340B Drug Pricing Program Omnibus Guidance

[RIN 0906-AB08]

Summary of Notice with Comment Period

TABLE OF CONTENTS

I. Introduction and Background

On August 28, 2015, the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services published in the *Federal Register* (80 *FR* 52300 - 52324) a notice of proposed guidance for covered entities enrolled in the 340B program and drug manufacturers that are required by section 340B of the Public Health Service Act (PHSA) to make their drugs available to covered entities under the 340B program. Public comments are due by October 27, 2015 after which the guidance will be finalized.

The guidance is intended to assist 340B covered entities and drug manufacturers in complying with the statute and addresses important definitions and eligibility criteria. It describes, clarifies and builds on important program definitions, processes, and compliance practices. The guidance describes the history of the 340B program and refers to the intent of the program as described in a House of Representatives report as allowing for covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] In many cases, the guidance incorporates existing practice as enumerated in various policy releases, including memorandums to participating entities and manufacturers, guidance, and frequently asked questions and answers. In addition, however, the guidance seeks to clarify and strengthen policies, especially in areas in which concerns about inadequate oversight, drug diversion, and duplicate discounts have been raised. To that end, the guidance proposes changes to the definition of a patient and covered outpatient drugs, adds processes for notice and hearing, specifies covered entity and manufacturer responsibilities and increases transparency. HRSA notes that future rulemaking will address the administrative dispute resolution process.

In this summary, we attempted to identify where the provisions of the guidance generally reflect current practice or existing guidance and note where the proposed guidance would reflect a

[1] H. Rept No. 102-384(II)

change. As a caution, however, because no single source of existing/current policy and practice appears to be available, some of the provisions identified as new may, in fact, be unchanged from what is currently expected/required.

II. Part A -- Program Eligibility and Registration

In this part of the guidance, HRSA describes the general eligibility requirements and registration processes for entities to participate in the 340B program. This section mostly retains existing practices, describing them and adding clarity. Existing guidance regarding registration processes for covered entities can be found on the 340B program website information pages and in a series of frequently asked question and answers. [http://www.hrsa.gov/opa/index.html].

HRSA notes that the statute describes the two main categories of covered entities:

- non-hospital covered entities (in sections 340B(a)(4)(A) through (K) of the PHSA); and
- hospital covered entities (in sections 340B(a)(4)(L)).

Non-hospital covered entities.

Eligibility for non-hospital covered entities. Under current rules, non-hospital entities, a group that includes federally-qualified health centers, family planning project grantees, black lung clinics and other clinics that receive certain federal grants, contracts or designations, may register to be included in a public 340B database. Under the guidance, the existing process is retained: a non-hospital entity will be listed on the public 340B database if it registers and establishes that it receives a qualifying grant, contract, or designation as defined in the sections of the PHSA noted above.

Associated site eligibility. The proposed guidance also retains, largely intact, existing registration and eligibility policies for non-hospital "child sites" or sites that are associated with a non-hospital covered entity and are authorized to provide health care services through the grant, project, designation, or contract of a covered entity.

Loss of eligibility. The proposed guidance would establish the following timelines for the loss of eligibility:

- A non-hospital covered entity and its child sites become immediately ineligible for the 340B program if the covered entity closes or if the parent covered entity's qualifying federal grant, project, designation, or contract ends. The entity may be liable to repay manufacturers for any 340B drug purchases made when the entity was ineligible for the 340B program. This information may be made available to the public.
- A child site will lose eligibility if the grant, project, designation, or contract of the child site is terminated. In that case, it loses eligibility immediately and separately from the parent covered entity.

Hospitals

Hospital eligibility. The proposed guidance retains its current practice of listing hospital covered entities on its public 340B database when determined eligible. It restates existing policy

guidance for most groups of hospitals but provides additional clarity (see text in italics) on the eligibility of certain hospitals.[2]

