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SUMMARY OF HRSA PROPOSED OMNIBUS GUIDANCE ON THE 340B DRUG DISCOUNT PROGRAM

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SUMMARY OF HRSA PROPOSED OMNIBUS GUIDANCE

ON THE 340B DRUG DISCOUNT PROGRAM

INTRODUCTION

In the Federal Register of August 28, 2015, the Health Resources and Services Administration ("HRSA") of the Department of Health and Human Services ("HHS") published an omnibus guidance document to implement the 340B Drug Discount Program (the "Proposed Guidance").[1] This program, which was established in 1992 pursuant to Section 340B of the Public Health Service Act ("PHS Act"),[2] requires a manufacturer of covered outpatient drugs, as a condition of having its drugs be eligible for federal payment under Medicaid and Medicare Part B, to enter into a Pharmaceutical Pricing Agreement ("PPA") with HHS. Under the agreement, the manufacturer is obligated to charge no more than a statutorily defined ceiling price to certain types of purchasers (called "Covered Entities") designated in the statute. The categories of Covered Entities include certain types of specialized clinics that receive federal funding (e.g., HIV/AIDS clinics receiving funding under the Ryan White HIV/AIDS program, black lung clinics, and family planning clinics), and certain types of safety net hospitals as further discussed below. The ceiling price is calculated using pricing data submitted by manufacturers under the Medicaid Drug Rebate Program ("MDRP"), and is intended to provide Covered Entities a discounted price equivalent to that received by Medicaid under the MDRP.[3]

Since the inception of the 340B Program in 1992, HHS has implemented the program by issuing a series of guidances on various topics, typically after notice and comment. The new Proposed Guidance accomplishes the dual purpose of consolidating and updating the previous guidances, and implementing a number of program integrity mandates added to the 340B statute by the Patient Protection and Affordable Care Act in 2010 ("ACA"). The Proposed Guidance was initially intended to be issued as a regulation, but before publication, HRSA transformed it into a guidance following a federal district court ruling, in a case involving a related 340B regulation, that HRSA has statutory authority to issue regulations only in specific, narrowly defined areas.[4]

The Proposed Guidance provides HRSA's interpretation of the 340B statute, along with implementing policies, in a number of key areas:

A. 340B Program eligibility and registration
B. Drugs eligible for purchase under the 340B program

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1 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (Aug. 28, 2015).
2 42 U.S.C. § 256b, added by the Veterans Health Care Act of 1992 , Pub. L. 102-585, § 602, 106 Stat. 4943.
3 Id. § 256b(a)(2).
4 Pharm. Research and Mfrs. of Am. v. Dep't of Health and Human Servs., 43 F. Supp. 3d 28 (D.D.C. 2014).

C. Individuals eligible to receive 340B drugs
D. Covered Entity responsibilities
E. Contract pharmacy arrangements
F. Manufacturer responsibilities
G. Rebate option for AIDS Drug Assistance Programs ("ADAPs")
H. HHS audits of Covered Entities and manufacturers, and manufacturer audits of Covered Entities

This memorandum summarizes HRSA's guidance in each of these areas, following the organization of the Proposed Guidance. Comments on the Proposed Guidance must be submitted on or before October 27, 2015.

A. 340B PROGRAM ELIGIBILITY AND REGISTRATION

Part A of the Proposed Guidance concerns eligibility and registration of Covered Entities for the 340B Program. The Proposed Guidance describes the eligibility and registration requirements for two categories of Covered Entities: non-hospital and hospital Covered Entities.[5]

1. Non-hospital Eligibility

Non-hospital Covered Entities include those entities that receive a qualifying federal grant, contract, designation, or project as set forth in section 340B(a)(4)(A)-(K) of the PHS Act. In addition to these entities directly eligible by virtue of federal funds or obligations, the Proposed Guidance would provide eligibility for "associated sites," also referred to as "child sites." HRSA explains in the preamble that child sites are "associated health care delivery sites located at a different address[es]" and are eligible if the non-hospital Covered Entity, referred to as the "parent site," registers the child site and "provides information demonstrating that each site is performing services under the main qualifying grant, contract, designation, or project."[6] HRSA further explains that child sites or other sub-recipients of federal grants can obtain their own 340B identification number (separate from the parent site) if they "provide information demonstrating their receipt of eligible Federal funds, or in-kind contributions purchased with eligible Federal funds, as well as the grant number under which they receive those funds."[7]

Under the Proposed Guidance, non-hospital Covered Entities and child sites could lose eligibility in a number of ways. First, both parent and child sites may lose eligibility if the parent site closes or loses the qualifying grant, contract, designation, or project. A child site may also lose eligibility if it no longer qualifies under the parent site's grant, contract, designation, or project. A child site associated with multiple Covered Entities remains eligible only for those Covered Entities that remain eligible to participate in the 340B Program.[8]

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5 80 Fed. Reg. at 52,316.
6 Id. at 52,301.
7 Id.
8 Id.

2. Hospital Eligibility

Covered Entities include six types of hospitals: children's hospitals and free-standing cancer hospitals excluded from the Medicare prospective payment system, disproportionate share hospitals ("DSHs"), critical access hospitals ("CAHs"), rural referral centers, and sole community hospitals. All six types of hospitals must meet the requirement that they be government-owned or -operated, be granted governmental powers, or be under contract with a state or local government. All but CAHs must also meet a disproportionate share requirement.[9]

Government Nexus: The Proposed Guidance provides additional detail regarding hospitals that are government-owned or -operated, granted governmental powers, or are under contract with a state or local government. Under the Proposed Guidance, government-owned or -operated would mean that the hospital is either wholly owned by a state or local government and is recognized as such in its Internal Revenue Service filings, or a state or local government is the "sole operating authority" of the hospital.[10]

The PHS Act requires that a hospital granted governmental powers must be formally granted governmental powers by a unit of a state or local government.[11] In order for a hospital to meet this requirement, the Proposed Guidance would require that a state or local government must formally delegate to the hospital a power usually exercised by the state or local government and must then certify to this delegation of power to HHS. The preamble explains that such powers may include, for example, the power to tax, issue government bonds, or act on the government's behalf, but the mere power to undertake acts within the scope of a government license (e.g., practice medicine or provide health care services) is not sufficient.[12] The Proposed Guidance also stipulates that this delegation of governmental power must be granted through: (1) regulation; (2) contract; (3) creation of a public corporation; or (4) "development of a hospital authority or district to provide health care services to the community on behalf of the government."[13]

