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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

RIN 0906–AB08

340B Drug Pricing Program Omnibus Guidance

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), which is referred to as the "340B Drug Pricing Program" or the "340B Program." This notice proposes guidance for covered entities enrolled in the 340B Program and drug manufacturers that are required by section 340B of the PHSA to make their drugs available to covered entities under the 340B Program. When finalized after consideration of public comments solicited by this notice, the guidance is intended to assist 340B covered entities and drug manufacturers in complying with the statute.

DATES: Submit comments on or before October 27, 2015.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB08, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions. The first is the preferred method.

- *Federal eRulemaking Portal:* [http:// www.regulations.gov](http://www.regulations.gov). Follow instructions for submitting comments. This is the preferred method for the submission of comments.
- *Email:* 340BGuidelines@hrsa.gov. Include RIN 0906–AB08 in the subject line of the message.
- *Mail:* Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, Maryland 20857.

All submitted comments will be available to the public in their entirety.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act (PHSA) "Limitation on Prices of Drugs Purchased by Covered Entities," codified at 42 U.S.C. 256b.

The intent of the 340B Program is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (*H.R. REP. No. 102–384(II), at 12 (1992).*)

Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, and only include health care organizations that have certain Federal designations or receive funding from specific Federal programs. These include:

- Federally Qualified Health Centers
- Ryan White HIV/AIDS Program grantees
- Certain types of hospitals and specialized clinics.

Section 7101 of the Patient Protection and Affordable Care Act (*Pub. L. 111–148*) ("*Affordable Care Act*") expanded the types of covered entities eligible to participate in the 340B Program.

As of January 1, 2015, there were 11,530 registered covered entities participating in the 340B Program.

Section 340B of the PHSA instructs HHS to enter into a pharmaceutical pricing agreement (PPA) with certain drug manufacturers. If a drug manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed 340B ceiling prices as defined by statute.

HRSA calculates the ceiling prices quarterly using pricing data reported to the Centers for Medicare & Medicaid Services (CMS). Pursuant to section 340B(a)(1) of the PHSA, the 340B ceiling price is calculated by subtracting the Unit Rebate Amount from the Average Manufacturer Price.

As of January 1, 2015, there were 644 drug manufacturers participating in the 340B Program. When an eligible entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs.

Since 1992, HHS has interpreted the statutory requirements of the 340B Program through guidances published in the *Federal Register*, typically after notice and opportunity for comment. HHS is proposing this omnibus guidance to provide increased clarity in the marketplace for all 340B Program stakeholders and strengthen HHS's ability to administer the 340B Program effectively. This notice clarifies many current 340B Program guidances. HHS encourages all stakeholders to provide comments on this proposed guidance. In September 2010, HHS published two advanced notices of proposed rulemaking in the *Federal Register*, 340B Drug Pricing Program Administrative Dispute Resolution Process (75 FR 57233 (September 20, 2010)) and 340B Drug Pricing Program Manufacturer Civil Monetary Penalties (75 FR 57230 (September 20, 2010)). HHS issued a proposed rule addressing manufacturer civil monetary penalties and calculation of ceiling prices in June 2015 (80 FR 34583 (June 17, 2015)). Future rulemaking will address the administrative dispute resolution process.

II. Summary of the Proposed Guidance

Part A—340B Program Eligibility and Registration

- Section 340B(a)(4) of the PHSA (42 U.S.C. 256b(a)(4)) lists the entity types eligible to participate in the 340B Program and further requires that such entities must meet the requirements of section 340B(a)(5) of the PHSA.
- An entity participating in the 340B Program is referred to as a covered entity.
- HHS lists all covered entity sites registered for the 340B Program on the public 340B database.

Covered Entities

Non-Hospital Eligibility: Non-hospital covered entities described in sections 340B(a)(4)(A) through (K) of the PHSA include entities that receive certain Federal grants Federal contracts, Federal designations, or establish Federal projects.

HHS will list non-hospital covered entities on the public 340B database if they demonstrate eligibility and provide information related to their qualifying grant, contract, designation, or project.

A non-hospital covered entity also may include associated health care delivery sites located at a different address. These associated health care delivery sites will be listed on the public 340B database as able to purchase and use 340B drugs for their eligible patients if the non-hospital covered entity ("parent site") registers the associated sites and provides information demonstrating that each site is performing services under the main qualifying grant, contract, designation, or project.

Once registered, the associated sites of a covered entity parent site are termed "child sites." For example, if a covered entity sexually transmitted disease (STD) clinic

demonstrates that an off-site location receives Federal funds, and is performing services within the scope of their grant, HHS will list that location on its database as a child site of the main clinic. HHS will list sites that are sub-recipients of Federal grants, but seeking their own 340B identification numbers separate from a parent entity, if those entities 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.