- A hospital is eligible on the basis of being "owned or operated by a unit of state or local government" if the hospital is either wholly owned by a state or local government and recognized as such by the Internal Revenue Service, or other documentation from federal entities; or operated through an arrangement where the state or local government is the sole operating authority of the hospital.
- A hospital is eligible for the 340B program on the basis of being "formally granted governmental powers by a unit of State or local government" if HRSA receives certification that a state or local government formally delegates to the hospital a power usually exercised by the state or local government. The delegation may be granted through statute or regulation; a contract with a state or local government; 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.
- A hospital is eligible for the 340B program on the basis of having 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 if it provides a signed certification by the hospital's 340B program authorizing official and an appropriate government official (such as the governor, county executive, mayor, or an individual authorized to represent and bind the governmental entity) attesting to such. *The contract should create enforceable expectations for the hospital for the provision of health care services, including the provision of direct medical care.*
- A hospital is eligible for the program on the basis of having a Medicaid disproportionate share (DSH) adjustment percentage that exceeds certain thresholds based on HRSA's review of a hospital's most recently filed Medicare cost report. HRSA will list those hospitals qualifying on this basis. A DSH hospital, children's hospital, or freestanding cancer hospital can alternatively be eligible for the program based on being a "Pickle hospital."[3] A children's hospital which is not required to file a Medicare cost report can provide a statement from a qualified independent auditor certifying that the hospital meets those criterion.

Eligibility of off-site outpatient facilities and clinics (child sites). A hospital can have one or more off-site outpatient facilities and clinics that deliver outpatient services for the hospital that may qualify for the 340B program. Those sites are also currently listed on the public 340B database, and are able to purchase or use 340B drugs for eligible patients. Under the proposed guidance, HRSA retains its current practice, elucidated in frequently asked questions http://www.hrsa.gov/opa/faqs/), to base eligibility of offsite outpatient facilities on information in the most recently filed Medicare cost report.

[2] 340B Drug Pricing Program Notice, Release No. 2013-3, Clarification of Eligibility for Hospitals that are not publically owned or operated
http://www.hrsa.gov/opa/programrequirements/policyreleases/hosptialeligibilitypolicy.pdf

[3] Named for a former member of Congress, a "Pickle" hospital is a large, urban hospital that serves a significantly disproportionate number of low income patients. They are defined under section 1886(d)(5)(F)(i)(II) of the Social Security Act.

For a children's hospital which does not file a Medicare cost report, HRSA proposes to list an off-site outpatient facility if the parent hospital submits a signed statement certifying that the requested outpatient facility is an integral part of the children's hospital whose patients meet the requirements of the guidance and would be included on a reimbursable line with associated Medicare outpatient costs and charges on a Medicare cost report, if filed.

HRSA is seeking comments on alternatives to demonstrating the eligibility of an off-site outpatient facility or clinic. The agency notes that it has explored the use of provider based designations, although in 2007, commenters on this issue thought that such designations would be difficult to verify. HRSA also considered using the Medicare Enrollment Application for Institutional Providers (CMS 855A) but found this form to be insufficient for 340B purposes.

Loss of eligibility. In the proposed guidance, HRSA establishes that when an entity loses 340B eligibility, HRSA will list that date on the public 340B database as the termination date and proposes the following timelines for loss of eligibility for hospitals and their child sites:

- A hospital and its child sites would be immediately ineligible for the program upon closing of the hospital or a change in ownership or contract status which results in the hospital failing to qualify under the statutory conditions.
- A hospital which qualifies on the basis of a DSH percentage would lose eligibility immediately upon filing of a Medicare cost report for which the DSH adjustment percentage falls below the statutory threshold.
- A hospital which qualifies for the program as a "Pickle hospital" would lose eligibility immediately upon filing a Medicare cost report for which the hospital does not meet the requirements for that designation.
- A children's hospital which does not file a Medicare cost report would lose eligibility immediately upon an annual independent audit which results in a DSH adjustment percentage less than or equal to 11.75.
- A registered child site would lose eligibility:
    - Immediately upon closing of the clinic or facility or when sold or transferred; or
    - Upon filing of a Medicare cost report that demonstrates that the site is not listed as reimbursable, or the services no longer have associated outpatient costs and charges reimbursed by Medicare.
- A hospital subject to the group purchasing prohibition would lose eligibility immediately upon use of a group purchasing arrangement.

Registration, termination, and annual recertification

HRSA publishes and regularly updates its list of covered entities and their registered associated sites on the public 340B database. In the preamble, HRSA notes that it publishes the conditions and procedures for registration and registration deadlines in the *Federal Register* and on its 340B program website. Current registration periods and effective dates are October 1 – 15 for an effective start date of January 1; January 1 – 15 for an effective start date of April 1; April 1-15 for an effective start date of July 1; and July 1-15 for an effective start date of October 1.