To be eligible as a hospital under contract with a state or local government, the hospital would have to provide a signed certification from the hospital's 340B authorizing official, as well as the appropriate government official (e.g., governor, county executive, mayor, or other official authorized to enter into binding agreements for the government) indicating that a contract is in place between the hospital and government to provide services to low-income individuals not otherwise qualified to receive services paid by Medicare or Medicaid.[14]

Disproportionate Share Percentage: Under the PHS Act, five of the six types of Covered Entity hospitals -- DSHs, children's hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals -- must meet a specified disproportionate share

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9 42 U.S.C. § 256b(a)(4).
10 80 Fed. Reg. at 52,317.
11 42 U.S.C. § 256b(a)(4)(L)(i).
12 80 Fed. Reg. at 52,301.
13 Id. at 52,317.
14 Id.

adjustment percentage.[15] The Proposed Guidance indicates that HHS would review a hospital's most recently filed Medicare cost report to confirm compliance with the disproportionate share adjustment percentage. For a children's hospital not required to file a Medicare cost report, the hospital would provide a statement from a qualified independent auditor that it would otherwise meet the required percentage.[16]

A hospital Covered Entity with off-site outpatient facilities would be able to purchase and use covered outpatient drugs for its eligible patients if such facilities are listed on the hospital's Medicare cost report on a separate line for Medicare reimbursement and if the Covered Entity demonstrates that the services provided have associated Medicare costs and charges. If a children's hospital Covered Entity's off-site outpatient facilities do not file a Medicare cost report, the hospital would have to certify that the facility is: (1) an integral part of the children's hospital whose patients are otherwise eligible under the statute and Proposed Guidance; and (2) would otherwise be listed on the Medicare cost report if filed.[17]

Loss of Eligibility: A hospital Covered Entity would lose eligibility upon closing or a change of ownership or contract status that results in the Covered Entity's failure to meet the 340B Program eligibility requirements.[18] For example, a hospital Covered Entity would become ineligible if its contract with a state or local government expired or was terminated. A hospital that is subject to a minimum disproportionate share adjustment percentage would lose eligibility immediately upon submitting a Medicare cost report showing that it no longer meets the required percentage. Also, a hospital subject to the group purchasing organization ("GPO") prohibition (see Section A.5, below) would lose eligibility immediately upon use of a GPO to purchase covered outpatient drugs.[19]

In addition, a registered child site would lose eligibility: (1) immediately upon closing, sale, or transfer of the facility; (2) upon filing a Medicare cost report indicating that the site is not listed as reimbursable, or the services no longer have associated outpatient costs and charges reimbursed by Medicare; or (3) immediately upon use of a GPO for covered outpatient drugs (for child sites subject to the GPO prohibition).[20] The preamble explains that child sites could lose eligibility separately from a parent site, but all child sites would immediately lose eligibility to purchase covered outpatient drugs upon the parent site becoming ineligible.[21]

3. Registration and Termination

Under the Proposed Guidance, a Covered Entity's eligibility to purchase covered outpatient drugs would continue to be conditioned on registration in the 340B Covered Entity database, as

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15 42 U.S.C. § 256b(a)(4)(L)(ii), (M)-(O). By statute, the percentage for DSHs, free-standing cancer hospitals, and children's hospitals is 11.75 percent, and the percentage for rural referral centers and sole community hospitals is 8 percent.

16 80 Fed. Reg. at 52,317.

17 Id.

18 Id. at 52,318.

19 Id. at 52,303.

20 Id. at 52,318.

21 Id. at 52,302-03.

is currently the case.[22] The database facilitates manufacturers' verification of a Covered Entity's eligibility to purchase covered outpatient drugs. Covered Entities may only register quarterly, during specified registration periods. Registration would be made by an authorized official of the entity, such as a chief executive officer, chief operating officer, chief financial officer, or other employee who is authorized to legally bind the entity. This authorized official would also attest that the Covered Entity meets the eligibility criteria and that it is able to comply with the 340B Program requirements.[23]

Only entity types that are identified in the 340B statute could register, and larger entities that contain Covered Entities would not be eligible to participate in the 340B Program. For example, if a hemophilia treatment center ("HTC"), an eligible Covered Entity, is part of a hospital that is not otherwise eligible independently from the HTC, the HTC would be registered, but not the hospital. As another example, the inclusion of a Covered Entity within an accountable care organization ("ACO") does not make the entire ACO eligible to purchase covered outpatient drugs. [24]

Covered Entities would be required to regularly review and update the information contained in the 340B database. If a parent site, child site, or contract pharmacy lost its eligibility to participate in the 340B Program, the Covered Entity would be required to immediately notify HHS and stop purchasing 340B Drugs. The Covered Entity would be liable to the manufacturer for repaying the 340B discount on drugs purchased by any parent or child site or any contract pharmacy when the Covered Entity was ineligible to purchase covered outpatient drugs.[25]

A Covered Entity that lost eligibility and was removed from the 340B database would be able to re-register during the next regular enrollment period after successfully demonstrating to HHS that it will comply with the 340B Program requirements and that it is in the process of repaying applicable 340B discounts to manufacturers.[26]

4. Annual Recertification

A Covered Entity would be required to annually recertify that it, any child sites, and any contract pharmacy arrangements meet eligibility and compliance requirements of the 340B Program. Failure to attest to eligibility and compliance with the 340B requirements would result in termination from the Program.[27] A Covered Entity that voluntarily terminated its enrollment in the 340B Program would have to provide an explanation and documentation that includes the timing of the termination and the date the Covered Entity has stopped or plans to stop purchasing and using covered outpatient drugs.[28]

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22 Id. at 52,318.
23 Id.
24 Id. at 52,303.
25 80 Fed. Reg. at 52,318.
26 Id.
27 Id.
28 Id. at 52,304.

