the child site. 80 Fed.Reg. at 52305.

<sup>31</sup> For a finding of non-systematic failure to maintain records (after notice and hearing procedures), HRSA proposes it may exercise discretion and require repayment rather than removal (e.g., the covered entity generally produces 340B records for patient eligibility but could not produce a record for a particular 340B patient).

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moving forward and has completed, or is in the process of offering, repayment to affected manufacturers, as necessary. HRSA is seeking comments on what type of information a covered entity would be required to submit to HRSA to demonstrate compliance in connection with particular removal scenarios.

### Manufacturer Changes of Note

*New Manufacturer Repayment Obligations.* The Proposed Guidance reiterates that in cases in which a covered entity was charged more than the 340B ceiling price by a manufacturer, the manufacturer must provide a refund or credit to the covered entity equal to the price difference between the sale price and the correct 340B price for that drug, multiplied by the units purchased. In addition, a manufacturer may owe a covered entity a refund or credit in the event of a drug price restatement (which may involve multiple price calculations), which HRSA expects to occur within ninety (90) days of the determination by the manufacturer or HRSA of an overcharge. Like covered entities, HRSA suggests manufacturers also must provide notification and certain information related to such refunds.

*Limited Distribution Networks.* While HRSA recognizes limited distribution networks (“LDNs”) may be required for covered outpatient drugs in certain instances, HRSA is proposing that manufacturers submit a proposed LDN to HRSA in writing before implementation. Such LDN must contain specific elements, and will be reviewed by HRSA to ensure that the manufacturer is treating 340B covered entities the same as non-340B providers. Additionally, HRSA proposes that it may make LDNs publicly available on the 340B website.

### Conclusion

340B Program stakeholders have through October 27, 2015 to comment on the Proposed Guidance. Given the sweeping nature of the changes that could occur upon the issuance and application of final guidance, all 340B stakeholders should review the Proposed Guidance carefully and consider providing comments.

Stakeholders should then closely track the progress of any final guidance, as well as the current challenge to the orphan drug guidance, and any potential challenges to the Proposed Guidance when finalized.

Finally, while the Guidance is only proposed, 340B stakeholders should review their current operations and seek legal advice and counsel as to how best to prepare for any 340B Program changes required upon the issuance of final guidance.

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