The proposed guidance retains a considerable amount of current practice related to registration, termination and annual recertification including, for example, that HRSA will assign a unique

identification number to entities listed on the public 340B database as eligible entities. HRSA clarifies that the inclusion of a covered entity within a larger organization does not make the entire organization eligible for the 340B program and that HRSA may provide for a special registration opportunity for entities during a public health emergency declared by the Secretary.

Other proposed clarifications would allow for covered entities removed from the program to re-enroll during the next regular enrollment period after satisfactorily demonstrating compliance with statutory requirements and offering repayment to affected manufacturers, if necessary.

The proposed guidance continues the existing policy enumerated through HRSA letters to participating entities that a covered entity must annually recertify that it continues to meet all program eligibility and compliance requirements.[4] The guidance clarifies that such recertification includes any child sites or contract pharmacies. If a covered entity voluntarily terminates its listing, it is expected to provide information and documentation for voluntary termination and whether it purchased 340B drugs during a period of ineligibility. HRSA may review submissions during recertification or at any time to determine if the covered entity remains eligible and may remove a covered entity from the public database for failure to meet eligibility requirements.

Group purchasing organization prohibition for certain covered entities.

The 340B statute prohibits the participation of DSH hospitals, children's hospitals and freestanding cancer hospitals in the 340B program if they purchase drugs through group purchasing organizations (GPO).[5] The prohibition extends to any pharmacy owned or operated by covered entities. The proposed notice retains a previously articulated exception to that rule and establishes two new exceptions:[6]

- It retains an exception for an off-site outpatient clinic of a 340B hospital if the outpatient clinic is located at a separate physical address from the 340B parent entity, is not participating in the program or listed on the 340B database, and purchases drugs through a separate account from the parent covered entity; and adds
- A GPO-purchased drug provided to an inpatient who, upon subsequent review, is designated as an outpatient for payment purposes; and
- A hospital which can only access a covered outpatient drug through a GPO account. In this case, the hospital must document attempts to purchase the drug at the 340B price and wholesale acquisition cost price and report the circumstances to HRSA, including drug name, manufacturer, and summary of attempts made to acquire the drug.

HRSA proposes that a covered entity electing to use a drug replenishment model should be able to clearly demonstrate through auditable records that it complies with the GPO prohibition. A covered entity subject to the GPO prohibition with GPO-purchased covered outpatient drugs

[4] February 10, 2012 Letter from the Department of Health Resources and Services Administration to 340B Program Participants, http://www.hrsa.gov/opa/programrequirements/policyreleases/programintegrity021012.pdf
[5] Section 340B(a)(4)(L)(iii) of the PHSA.
[6] 340B Drug Pricing Program Notice, Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization Participation, http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf

remaining in inventory on the effective date of enrollment in the 340B program may use those drugs until expended.

The proposed notice would provide that a covered entity removed from the program because of a violation of the GPO prohibition would be provided with an opportunity for a notice and hearing that would allow the entity to demonstrate that a violation is an isolated error. If HRSA agrees, then it could allow the covered entity to continue to participate under a corrective action plan. The existing policy is retained that requires a covered entity found in violation to offer to repay affected manufacturers.

The guidance clarifies that if a violation is limited to certain child sites, only those child sites where the violation occurred would be removed.

A covered entity removed from the program would be able to re-enroll during the next regular registration period after it has satisfactorily demonstrated to HRSA that it will comply with the GPO prohibition going forward and is in the process of offering repayment to affected manufacturers.

III. Part B - Drugs Eligible for Purchase under the 340B Program

Existing statute and guidance[7] provide that all drugs meeting the definition of outpatient covered drugs in 1927(k)(2) qualify for 340B discounts so long as they are not reimbursed under the Medicaid drug rebate program.

HRSA proposes to clarify that, for purposes of the 340B program, drugs reimbursed under Medicaid as part of a bundle are excluded from the definition of covered outpatient drug.

IV. Part C - Individuals Eligible to Receive 340B Drugs

HRSA proposes to add additional conditions to the definition of a patient eligible to receive 340B drugs to better ensure that covered entities are not able to resell or transfer a 340B drug to a person who is not a patient of the entity.