5. GPO Prohibition

DSHs, children's hospitals, and free-standing cancer hospitals are prohibited by statute from obtaining covered outpatient drugs through a GPO.[29] However, the preamble makes clear that this does not prohibit such hospitals from obtaining inpatient drugs or non-covered outpatient drugs through a GPO.[30] There are a number of exceptions to the GPO prohibition, including:

- An off-site outpatient clinic of a hospital Covered Entity if such clinic is located at a separate physical address from the parent site, does not participate in the 340B Program and is not listed in the 340B database, and purchases drugs through a separate account from the parent site;
- A drug purchased through a GPO that was provided to an inpatient who, upon subsequent review, is designated as an outpatient for payment purposes; and
- A hospital that can only obtain a covered outpatient drug through a GPO. In this case, the hospital must document its attempts to purchase the drug at the 340B price and report the circumstances to HHS.[31]

HRSA recognizes that many hospital Covered Entities use "replenishment models" where covered outpatient drugs are purchased to replenish prior dispensings to 340B-eligible patients. Under the Proposed Guidance, hospital pharmacies would be required to account for dispensed drugs for inventory replenishment as inpatient, outpatient 340B-eligible, or outpatient non-covered outpatient drugs. Covered Entities would be required to maintain adequate records demonstrating that the methods used in replenishment models maintain the Covered Entity's compliance with the GPO prohibition.[32]

Compliance with the GPO prohibition is a condition of eligibility. Thus, a Covered Entity that does not maintain compliance would be ineligible to participate in the 340B Program and would be removed from the list of eligible Covered Entities, pending a notice and hearing process. However, the Proposed Guidance indicates that if a Covered Entity can demonstrate that a violation of the GPO prohibition is an isolated error, the Covered Entity may be allowed to continue participation in the 340B Program under a corrective action plan. A Covered Entity that has violated the GPO prohibition would be required to offer to repay 340B discounts to affected manufacturers for any covered outpatient drug purchase made after the date of the first GPO prohibition violation. Furthermore, GPO prohibition violations occurring at a parent site, such that the parent site is removed from the 340B Program, would result in all child sites being removed from the 340B Program as well. However, if the GPO prohibition violation can be limited to certain child sites, the Proposed Guidance would require only those child sites where the violation occurred to be removed.[33] The effect of GPO violations on removal of select child sites would only be limited if the child site has auditable records that show that (1) the child site is located in a building separate from the parent site and other child sites; and (2) all drug

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29 42 U.S.C. § 256b(a)(4)(L)(iii).
30 80 Fed. Reg. at 52,304.
31 Id. at 52,318.
32 Id. at 52,318-19.
33 Id.

purchasing for each site uses separate purchase accounts.[34]

A Covered Entity would be allowed to re-register following GPO violations upon demonstrating to HHS that it will comply with the GPO prohibition and that it is in the process of repaying applicable 340B discounts to manufacturers.[35]

B. DRUGS ELIGIBLE FOR PURCHASE UNDER THE 340B PROGRAM

Covered outpatient drugs in the 340B Program have the same definition as in the Medicaid Rebate statute.[36] This definition is limited by excluding any drug, biological product, or insulin that is "provided as part of, or as incident to and in the same setting as" certain services (e.g., inpatient or outpatient hospital services; physicians' services; nursing facility services) and for which payment is made under a state Medicaid program as "part of payment for the [service] and not as direct reimbursement for the drug."[37] HRSA clarifies in the preamble that this "incident to" exclusion only applies when the drug is "bundled for payment under Medicaid as part of a service in the settings described in the limiting definition." In contrast, drugs provided in the outpatient setting billed to a third-party payor or directly billed to Medicaid are eligible for purchase under the 340B Program.[38]

C. INDIVIDUALS ELIGIBLE TO RECEIVE 340B DRUGS

1. Criteria for Eligibility and Exceptions

In this section of the Proposed Guidance, HRSA provides criteria to identify patients of a Covered Entity that are eligible to receive 340B covered drugs. This is important because section 340B(a)(5)(B) of the PHS Act prohibits Covered Entities from reselling or transferring drugs purchased under the 340B Program to individuals who are not patients of the Covered Entity (generally referred to as diversion).[39] The prior guidance pertaining to the definition of a patient was less specific. HRSA states in the preamble to the Proposed Guidance that the proposed criteria were "informed by 340B program audits, through which HHS has learned more about how the definition of patient is applied in different health care settings."[40]

a. Proposed Criteria

The proposed criteria for being a patient of a Covered Entity (on a prescription-by-prescription or order-by-order basis) are as follows:[41]

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34 Id. at 52, 319.
35 Id.
36 See 42 U.S.C. 1396r–8(k)(2)-(3).
37 See id. § 1396r–8(k)(3).
38 80 Fed. Reg. at 52,306.
39 42 U.S.C. § 256b(a)(5)(B).
40 80 Fed. Reg. at 52,306.
41 Id. at 52,319.

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.

In the preamble, HRSA clarifies that it interprets this criterion to mean that an individual would not be considered a patient under the following circumstances:

- The individual sees a physician in his or her private practice that is not listed in the public 340B database or any other non-340B site, even if it is follow-up to care at a registered site.
- The individual's health care is provided by another health care organization that has an affiliation arrangement with the Covered Entity, even if the Covered Entity has access to the affiliated organization's records.

The use of telemedicine would not preclude an individual from being considered a patient, so long as the practice is authorized by relevant laws and the drug purchase otherwise complies with the 340B Program.[42]

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.

In the preamble, HRSA provides the following examples of Covered Entity-provider relationships that would meet this criterion:

- Faculty practice arrangements.
- Established residency, internship, locum tenens, and volunteer health care provider programs.

However, a physician having privileges or credentials at a Covered Entity would not be sufficient to demonstrate that an individual treated by that physician is a patient of the Covered Entity. Similarly, a referral to an outside provider from a Covered Entity does not render an individual a patient of the Covered Entity for purposes of any prescriptions received from the outside provider.[43]

[42] Id. at 52,306.
[43] Id. at 52,306-07.

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.

The preamble clarifies that the use of telemedicine, telepharmacy, remote, and other health care service arrangements are permitted, as long as the practices are authorized by relevant laws.[44]

4) The individual receives a health care service that is consistent with the Covered Entity's scope of grant, project, or contract.