Hospital Eligibility: Section 340B(a)(4)(L) of the PHSA defines the 340B Program eligibility requirements for hospitals defined in section 1886(d)(1)(B) of the Social Security Act (commonly referred to as "subsection (d) hospitals"). Section 340B(a)(4)(L)(i) specifies three categories of hospital eligibility.

- The first category of hospital eligibility under section 340B(a)(4)(L)(i) of the PHSA requires hospital ownership or operation by a State or local government. HHS will list hospitals qualifying under this category if they are wholly owned by a State or local government and recognized as such in Internal Revenue Service filings and acknowledgements, if applicable, or other documentation from Federal entities. HHS also will list hospitals operated through an arrangement where the State or local government is the sole operating authority of a hospital.
- The second category of hospital eligibility under section 340B(a)(4)(L)(i) of the PHSA requires a hospital to be a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government. HHS will list hospitals qualifying under this provision if they are formally granted a power usually exercised by the State or local government through State or local statute or regulation, through creation of a public corporation, or through development of a hospital authority or district to provide health care to a community on behalf of the government. Examples of governmental powers include, but are not limited to, the power to tax, issue government bonds, and act on behalf of the government.

HHS interprets section 340B(a)(4)(L)(i) of the PHSA as excluding hospitals that have been granted powers generally granted to private persons or corporations upon meeting of licensure requirements, such as a license to practice medicine or provide health care services commercially. HHS will list a hospital qualifying under this provision when it submits, as a part of its registration:

- (1) The name of the government entity granting the governmental power to the hospital;
- (2) a description of the governmental power granted to the hospital and a brief explanation as to why the power is considered to be governmental; and
- (3) a copy of any official documents issued by the State or local government to the hospital that reflect the formal grant of governmental power.

- The third category of hospital eligibility under section 340B(a)(4)(L)(i) of the PHSA includes a private non-profit hospital which has a contract with a State or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid. HHS will list hospitals qualifying under this provision that provide 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). The signed certification indicates that a contract is currently in place between the private, non-profit hospital and the State or local government to provide health care services to low-income individuals who are not entitled to Medicare or Medicaid. For the purposes of the 340B Program, such contract should create enforceable expectations for the hospital for the provision of health care services, including the provision of direct medical care.

Sections 340B(a)(4)(M) through (O) of the PHSA extend the 340B Program eligibility requirements under section 340B(a)(4)(L)(i) of the PHSA to children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, and establish the criteria by which these entity types are eligible to participate.

Medicare Disproportionate Share Adjustment Percentage: In addition to the requirements of section 340B(a)(4)(L)(i) of the PHSA, certain hospitals are required to exceed a Medicare disproportionate share hospital adjustment percentage to be eligible for the 340B Program. Calculation of the disproportionate share adjustment percentage is described in section 1886(d)(5)(F) of the Social Security Act. Disproportionate share hospitals (DSH), children's hospitals, and freestanding cancer hospitals must have a Medicare disproportionate share adjustment percentage greater than 11.75 or be a "Pickle hospital" as described in section 1886(d)(5)(F)(i)(II) of the Social Security Act to be eligible for the 340B Program (sections 340B(a)(4)(L) and (M) of the PHSA).

Rural referral centers and sole community hospitals must have a disproportionate share adjustment percentage equal to or greater than 8.0 (section 340B(a)(4)(O) of the PHSA).

Critical access hospitals are not eligible for Medicare disproportionate share hospital payments and do not have a disproportionate share adjustment percentage threshold for 340B Program eligibility (section 340B(a)(4)(N) of the PHSA).

HHS will list any hospital qualifying under this provision whose latest filed Medicare cost report demonstrates that its disproportionate share adjustment percentage meets the statutorily required threshold to be eligible for the 340B Program.

HHS will list children's hospitals that do not submit a Medicare cost report if they provide a statement from a qualified independent auditor certifying that the hospital would

meet one or both of the criteria in section 340B(a)(4)(L)(ii) of the PHSA and including the basis for that conclusion.

Eligibility of Off-Site Outpatient Facilities and Clinics (Child Sites): All off-site outpatient facilities and clinics (child sites) not located at the same physical address as the parent hospital covered entity will be listed on the public 340B database, and are able to purchase and use 340B drugs for eligible patients, if the hospital covered entity provides its most recently filed Medicare cost report demonstrating that:

- (1) Each of the facilities or clinics is listed on a line of the cost report that is reimbursable under Medicare; and
- (2) the services provided at each of the facilities or clinics have associated outpatient Medicare costs and charges.