Current guidance provides for a 3-part test to determine if an individual is a patient of a covered entity. In this guidance, HRSA proposes to provide that an individual will be considered a patient of a covered entity on a prescription-by-prescription or order-by-order basis and extends the conditions to include those described in Table 1.

[7] HHS published guidance on May 7, 1993, and additional guidance on May 13, 1994 addressing 340B(a) coverage of outpatient drugs as defined in 1927(k)(2) of the Social Security Act: http://www.hrsa.gov/opa/programrequirements/federalregisternotices/limitationsondrugprices050793.pdf and http://www.hrsa.gov/opa/programrequirements/federalregisternotices/entityguidelines051394.pdf.

Table 1. Definition of an Eligible Patient

Existing Guidance (61 FR 55157-8, October 24, 1996)	Proposed Guidance
(1) The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.	(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. (Records are addressed in (6) below.)
(2) The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.	(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) The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.	(4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract.
In addition, an individual will not be considered a 'patient' of the entity for purposes of 340B if the only health care received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.	(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.
	(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

Existing Guidance (61 FR 55157-8, October 24, 1996)	Proposed Guidance
	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 in this section is met for each 340B drug.
In addition: An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHSA will be considered a 'patient' of the covered entity for purposes of this definition if so registered as eligible by the State program.	In addition: An individual enrolled in a Ryan White HIV/AIDS Program AIDS Drug Assistance Program funded by Title XXVI of the PHSA will be considered a patient of the covered entity for purposes of this definition. If a public health emergency is declared by the Secretary, a covered entity can request, and HHS can authorize, a covered entity to temporarily follow alternate patient eligibility criteria. Auditable records must be maintained.

The notice includes additional examples and conditions to help clarify the proposed changes to the definition of an eligible patient:

- A patient who sees a physician at a non-340B site, even if receiving follow-up care to care initially provided at a 340B site, would not be eligible to receive 340B drugs at the non-340B site.
- Access to an individual's medical records would not, by itself, make the individual a patient of a covered entity.
- If a patient is referred to a provider who is outside of the covered entity, prescriptions from that provider would not be eligible for a 340B discount. If the patient returns to the covered entity for ongoing medical care, subsequent prescriptions written by the covered entity's providers would be eligible for the 340B discount.
- The use of telemedicine, telepharmacy, remote and other health care service arrangements is permitted, as long as such use is consistent with state and federal law.
- Having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that provider is a patient of the covered entity for 340B purposes.

To avoid the prohibition on diverting drugs purchased under 340B to ineligible individuals, the proposed guidance would require a covered entity that uses a drug replenishment model to only order 340B drugs based on actual prior usage for eligible patients. If a 340B drug is found to have been diverted to an ineligible individual, the covered entity would be responsible for repayment to affected manufacturers and for any such repayments for 340B drugs diverted from a child site or through contract pharmacy arrangements. The covered entity would be required to

notify HRSA of its corrective actions regarding diversion, including any arrangements on repayment.

HRSA provides additional guidance in the preamble regarding the practice of some covered entities of retroactively reviewing drug purchases over long periods of time in order to re-characterize purchases as 340B eligible and collect rebates. HRSA instructs those entities to first notify manufacturers and to ensure that all processes are fully transparent with a clear audit trail.

V. Part D – Covered Entity Responsibilities

Prohibition of duplicate discounts.

Under the 340B program, duplicate discounts are prohibited – as such, a covered entity cannot collect Medicaid rebates for drugs provided to a Medicaid beneficiary in addition to rebates or discounts offered under the 340B program for those same individuals. HRSA established the 340B Medicaid Exclusion File as the mechanism to prevent duplicate discounts. The proposed notice explicitly lays out the process for using the file to prevent duplicate discounts for Medicaid fee-for-service (FFS) enrollees and for addresses the issue when enrollees are in Medicaid Managed Care plans, recognizing that covered entities may want to make different decisions about whether to obtain drugs using Medicaid rebates or 340B rebates based on whether a patient is a Medicaid FFS enrollee or a managed care enrollee.

Preventing duplicate discounts for Medicaid FFS enrollees. Under the guidance, HRSA retains its current practice of listing the covered entity's Medicaid provider number and/or National Provider Identifier (NPI) used by a covered entity or its child sites to purchase 340B drugs for its Medicaid Fee-For-Service (FFS) patients on the 340B Medicaid Exclusion File. If a covered entity's provider number or NPI is not listed on the 340B Medicaid Exclusion File, all drugs billed under the Medicaid provider number or NPI are purchased outside of the 340B program.