To illustrate this criterion, the preamble provides the following examples:

- The scope of eligibility for a child site of a Covered Entity must be consistent with the health care services delegated to the child site (e.g., if the scope of grant to a child site of a federally qualified health center is limited to treating pediatric individuals, then only individuals receiving pediatric care as specified in the scope of grant would be eligible to receive 340B covered drugs).
- A hospital that is enrolled in the 340B Program on the basis of a grant, project, or contract (e.g., a family planning grant) cannot access 340B drugs for patients receiving care outside of the facilities or outside the scope of the family planning project; however, if the hospital is registered as one of the hospital Covered Entity categories would not be subject to such a limitation. [45]

5) The individual is classified as an outpatient when the drug is ordered or prescribed.

Under the Proposed Guidance, 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. The preamble states that, as section 340B(a)(1) of the PHS Act established the 340B Program as a drug discount program for Covered Entities furnishing covered outpatient drugs, "an individual cannot be considered a patient of the entity furnishing covered outpatient drugs if his or her care is classified as inpatient." The preamble further states that "[a]n individual is considered a patient if his or her health care service is billed as outpatient to the patient's insurance or third party payor."[46] By tying the determination to billing records, it appears that HRSA is trying to establish a system that results in auditable records to protect against diversion.

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44 Id. at 52,307.
45 Id.
46 Id.

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 the patient definition is met for each 340B drug.

Under this criterion, the preamble emphasizes "that the Covered Entity retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to an individual."[47]

b. Exceptions

The Proposed Guidance makes clear, consistent with long-standing practice, that individuals enrolled in an ADAP will be considered a patient of the Covered Entity for purposes of this definition.[48] The guidance also proposes to provide an exception so that Covered Entities can temporarily follow alternate patient eligibility criteria (with auditable records documenting the alternate criteria and the dates for which those criteria are in effect) in the event of a public health emergency declared by the Secretary.[49]

2. Replenishment

In the preamble, HRSA acknowledges that Covered Entities may use replenishment models to manage drug inventory, including 340B drugs.[50] In such a model, a Covered Entity may provide health care services to many different types of patients (e.g., inpatients, 340B-eligible outpatients, and other outpatients), tally the drugs dispensed to each type of patient, including through the use of accumulator software, and then replenish the drugs by ordering from the appropriate accounts. The Proposed Guidance states that such models are acceptable and do not violate the statutory prohibition on diversion if they "only order 340B drugs based on actual prior usage for eligible patients of that Covered Entity as defined by this guidance."[51] The preamble clarifies that each 340B order should be supported by auditable records demonstrating prior receipt of that drug by a 340B-eligible patient. The preamble also states that a violation of the diversion prohibition can occur if a Covered Entity improperly accumulates or tallies 340B drug inventory, or if the recorded number of 340B drugs does not match the actual number in inventory, if the Covered Entity maintains a virtual or separate physical inventory. HRSA acknowledges in the preamble that manufacturers and Covered Entities often work together to identify and correct errors through a credit and rebill process and encourages continued use of this practice, which requires frequent monitoring of compliance by the Covered Entity.[52]

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47 Id.
48 Id. at 52,318.
49 Id. at 52,319.
50 Id. at 52,308.
51 Id. at 52,319.
52 Id. at 52,308.

The preamble also discusses a practice called "banking," in which a Covered Entity retroactively looks back over long periods of time at drug purchases not initially identified as 340B eligible and attempts to re-characterize such purchases as 340B eligible and then obtain 340B pricing for these previous transactions. HRSA first states that "Covered entities are responsible for requesting 340B pricing at the time of the original purchase," which suggests that such a practice is discouraged. However, the preamble then provides guidance to a Covered Entity for interacting with manufacturers in such cases, stating that "[i]f a covered entity wishes to re-characterize a previous purchase as 340B, covered entities should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction."[53] HRSA did not address the question of how far back a Covered Entity might be able to look to re-characterize sales.

The preamble also recommends regular review of 340B drug inventory by Covered Entities, standard business procedures to return unused or expired 340B drugs, and implementation of policies and procedures regarding inventory discrepancies to demonstrate that inventory discrepancies do not results in diversion of 340B drugs.[54]

3. Repayment and Corrective Actions

Under the Proposed Guidance, a Covered Entity is responsible for offering repayment to a manufacturer if a 340B drug has been found to be diverted, including diversion through child sites or contract pharmacies.[55] The preamble (but not the Proposed Guidance itself) specifies that "Covered entities are expected to work with manufacturers regarding repayment within 90 days of identifying the violation."[56] HRSA acknowledges that manufacturers have the discretion to accept or decline payments based on their own business practices or request that repayments be processed through a credit/rebill process. The preamble also cautions manufacturers, when deciding whether to accept repayment from a Covered Entity, to comply with applicable laws, including the federal anti-kickback statute, and consider the potential impact of such decisions on price reporting requirements under the MDRP.[57] Under the Proposed Guidance, the Covered Entity should notify HRSA of any diversion and its corrective actions, including any manufacturer agreements on repayments.[58]

D. COVERED ENTITY RESPONSIBILITIES

1. Prohibition of Duplicate Discounts

Section 340B(a)(5)(A)(i) of the PHS Act prohibits duplicate discounts -- i.e., where the State obtains a Medicaid rebate (either for a fee-for-service ("FFS") patient or a Medicaid managed care organization ("MCO") patient) for a drug that was discounted under the 340B

53 Id.
54 Id.
55 Id. at 52,319.
56 Id. at 52,308.
57 Id.
58 Id. at 52,319.

Program.[59] Under the Proposed Guidance, Covered Entities would have a number of responsibilities to ensure that duplicate discounts do not occur.