These facilities and clinics will be listed individually even if they share the same physical address and/or common off- site location. HHS may also review other documentation as necessary to verify eligibility (*i.e.*, a trial balance report—a basic summary used by hospitals for financial statements). HHS does not list the outpatient clinics or departments within the same building (*i.e.*, same physical address) of a registered 340B parent hospital covered entity on its public 340B database, unless specifically requested by the covered entity. However, the hospital covered entity remains responsible for ensuring that those outpatient clinics or departments within the same building of the hospital meet all eligibility and 340B Program requirements in statute.

HHS will list an outpatient facility of a children's hospital when the registration submitted by the hospital demonstrates that the requested outpatient facility:

- (1) Is an integral part of the hospital, and
- (2) would be correctly included on a reimbursable line with associated Medicare costs and charges on a Medicare cost report, if filed.

HHS is actively seeking comments on alternatives to demonstrating the eligibility of an off-site outpatient facility or clinic. In considering alternatives, HHS has explored use of provider-based standards (42 CFR413.65); however, many hospitals choose not to seek provider-based designation for their departments or facilities for unrelated reasons even though these facilities may qualify for the designation. Comments on previously proposed guidance at 72 FR 1543 (January 12, 2007), highlighted the difficulty in verifying whether outpatient facilities and clinics meet provider-based standards. HHS has also previously considered use of form CMS 855A, Medicare Enrollment Application for Institutional Providers, which is used by hospitals to apply to enroll in the Medicare program or make a change in the hospital's enrollment information. HHS has found this form insufficient as an accurate indicator of the facility's reimbursement under Medicare for purposes of 340B Program administration. For those parties proposing forms submitted to CMS, please

include information regarding the deadline for submission of the proposed form, the proposed form's relationship to Medicare reimbursement, and other key factors.

Non-Hospital Loss of Eligibility: In all scenarios, the covered entity must immediately notify HHS regarding any changes in eligibility for itself or a child site. When a covered entity loses 340B Program eligibility, HHS will list that date on the public 340B database as the termination date. HHS will update the public 340B database as soon as the entity notifies HHS or HHS becomes aware that it no longer meets a 340B eligibility requirement.

If a parent covered entity site is terminated, all child sites and contract pharmacy arrangements will be removed from the public 340B database with the same termination date.

A covered entity is liable to manufacturers for repayment for the 340B discounts on any drugs purchased for itself, any child site, or any contract pharmacy when the covered entity was ineligible for the 340B Program for any reason.

A non-hospital covered entity would lose 340B Program eligibility immediately upon loss of its qualifying Federal grant, contract, designation, or project or upon closing of the entity.

A child site's 340B Program eligibility is tied to the eligibility of the parent covered entity; if a non-hospital parent covered entity loses eligibility to participate in the 340B Program, all registered child sites will simultaneously lose eligibility and must cease purchasing and using 340B drugs.

A child site of a non-hospital covered entity will always lose eligibility if the child site closes, or if the child site no longer qualifies under the parent covered entity's grant, project, designation, or contract.

If a parent or child site is registered under multiple covered entity types, loss of eligibility for any one covered entity type requires the parent and child sites to stop purchasing and using 340B drugs under the covered entity type for which the sites are no longer eligible. For example, if a site is registered for the 340B Program as a Federally qualified health center (FQHC) and tuberculosis (TB) clinic, and the parent site loses TB funding, both the parent and child sites must immediately stop purchasing and using 340B drugs under the TB grant and must have its TB 340B identification number terminated. The sites may continue purchasing and using 340B drugs under its registered FQHC 340B ID for eligible patients.

Hospital Loss of Eligibility: In all scenarios, the covered hospital entity must immediately notify HHS regarding any changes in eligibility for itself or an off-site outpatient facility or clinic. When a covered entity loses 340B Program eligibility, HHS will

list that date on the public 340B database as the termination date. HHS will update the public 340B database as soon as the entity notifies HHS or HHS becomes aware that it no longer meets a 340B eligibility requirement.

If a parent covered entity site is terminated, all off- site outpatient facilities or clinics or contract pharmacies will be removed from the public 340B database with the same termination date.

If any non- eligible entity purchased 340B drugs after the date of loss of eligibility, it will be noted in the public 340B database.

Pursuant to section 340B(a)(4)(L)(ii) of the PHSA, a hospital covered entity loses 340B Program eligibility immediately upon filing of a Medicare cost report that demonstrates the hospital's disproportionate share adjustment percentage has fallen below the required threshold for the hospital type for which it is registered. For example, if a freestanding cancer hospital files its cost report on May 30, 2016, with a disproportionate share percentage of 10 percent (which is below the required threshold for freestanding cancer hospitals, 11.75 percent), that hospital and all of its child sites and contract pharmacies will be terminated effective May 30, 2016; and the covered entity must stop purchasing and using 340B drugs on May 30, 2016, or be subject to repayment to manufacturers for 340B drugs purchased after May 30, 2016. In the case of a children's hospital that does not file a Medicare cost report, the hospital would lose eligibility upon its required annual independent audit which results in a disproportionate share adjustment percentage less than or equal to 11.75 being issued.