Preventing duplicate discounts for Medicaid Managed Care enrollees. Under the guidance, a covered entity would be able to choose whether to use 340B drugs for its Medicaid Managed Care Organization (MCO) patients and can exercise that choice with different selections for different 340B sites as long as such distinction is made available to HRSA. The preamble states that this information may be made available on a 340B Medicaid Exclusion File. The entity would be expected to have mechanisms in place to identify Medicaid MCO patients and HRSA may make this information available publicly through an Exclusion File or other mechanism.

Change requests. A covered entity would be able to make changes, effective on a quarterly basis, to its use of 340B drugs for Medicaid FFS or MCO patients after initial registration for itself or its child sites during HRSA-specified timeframes after informing HRSA of the change.

HRSA is seeking comments regarding alternative mechanisms to supplement the 340B Medicaid Exclusion File to allow for more nuanced approaches to purchasing 340B drugs that allow for only using 340Bdrugs when it is appropriate for service delivery – but that prevent duplicative discounts. HRSA seeks information about current state arrangements that could be adopted for this use.

Contract pharmacy. Because the risk of duplicate discounts rises when contract pharmacies are used, HRSA proposes that contract pharmacies not dispense 340B drugs for Medicaid FFS or MCO patients. If a covered entity wishes to purchase 340B drugs for its Medicaid patients and dispense them at a contract pharmacy, the covered entity would be required to provide a written agreement to HRSA for its approval that describes a system to prevent duplicate discounts.

State notification. Under the proposed guidance, if a covered entity is unable to use a 340B drug for a Medicaid FFS or MCO patient, it is expected to document the reason and have a mechanism in place to notify the State Medicaid agency or MCO.

Repayment. The guidance provides that if the information provided to HRSA does not reflect the covered entity's actual billing practices, the covered entity could be found in violation of the duplicate discount prohibition and could be required to repay rebates to manufacturers.

Maintenance of auditable records.

HRSA proposes 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. HRSA points out in the preamble, however, that if it finds a pattern of failure to comply with the program's requirements, it would not be precluded from accessing records prior to the 5-year period and notes that this record retention standard responds to stakeholders' request. Under the proposed standard, such records must be made available to HRSA at any time and to certain manufacturers in the event of an audit.

If an entity fails to maintain such records, it could be presumed to be out of compliance and subject to a penalty. If a covered entity systematically fails to maintain auditable records, or fails to provide them as requested by HRSA or a manufacturer authorized to conduct an audit, the covered entity would be removed from the 340B program after a notice and hearing process. The covered entity could also be liable for repayment to manufacturers for periods of ineligibility.

HRSA proposes to use discretion regarding removing covered entities from the program when the inability to produce records is not systematic. For example, if an entity is unable to provide a specific record for a particular patient, the entity may be required to repay the rebate for that particular incidence but HRSA would maintain the discretion to enable the entity to remain in the program.

A covered entity removed from the program for failure to maintain auditable records would be allowed to re-enroll during the next regular registration period after it has demonstrated its ability to comply with all 340B program requirements, including the ability to maintain auditable records.

VI. Part E - Contract Pharmacy Arrangements

Existing guidance[8] allows that a covered entity, regardless of the availability of an in-house pharmacy, may contract with one or more licensed pharmacies to dispense 340B drugs to eligible patients provided the arrangement is in accordance with all other statutory 340B requirements and applicable laws -- including the federal anti-kickback statute (42 U.S.C. 1320a-7b(B)).

The proposed guidance includes additional standards and clarifications for contract pharmacy arrangements. HRSA proposes that

- In the case of a covered entity whose 340B program eligibility is based on a federal grant, contract, designation or project, any contract pharmacy arrangement must comply with all grant, contract, or project requirements; and
- A covered entity can contract with one or more pharmacies on behalf of child sites if permitted by law in the applicable jurisdiction and the relationship is recognized and reflected in the covered entity's 340B database record. A child site could contract directly with a pharmacy if not prohibited by Federal, State, or local law.

The proposed guidance includes additional detail regarding the process of implementing contract arrangements. As part of that process, HRSA will list contract pharmacies on the public 340B database if a written contract exists between the covered entity and contract 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.