First, consistent with current practice, a Covered Entity would have to decide if it intends to access 340B pricing for its Medicaid patients. With regard to FFS patients, the Covered Entity would provide its Medicaid provider number and/or National Provider Identifier ("NPI") to HHS for inclusion on the Medicaid Exclusion File (known as carving-in).[60] If a Covered Entity's provider number or NPI is not on the Medicaid Exclusion File, this means that all drugs billed under the Medicaid provider number or NPI are purchased outside of the 340B Program (carve-out). With regard to MCO patients, a Covered Entity may choose whether to use 340B drugs for those patients. A Covered Entity could make differing selections by Covered Entity site and MCO as long as HRSA is informed.[61]

Second, a Covered Entity could make changes to its use of 340B drugs for Medicaid FFS or MCO patients; however, it would have to notify HRSA of the change before it is implemented.[62] Even though a change could be submitted at any time, it would only be effective on a quarterly basis.[63] In addition, HRSA is seeking comments regarding alternative mechanisms to supplement the Medicaid Exclusion File to allow Covered Entities more flexibility but to also ensure that such mechanisms prevent duplicate discounts.[64]

Third, the Proposed Guidance states that, unless otherwise noted in the public 340B database, contract pharmacies will not dispense 340B drugs for Medicaid FFS or MCO patients.[65] This is due to the potential increased risk for duplicate discounts when drug purchasing occurs through a contract pharmacy. If a Covered Entity wished to use a contract pharmacy to dispense 340B drugs for its Medicaid FFS or MCO patients, it would need to have a written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts. This agreement will need to be provided to HRSA, and, once approved, the contract pharmacy would be identified in the 340B database as dispensing 340B drugs for Medicaid FFS and/or MCO patients.

Fourth, under the Proposed Guidance, a Covered Entity could be found in violation of the duplicate discount prohibition if the information provided to HRSA did not reflect the Covered Entity's actual billing practices.[66] In such a case, the Covered Entity would be required to repay rebate amounts to manufacturers if the duplicate discounts occurred as a result of the inaccurate information.

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59 42 U.S.C. § 256b(a)(5)(A)(i).
60 80 Fed. Reg. at 52,320.
61 Id.
62 Id.
63 Id. at 52,309.
64 Id.
65 Id. at 52,320.
66 Id.

2. Maintenance of Auditable Records

Under section 340B(a)(5)(C) of the PHS Act, a Covered Entity is required to permit HHS and a manufacturer with a PPA to audit its records that pertain to the Covered Entity's compliance with the prohibitions against diversion and duplicate discounts.[67] HRSA notes in the preamble that stakeholders have been requesting a standard for records retention, and HRSA has agreed that a standard would be important for Covered Entities and manufacturers preparing for audits.[68] HRSA is therefore proposing that a Covered Entity "must maintain auditable records demonstrating compliance with all 340B Program requirements for itself, any child site, and any contract pharmacy for 5 years from the date the 340B drug was ordered or prescribed, regardless of whether the entity continues to participate in the 340B Program."[69] The records must be made available to HRSA at any time and to manufacturers pursuant to an audit. If 340B participation is terminated, a Covered Entity, including child sites and contract pharmacies, must retain records for 5 years after the termination date.

The Proposed Guidance also proposes penalties for a Covered Entity's failure to maintain records. If a Covered Entity is unable to produce records pertaining to compliance with any specific Program requirement during an audit or pursuant to a request from HHS, the Covered Entity may be presumed to be out of compliance with that requirement.[70] Systematic failures to maintain or produce auditable records would result in a Covered Entity being removed from the 340B Program after a notice and hearing process. A Covered Entity that is deemed ineligible and removed from the 340B Program would be liable to manufacturers for repayment for periods of ineligibility. A Covered Entity that has been removed from the 340B Program could re-enroll in the Program after it has demonstrated to HRSA that it can comply with all 340B Program requirements, including record retention requirements.[71]

E. CONTRACT PHARMACY ARRANGEMENTS

In the Proposed Guidance, HRSA has streamlined its guidance pertaining to contract pharmacies from that provided in its 2010 guidance on this subject.[72] Consistent with the prior guidance, the new Proposed Guidance states that a Covered Entity can contract with one or more licensed pharmacies to dispense 340B drugs to eligible patients, regardless of the availability of an in-house pharmacy, provided the arrangement is in accordance with all other statutory 340B Program requirements and all other applicable laws, including the federal anti-kickback statute.[73] A child site may also contract directly with a pharmacy. However, "[g]roups or networks of

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67 42 U.S.C. § 256b(a)(5)(C).

68 80 Fed. Reg. at 52,309.

69 Id. at 52,320.

70 Id. at 52,319-20.

71 Id. at 52,320.

72 See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 - Patent and Entity Eligibility, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

73 80 Fed. Reg. at 52,320. In the preamble, HRSA stated that it will continue its policy of referring cases of suspected violations of the anti-kickback statute to the HHS Office of Inspector General (OIG). Id. at 52,310.

covered entities may not register or contract for pharmacy services on behalf of their individual covered entity members."[74]

The preamble and Proposed Guidance make clear that the contract pharmacy is not a 340B Covered Entity and therefore does not receive a 340B identification number.[75] Rather, since the Covered Entity maintains complete responsibility for compliance with 340B requirements, only the Covered Entity can submit a contract pharmacy registration and related information to HRSA.[76] HRSA will only list a contract pharmacy on the 340B database if a written contract exists between the Covered Entity and contact pharmacy that includes all locations of a single pharmacy company that the Covered Entity plans to use and all child sites that plan to use the contract pharmacies.[77] Once the pharmacy is listed on the 340B database, the contract pharmacy may dispense 340B drugs to eligible patients of the Covered Entity. A contract pharmacy may be removed from the 340B Program if HRSA determines that it is not complying with 340B Program requirements, and the Covered Entity is responsible for offering repayment to a manufacturer if a contract pharmacy has not adhered to 340B Program requirements.[78]

Unlike the prior guidance, the new Proposed Guidance does not specify what terms should be in the written agreement between the Covered Entity and the contract pharmacy. The preamble merely states that the written agreement should "set forth the requirements contained in this Proposed Guidance."[79] The Proposed Guidance states that "a covered entity must follow all 340B statutory requirements when utilizing a contract pharmacy" and identifies three specific categories of requirements: prevention of diversion to ineligible patients, prevention of duplicate discounts, and contract pharmacy oversight.[80] The last category, contract pharmacy oversight, is where the most emphasis was placed. According to the preamble, "HHS has observed that not all covered entities have sufficient mechanisms in place to ensure their contract pharmacies' compliance with all 340B Program requirements."[81] Under the proposed guidance, a "covered entity is expected to conduct quarterly review and annual independent audits of each contract pharmacy location."[82] According to the preamble, the quarterly reviews should entail the Covered Entity comparing its 340B prescribing records with the contract pharmacy's 340B dispensing records to make sure that diversion and/or duplicate discounts are not occurring. Consistent with the prior guidance, HRSA is reiterating its expectation that the Covered Entity conduct independent annual audits of its contract pharmacy locations "to provide covered entities

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74 Id.

75 Id. at 52,310, 52,320.

76 According to the preamble, "required documentation for registration would include a series of compliance requirements and a covered entity's attestation regarding its arrangement with the contract pharmacy." Id. at 52,310. The preamble also provides other limitations, such as manufacturers and wholesalers may ship 340B drugs only to the authorized shipping address listed for the Covered Entity in the 340B database, and 340B drugs may be provided to patients of the Covered Entity only after the pharmacy's start date in the 340B database and on or before a contract pharmacy location is terminated. Id.

77 Id. at 52,320.

78 Id.

79 Id. at 52,310.

80 Id. at 52,320-21.

81 Id. at 52,311.

82 Id. at 52,321 (emphasis added). It is not clear what will happen if the "expected" quarterly reviews and annual independent audits do not occur.

a regular opportunity to review and reconcile pertinent 340B patient eligibility information at the contract pharmacy and help prevent diversion."[83] The records of such reviews and audits are among the records that can be audited by HRSA and manufacturers. Any violations observed through quarterly reviews and audits should be corrected and disclosed to HRSA (including corrective action), and Covered Entities are subject to applicable penalties for instances of diversion or duplicate discounts.[84]

F. REQUIREMENTS FOR MANUFACTURERS

1. Requirement to Enter Into PPA

PPA and price limitation: Under the Proposed Guidance, a manufacturer that has a Medicaid Rebate Agreement would be required to enter into a PPA within 30 days after enrolling in the MDRP.[85] Tracking the statutory mandate, the Proposed Guidance would require a manufacturer that has entered into a PPA to offer all of its covered outpatient drugs at no more than the 340B ceiling price to Covered Entities listed on 340B database. The Proposed Guidance would require a manufacturer to offer a covered outpatient drug to 340B Covered Entities if the drug is offered to any other purchaser at any price, and, consistent with long-standing HRSA policy, would prohibit a manufacturer from conditioning its offer of 340B prices on a Covered Entity's assurance of compliance with 340B Program requirements. When a new covered outpatient drug is marketed, 340B pricing would become effective on the date the drug is available for sale.[86] Voluntary pricing below the 340B ceiling price would continue to be permitted, as provided in the statute.[87]

Other requirements for manufacturers: In addition to the ceiling price limitation, the Proposed Guidance would require manufacturers to (1) submit timely updates when a new covered outpatient drug is added to the 340B Program; (2) maintain auditable records demonstrating compliance with 340B program requirements for no less than 5 years; (3) provide such records to HHS upon request; and (4) permit HHS to audit manufacturer compliance.[88] (See section H, below, for a discussion of the audit requirement.)

The Proposed Guidance would also require manufacturers to "review and update 340B database information on an annual basis."[89] The preamble elaborates that manufacturers should update their database information as changes occur, but they will be required to recertify the

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83 Id.

84 Id.

85 Id. Strictly speaking, neither the Medicaid rebate statute nor the PHS Act imposes on a manufacturer an absolute requirement to enter into a PPA, whether or not the manufacturer has a Medicaid Rebate Agreement. However, a PPA is a pre-condition of federal payment for a manufacturer's covered outpatient drugs under Medicaid (and Medicare Part B). Therefore, a manufacturer with a Medicaid Rebate agreement would obtain no benefit from that agreement unless the manufacturer also entered into a 340B PPA.

86 Id.

87 See 42 U.S.C. § 256b(a)(10).

88 80 Fed. Reg. at 52,321.

89 Id. at 52,322.

accuracy of the information in the database annually.[90] The Proposed Guidance does not specify when this certification will occur, whether it will be done electronically or otherwise, what the text of the certification will be, or whether the certification will pertain to the pricing and other information regarding all of the manufacturer's covered outpatient drugs, or merely the information about the manufacturer itself (i.e., address, contact name, labeler code, etc.)

2. Limited Distribution Plans

The Proposed Guidance sets forth special provisions for limited distribution plans, which would apply where a manufacturer (1) uses a specialty pharmacy or restricted distribution network, or (2) needs to limit distribution due to potential or actual shortages. As examples of restricted distribution, the preamble refers to drugs that require special handling, or are required (for example, under a risk evaluation and mitigation strategy, or REMS) to be distributed through a restricted network of specialty pharmacies.[91] However, the terms of the Proposed Guidance itself are not limited to situations where restricted distribution is required, but more broadly where it is "used" – whether or not required. In fact, new, expensive new drugs are increasingly being marketed exclusively through specialty pharmacies where no REMS or special handling requirements exist. 340B Covered Entities have complained that they cannot obtain 340B pricing under such arrangements because the specialty pharmacies are not 340B contract pharmacies and the Covered Entity cannot purchase the drugs elsewhere.

The Proposed Guidance would require manufacturers that use restricted distribution networks of specialty pharmacies to find a way to make the 340B price available to patients of Covered Entities. Citing the statutory requirement that manufacturers must offer a covered outpatient drug for purchase under the 340B Program if it is made available to any other purchaser at any price, HRSA would require manufacturers with limited distribution plans to provide for "restricted distribution to all purchasers, including 340B covered entities," in a non-discriminatory manner.[92] Before implementing a limited distribution plan, a manufacturer would be required to submit to HRSA details of the plan; an explanation of the rationale for restricted distribution; an assurance that restrictions will be imposed equally on both 340B Covered Entities and other purchasers; and a plan for notifying Covered Entities and wholesalers about the plan. The plan would be published on the 340B web site.[93]

3. Refunds and Credits to Covered Entities

The Proposed Guidance contains provisions to implement the statutory mandate, added by the ACA, that HRSA establish procedures for manufacturers to "issue refunds to covered entities in the event that there is an overcharge by the manufacturers."[94] The preamble makes clear that the refund obligation may arise either from a routine restatement of AMP or best price, or exceptional circumstances such as erroneous or intentional overcharging of Covered

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90 Id. at 52,312.
91 Id.
92 Id.
93 Id.
94 42 U.S.C. § 256b(d)(1)(B)(ii).