Under the guidance, a covered entity would be the only party that can submit a contract pharmacy registration, certify a contract pharmacy, make changes to the contract pharmacy arrangements on the public 340B database, and verify that the information in the 340B database regarding contract pharmacies is accurate. A covered entity could request additional contract pharmacy locations under a public health emergency as declared by the Secretary.

HRSA clarifies that it may remove a contract pharmacy from the 340B program if the agency finds that the pharmacy is not complying with program requirements in which case, the covered entity would be responsible for offering repayment of the 340B discount to manufacturers.

The notice retains guidance requiring that contract pharmacy arrangements comply with statutory requirements including prevention of diversion and prevention of duplicate discounts. HRSA proposes to add, as a condition of participation for a contract pharmacy, the expectation that the covered entity conduct oversight including quarterly reviews and annual independent audits of each contract pharmacy location. As part of this oversight, any program violation detected through quarterly reviews or annual audits of a contract pharmacy should be disclosed to HRSA and covered entities could be subject to applicable penalties for instances of duplicate discounts and diversion.

The 340B program registration deadlines and effective date announced in the *Federal Register* would apply to any changes to a covered entity's list of contract pharmacies. As contract pharmacies are not covered entities, they would not receive a 340B identification number.

[8] Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 *FR* 10772, March 5, 2010.

VII. Part F – Manufacturer Responsibilities

Pharmaceutical pricing agreement. Part F of the proposed guidance retains certain existing requirements for manufacturers and builds upon those requirements in a number of areas. It retains existing requirements that manufacturers enter into a pharmaceutical pricing agreement (PPA) with HRSA, and that under the agreement, a manufacturer must offer all required covered outpatient drugs to covered entities participating in the 340B program at no more than the statutory 340B ceiling price. HRSA adds clarification that covered outpatient drugs include drugs from each of the manufacturer's labeler codes. In the event of a transfer of ownership of the manufacturer, the PPA is automatically assigned to the new owner.

HRSA proposes to establish the following expectations for participating manufacturers:

- They must submit timely updates to its 340B database record and PPA to add new covered outpatient drugs to the 340B;
- Maintain auditable records demonstrating 340B program compliance for no less than 5 years and provide such records to HRSA when requested;
- Permit HRSA to audit manufacturer compliance; and
- For a manufacturer participating in the Medicaid Drug Rebate Program, they must sign a PPA within 30 days of enrolling in that program.

Additional proposed guidelines state explicitly that manufacturers without a Medicaid Drug Rebate Agreement can voluntarily enter into a PPA and may terminate their participation at any time in accordance with the terms of their PPA. When requesting termination, the manufacturer should provide an explanation and documentation of the termination, the timing of the termination, and the date the manufacturer will cease offering 340B.

Effective dates of PPAs. For manufacturers participating in the Medicaid Drug Rebate Program, the effective date for 340B pricing is proposed to be the same date the drug is first included in the Medicaid Drug Rebate Program, or the date of enactment of section 340B of the PHSA, if their participation in the Medicaid Drug Rebate Program preceded November 4, 1992. For manufacturers voluntarily signing a PPA, the effective date for 340B pricing is the date the agreement is signed by both parties. For manufacturers with an existing PPA that have a new drug approved, the effective date for 340B pricing for the new drug is the date the drug is available for sale.

Limited distribution. A manufacturer may limit distribution of a drug for a number of reasons – if it is required by an FDA risk evaluation and mitigation strategy, if there are special handling requirements or if there is a limited supply. In order to ensure that drug supplies are not limited in a discriminatory fashion or to discourage entities from participating in the program, HRSA requires manufacturers to notify HRSA in advance in writing where there is a limited distribution or alternate allocation of drugs and explain the reasons.[9]

[9]See 340B Drug Pricing Program Notice, Release No. 2011-1.1, Clarification of Non-Discrimination Policy, November 21, 2011, http://www.hrsa.gov/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf

The guidance incorporates these provisions. In addition, in the preamble, HRSA states that if the agency has concerns about the plan, it will work with the manufacturer to incorporate mutually agreed upon revisions prior to posting the plan on the 340B website.

Procedures for issuing refunds and credits. The proposed guidance includes the following procedures for when a manufacturer overcharges for 340B drugs. In the preamble, HRSA notes that the provisions are intended to improve clarity and to ensure that refunds are issued accurately and within a reasonable period of time.