Entities.[95] In either case, a manufacturer would have to submit to HRSA the 340B price recalculation information, and an explanation of why the overcharge occurred, how the refund will be calculated, and to whom refunds will be issued.[96]

HRSA proposes that a manufacturer must issue a refund or credit "within 90 days of the determination by the manufacturer or HHS that an overcharge occurred."[97] This timeline is patently unrealistic in many situations. In the case of a recalculation and restatement of AMP or best price for multiple quarters, the manufacturer may not complete the required recalculations of AMP and best price until many months after the manufacturer initially determines that a restatement is necessary. If a "determination that an overcharge occurred" is deemed to take place when the manufacturer first knows that an MDRP restatement is necessary, a 90-day period to make refunds to Covered Entities is clearly impracticable. It is not feasible to calculate a 340B refund until after the MDRP recalculation has been completed.

Moreover, it is often logistically impossible to calculate 340B refunds, make necessary arrangements with wholesalers, send communications to hundreds or thousands of Covered Entities, and pay refunds or credits within 90 days after determining that an overcharge occurred – particularly where numerous drugs and/or quarters are involved. Manufacturers should consider submitting comments objecting to the proposed timeline. A more workable provision might require a manufacturer to provide a refund or credit to Covered Entities: (1) in the case of an overcharge arising from an MDRP recalculation, within 120 days after the restatement for the entire recalculated period has been completed and submitted to CMS, and (2) in all other cases, within 120 days after the determination by the manufacturer of the amount of the overcharge, with a provision for extensions in both cases upon approval by HRSA.

Under the Proposed Guidance, the amount of refund would be the difference between the sale price and the correct 340B price, multiplied by the number of units.[98] Though not addressed in the Proposed Guidance, the issue of offsets is briefly discussed in the preamble, which states that "[a] manufacturer may only calculate the refund by NDC, and would not be allowed to calculate refunds in any other manner, including (but not limited to) aggregating purchases, *de minimis* amounts, and netting purchases."[99] The term "netting purchases" appears to be a reference to HRSA's long-standing policy that overcharges may not be offset by undercharges to a Covered Entity for the same drug or other drugs. This position is also reflected in HRSA's recently proposed regulation on civil monetary penalties.[100] Nevertheless, opposing arguments could be advanced that, at least where a manufacturer has corrected an inadvertent error in AMP or best price, a 340B Covered Entity should not be permitted to receive a windfall from the error by retaining all underpayments (i.e., discounts it was not entitled to) while receiving refunds of all overpayments. Such an approach is contrary to manufacturers' treatment of price adjustments

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95 80 Fed. Reg. at 52,312.

96 Id. at 52,321.

97 Id.

98 Id.

99 Id. at 52,312.

100 See Notice of Proposed Ruling; 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583, 34,588 (June 17, 2015) (an instance of overcharging "may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchasers").

for all other customers, and is also inconsistent with the treatment of recalculated rebates under the MDRP.

In addition, as any manufacturer knows who has refunded overcharges to Covered Entities pursuant to an MDRP recalculation, large numbers of refunds for miniscule amounts present an enormous burden that is not justified by the negligible benefit to Covered Entities. Manufacturers should consider advocating a *de minimis* exception on this basis.

The Proposed Guidance does provide that if a Covered Entity receiving a refund fails to take action to accept or execute the repayment (e.g., cash a check) within 90 days after receipt, the Covered Entity will waive the right to the refund.[101]

G. REBATE OPTION FOR AIDS DRUG ASSISTANCE PROGRAMS

The Proposed Guidance would provide a degree of clarification regarding the offer of 340B prices to ADAPs through rebates. Many ADAPs are third party payors, rather than purchasers, of drugs dispensed to ADAP patients, so the 340B price cannot be obtained simply as a discount on a direct purchase. Prior HRSA guidance provides few parameters for ADAP rebate invoicing, payment, and calculation, instead advising ADAPs and manufacturers to use "standard business practices."[102] The new Proposed Guidance would establish more specific requirements in certain areas.

HRSA proposes that manufacturers must pay rebates to an ADAP that has registered with HRSA under the rebate option (or a hybrid option under which an ADAP purchases some, but not all, drugs directly), and where the ADAP has made a "qualified payment" for the covered outpatient drug. A qualified payment is either (1) a direct purchase of the drug for a price greater than the 340B ceiling price, or (2) a payment by the ADAP of the health insurance premiums that cover the drug purchases at issue as well as payment of a copayment, coinsurance, or deductible for the covered outpatient drug. The Proposed Guidance would provide that the amount of the rebate is equal to the unit rebate amount under the MDRP, multiplied by the number of units in the ADAP's rebate claim. An ADAP would be required to submit claims-level data to manufacturers documenting that a qualified payment was made for each rebate request. The type of documentation is not specified.[103]

Of course, manufacturers are not in a position to know whether an ADAP has met condition (2) above. The Proposed Guidance specifically provides that ADAPs receiving rebates are subject to audits by HHS, but does not mention audits by manufacturers. This is an unwarranted omission. As discussed in Section H, below, manufacturers do have authority to audit 340B Covered Entities' compliance with the diversion prohibition. An ADAP claim for a rebate where the ADAP's payment was not a "qualified payment" is essentially a violation of this prohibition, because the ADAP will receive the rebate on a unit of drug provided to an ineligible patient. Manufacturers should consider requesting that the Proposed Guidance be

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101 80 Fed. Reg. at 52,322.

102 Notice Regarding Section 602 of the Veterans Health Care Act of 1992 - Rebate Option, 63 Fed. Reg. 35,241 (June 29, 1998).

103 80 Fed. Reg. at 52,322.

revised to provide for audits of ADAPs receiving rebates, not only by HHS, but also by manufacturers.