Within 90 days of the determination that an overcharge has occurred, a manufacturer would be expected to provide a refund or credit in an amount equal to the difference between the sale price and the correct 340B price for that drug, multiplied by the number of units. A manufacturer would be required to submit to HRSA the 340B ceiling price recalculation information, an explanation of why the overcharge occurred, how the refunds will be calculated, and to which covered entities refunds or credits will be issued. Unless the refund amount is subject to a dispute, if the covered entity receiving a direct repayment fails to take action to accept or execute the repayment within 90 days of receipt of the repayment, the covered entity has waived the right to that repayment.

Manufacturer recertification. Under this guidance, HRSA is proposing to establish an annual recertification process for manufacturers to improve their ability to prevent pricing violations and to improve the accuracy of the public 340B database. As part of that process, a participating manufacturer would be required to review and update 340B database information on an annual basis and provide any changes to the 340B database as they occur.

VIII. Part G - Rebate Option for AIDS Drug Assistance Programs

HRSA proposes to continue the long-standing practice of allowing AIDS Drug Assistance Programs (ADAPs) access to 340B pricing but to add to the flexibility of the ADAPs to participate by accessing rebates or by directly purchasing drugs at discounted prices (or a hybrid of the two).

The guidance first establishes that ADAPs that participate in the 340B program are subject to all the same obligations, requirements, and duties imposed on other covered entities and that to participate in the 340B rebate option, an ADAP would be expected to—

- Be listed on the public 340B database and indicate at registration whether it will participate in the rebate option, direct purchase of 340B drugs, or a hybrid of the two;
- Make a *qualified payment* for an eligible patient; and
- Submit claims-level data to manufacturers documenting that a qualified payment was made to support each request for a rebate. In the preamble, HRSA indicates that it will provide subsequent guidance regarding the data to be provided by ADAPs in support of rebate requests.

A qualified payment by an ADAP for a covered outpatient drug would be defined as:

- A direct purchase by the ADAP of a covered outpatient drug at a price greater than the 340B ceiling price; or

- A payment by the ADAP of the health insurance premiums that cover the covered outpatient drug purchases at issue as well as payment of a copayment, coinsurance, or deductible for the covered outpatient drug.

The proposed guidance establishes that an ADAP participating via the rebate option or hybrid option would not be allowed to request a 340B rebate for a drug purchased by another covered entity or for a drug purchased at a price below the 340B ceiling price. This change is proposed to address concerns that ADAPs were able to access discounts for drugs for which the ADAP only paid a component of the drug's price (such as a copayment or coinsurance) rather than at full price. Because this provision may require tracking systems to ensure 340B prices are only available for qualified drug purchases, HRSA proposes that the effective date of Part G will be 12 months after the publication date of the final guidance.

Manufacturer obligations. Consistent with current practice, a manufacturer must pay a rebate for a covered outpatient drug to an ADAP which has registered for the program and has made a qualified payment for a covered outpatient drug. HRSA proposes to establish that the amount owed to an ADAP for a 340B discounted drug would be equal to the rebate (as calculated under statutory requirements) multiplied by the units of the drug – and that calculation applies whether or not the ADAP is participating via the rebate option, the direct pay option, or a hybrid of the two.

IX. Part H – Program Integrity

HRSA audit of a covered entity

HRSA retains its existing policies on audits of covered entities as described on HRSA's website, in letters to covered entities and manufacturers, and through audit findings, including:[10]

- Covered entities are subject to audits, and are expected to provide access to all specified records on behalf of the parent site, as well as its child sites and contract pharmacies by the deadlines specified. Failure to do so could result in penalties or termination from the 340B program;
- HRSA's assurance that only one 340B program audit, including audits by manufacturers, of a covered entity, its child sites, and contract pharmacies would be in process at any given time; and
- HRSA has the option to conduct an on-site review, a review of documentation, or both.

HRSA proposes in this guidance to establish a notice and hearing process under which a covered entity will have the opportunity to respond to an adverse audit. HRSA would initiate the process by providing written notice that will specify a 30 day response deadline. The covered entity would respond in writing to each issue of noncompliance, providing supporting documentation as necessary. If HRSA determined that the covered entity was no longer eligible, HRSA would identify a removal date. The covered entity would be liable for repayment to manufacturers for purchases made after the date the entity loses its eligibility.