The Proposed Guidance still does not address issues such as the deadlines for ADAPs to submit rebate claims or for manufacturers to pay them, the frequency of rebate payments, or dispute procedures. HRSA apparently intends to permit ADAPs and manufacturers to continue to rely on "standard business practices" in these areas.

H. AUDITS

1. Manufacturer Audit of Covered Entity

The Proposed Guidance would authorize a manufacturer to audit a Covered Entity for compliance with only two requirements: (1) the prohibition against duplicate discounts (i.e., 340B discount and Medicaid rebate); and (2) the prohibition against diversion of 340B drugs to individuals who are not patients of the Covered Entity. Manufacturers would not be authorized to audit a Covered Entity's compliance with other 340B requirements (e.g., the GPO prohibition or conditions of eligibility), but could refer such issues to HHS for its review.[104] The statute does not require a manufacturer to show "reasonable cause" for an audit of a Covered Entity,[105] but HRSA has nevertheless added such a requirement in the Proposed Guidance, consistent with its long-standing policy. The Proposed Guidance does not define "reasonable cause," but the preamble explains that reasonable cause exists when a "reasonable person could conclude, based on reliable evidence, that a Covered Entity and/or its child sites or contract pharmacies may have violated" one or both of the two prohibitions above. Examples of reasonable cause include significant changes in quantities ordered, deviations from national averages of use, evidence of duplicate discounts, or a Covered Entity's refusal to answer questions about compliance with the duplicate discount and diversion prohibitions.[106]

Following are HRSA's proposed steps for a manufacturer audit of a Covered Entity:

- The manufacturer notifies the Covered Entity in writing of a suspected violation. The manufacturer and Covered Entity attempt for at least 30 days to resolve the issue.
- If the issue is not resolved, the manufacturer submits an audit work plan to HHS, along with documentation of reasonable cause for the audit and of its attempts to negotiate a resolution.
- HHS reviews the work plan and may request changes.
- The audit is conducted at the manufacturer's expense. The Covered Entity must provide access to requested records relating to the duplicate discount and diversion provisions, and must also arrange for access to its contract pharmacy's records.
- The manufacturer submits a final audit report to the Covered Entity, which has 30 days to respond to audit findings and/or describe corrective actions to be taken.
- The manufacturer submits copies of the final audit report and Covered Entity responses to HHS, which may refer findings to the OIG or other federal agencies.

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104 Id. at 52,322-23.

105 42 U.S.C. § 256b(a)(5)(C).

106 80 Fed. Reg. at 52,315.

A manufacturer would be required to sell covered outpatient drugs to the Covered Entity at or below the 340B ceiling price unless and until HHS determines that the Covered Entity has committed a violation.[107]

2. HHS Audit of Manufacturer

To implement a new audit authority added to the statute by the ACA, the Proposed Guidance describes procedures for HHS to audit manufacturers (or wholesalers performing 340B Program requirements for them) for compliance with 340B Program requirements. Under the proposed procedures, HHS would notify the manufacturer of its intent to conduct an audit, which could be either an on-site review, an off-site document review, or both.[108] Following the audit, HHS would provide notice of its findings to the manufacturer, which would have 30 days to object in writing and provide supporting documentation. Following HHS's review of this material (which has no deadline), HHS would issue its final findings, and request a corrective action plan to address them. The manufacturer would have 30 days to submit a corrective action plan, which would include, among other things, refunds of any overcharges to Covered Entities. HHS would then determine (again, with no deadline) whether the corrective action plan is sufficient.

The Proposed Guidance provides that, "[i]f HHS determines that a manufacturer no longer meets the requirements of the 340B Program, HHS will provide the manufacturer with notice and hearing pursuant to this section."[109] However, neither the Proposed Guidance nor the preamble provide any further information about the hearing – for example, how a manufacturer may request one, who will adjudicate the hearing, or what hearing procedures will apply. Manufacturers should consider comments requesting HRSA to provide details on these issues.

Under the Proposed Guidance, a manufacturer would be required to provide requested documents, not only on its own behalf, but also on behalf of "any wholesaler or organization which performs 340B Program requirements or contracts for the manufacturer." A failure to provide records could result in further action by HHS or referral for investigation.[110] Most manufacturers sell to Covered Entities indirectly through wholesalers, and the wholesalers are instrumental in ensuring that Covered Entities are loaded onto the correct manufacturer contract to receive the correct 340B price. However, manufacturers do not have access to wholesalers' records and are not in a position to force wholesalers to provide such records to HHS. Under the statute, HHS has the direct authority to conduct auditing of wholesalers.[111] If HHS requires records from a wholesaler, HHS should request them directly from the wholesaler, rather than holding a manufacturer responsible for producing wholesaler records that manufacturers typically do not have and cannot obtain.

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107 Id.
108 Id.
109 Id. at 52,323.
110 Id.
111 42 U.S.C. § 256b(d)(1)(B)(v).

3. HHS Audit of Covered Entity

HHS is authorized by statute to audit Covered Entities for compliance with 340B Program requirements.[112] The Proposed Guidance would make clear that this audit authority extends to a Covered Entity's child sites and contract pharmacies as well. The provisions on HHS audits of Covered Entities parallel those pertaining to audits of manufacturers. HHS would first notify the Covered Entity of its intent to conduct an audit, which might include an on-site review, a document review, or both. Following the audit, HHS would notify the Covered Entity of any adverse findings, and the Covered Entity would have 30 days to respond in writing with supporting documentation. HHS would then issue a final determination regarding noncompliance. If a finding of non-compliance is made, the Covered Entity may be required to submit a corrective action plan in order to continue to participate in the 340B Program. The corrective action plan would have to include, among other things, plans to offer repayment to manufacturers for discounts improperly received. A failure of a Covered Entity to correct compliance issues or submit a corrective action plan may result in termination from the 340B Program.[113]

As in the manufacturer audit provisions, although the Covered Entity guidance refers to "notice and a hearing," neither the Proposed Guidance nor the preamble provide further information on how or when a Covered Entity may request a hearing, or the procedures under which hearings will be conducted.

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112 Id. § 256b(a)(5)(C).

113 80 Fed. Reg. at 52,322.