[10] The following HRSA webpage includes links to material describing program audits and program integrity: http://www.hrsa.gov/opa/programrequirements/index.html.

If a final determination of noncompliance is made, the entity would need to submit a corrective action plan. Failure to do so could result in further HRSA action, including termination from the 340B program.

HRSA may make the final audit results available to the public.

Manufacturer audit of a covered entity.

Under current law, and existing program guidance, a drug manufacturer may audit covered entities so long as the audit directly pertains to drug diversion or the generation of duplicate discounts. [11] Manufacturers must submit their audit plans to HRSA for review before conducting the audit. While reasonable cause is required for a manufacturer audit under existing guidance, the proposed guidance would require that the manufacturer provide reasonable cause to HRSA prior to the audit, and document to HRSA's satisfaction that a reasonable person could conclude, based on reliable evidence, that a covered entity (or its child sites or contract pharmacies) may have violated the prohibitions against diversion or duplicate discounts. In addition, the proposed guidance adds specificity to the required components of a manufacturer's audit plan as well as for the process for a manufacturer audit. In addition, it clarifies that until HRSA makes a determination of a violation, a manufacturer must continue to sell covered outpatient drugs at no more than the 340B ceiling price to the covered entity.

The guidance proposes the following steps for a manufacturer audit:

- The manufacturer notifies the covered entity in writing if it believes the entity has violated the prohibitions and engages the covered entity in good faith to resolve the issues for at least 30 days from the covered entity's receipt of such notification.
- The manufacturer submits the basis for reasonable cause and its work plan to HRSA if the manufacturer cannot resolve the matter through good faith negotiations.
- HRSA reviews the request, the audit work plan, and all submitted documentation.
- The covered entity must provide access to its records as well as to those of its child sites and contract pharmacies.
- The scope of the audit would be limited to those drugs provided by the manufacturer and to records within the 5 year record retention standard.
- Patient confidentiality and the confidentiality of proprietary information must be maintained.
- The manufacturer submits the final audit report to the covered entity. The covered entity would provide a response to the manufacturer within 30 days of receipt of the audit report. A covered entity's failure to respond would be considered as agreement with the findings. If the covered entity agrees with the findings or recommendations in full or in part, the covered entity would include in its response to the manufacturer a description of the actions to address the audit findings.
- The manufacturer would submit copies of the final audit report and covered entity responses to HRSA. HRSA may also refer findings to other Federal agencies, the HHS, the Office of the Inspector General, or other departmental divisions, as appropriate.

[11] Final Notice on Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 FR 65406, ftp://ftp.hrsa.gov/bphc/pdf/opa/FR12121996.pdf.

The manufacturer's audit work plan would be expected to include audit objectives, scope, and methodology; skill and knowledge of the auditor's personnel including supervisors, and any intended use of consultants, experts, and specialists; tests and procedures to be used to assess a covered entity's system of internal controls; procedures to be used to determine the 340B purchases questioned as potential violations; and procedures to be used to protect patient confidentiality and proprietary information.

HRSA audit of a manufacturer and its contractors.

Current law provides for HRSA to audit a manufacturer (or its contractors, including wholesalers) participating in the program to determine whether it is complying with program requirements in statute, regulations, and the PPA. The proposed guidance would establish standards for such audits.

Under the standards, HRSA would notify the manufacturer or wholesaler in writing of HRSA's intent to audit. The manufacturer would be required to provide all requested records demonstrating compliance on behalf of itself and any affected wholesaler. HRSA would provide the manufacturer with written notice of any proposed audit findings and would request a response within 30 days. The manufacturer would be given the opportunity to respond to HRSA with its agreement or disagreement with each audit finding and provide documentation to support its disagreement within the specified deadline. The manufacturer would be deemed to agree with any finding that it does not address. HRSA would review the documentation and advise the manufacturer or wholesaler of its final determination regarding audit findings. HRSA will request a corrective action plan within a specified time to address findings, as needed. If HRSA determined that a manufacturer no longer met the requirements of the 340B program, HRSA would provide the manufacturer with notice and hearing pursuant to this section.

A corrective action plan that addresses each finding would be submitted within 30 days of receiving HRSA's audit findings of noncompliance that would include a timeline for corrective actions to occur.