A hospital covered entity eligible on the basis of having a contract with a State or local government will lose 340B Program eligibility if its contract with a State or local government expires or is terminated.

A critical access hospital would lose its eligibility for the 340B Program upon losing its critical access hospital designation from CMS.

In addition, a hospital subject to the group purchasing organization prohibition will lose 340B Program eligibility as described in this proposed guidance if it fails to comply with the prohibition.

An off-site outpatient facility's eligibility to participate in the 340B Program is tied to the eligibility of the parent hospital. If a parent hospital loses eligibility to participate in the 340B Program, all registered child sites will simultaneously lose eligibility and must immediately cease purchasing and using 340B drugs.

A child site may lose eligibility separately from the parent covered entity in certain circumstances.

An off-site hospital outpatient facility registered as a child site will lose 340B Program eligibility immediately upon closing, sale or transfer of the outpatient facility, or the parent covered entity's filing of a Medicare cost report which demonstrates the facility is no longer reimbursable or services provided at the facility no longer have associated outpatient costs and charges under Medicare.

Additionally, a child site may lose eligibility separately from the parent hospital covered entity if the child site violates the group purchasing organization prohibition.

A parent covered entity may be liable for repayment to manufacturers for any 340B drug purchase made after the child site loses eligibility. A parent covered entity must immediately notify HHS of any change in eligibility.

Compliance and Loss of 340B Program Eligibility: Once enrolled in the 340B Program, the covered entity must comply with all 340B Program statutory requirements as of the covered entity participation start date listed on the public 340B database. The covered entity must continue to meet all eligibility requirements for the entity type for which it is registered and listed on the public 340B database.

A parent covered entity and its authorizing official will be responsible for the compliance of any related child sites.

A covered entity is also responsible for the compliance of contract pharmacy sites that dispense drugs on behalf of the covered entity.

Registration and Termination

Registration: Sections 340B(d)(2)(B)(i), (ii), and (iv) of the PHSA authorize HHS to maintain a single, universal, and standardized identification system listing participating covered entities. HHS lists covered entities, including any registered associated sites, on its public 340B database. The registered covered entity is listed as the "parent" site and the registered off-site outpatient facility, clinic, eligible off-site location or associated site is listed as the "child" site.

The list of covered entity sites on the public 340B database assists manufacturers in verifying eligibility for 340B drug purchases. The public 340B database includes the name, location, eligibility type, and eligibility date for each covered entity, including parent and child sites and, when applicable, the date and reason for termination.

The parent covered entity is given a unique 340B identification number and any child site is designated by the same 340B identification number followed by a letter or letters (e.g., if the parent entity is registered as a disproportionate share hospital with the identification number DSH000001, that hospital's eligible off-site outpatient facilities or clinics, once registered, will be listed as DSH000001A, DSH000001B).

Registered parent and child sites are able to purchase and use 340B drugs for their eligible patients. HHS publishes the conditions and procedures for registration and registration deadlines in the *Federal Register* and on the HHS 340B Program Web site (www.hrsa.gov/opa).

The current registration periods and effective dates for the 340B Program are:

- October 1–October 15 for an effective start date of January 1;
- January 1– January 15 for an effective start date of April 1;
- April 1–April 15 for an effective start date of July 1; and
- July 1–July 15 for an effective start date of October 1.

If the 15th falls on a Saturday, Sunday, or Federal holiday, the deadline for submitting registrations will be the next business day (77 FR 43342 (July 24,2012)).

Special registration procedures apply in the case of a public health emergency declared by the Secretary. Information will be posted on the 340B Program Web site as to the geographic scope and duration of such registration opportunities.

HHS lists a covered entity on its public 340B database after receiving the entity's registration from an appropriate authorizing official, such as a chief executive officer, chief operating officer, chief financial officer, or an employee who can legally bind the covered entity. During registration, the authorizing official attests to the covered entity meeting the eligibility criteria and its ability to comply with the 340B Program requirements.

HHS will not list a covered entity on the public 340B database when the information submitted pursuant to 340B Program registration does not demonstrate the entity is eligible for the 340B Program according to the statutory requirements.

HHS will not list a non-hospital covered entity if the appropriate HHS operating division that administers the statutory programs to which eligibility is linked does not verify the entity's eligibility.

HHS will not list covered entities that are hospitals if their latest filed Medicare cost reports (or such documentation described for children's hospitals that do not file a Medicare cost report) do not verify eligibility of the hospital and off-site outpatient facilities or clinics at issue.

Eligibility for the 340B Program is limited to the categories of entities specified in statute. Inclusion of a covered entity in a larger organization such as a health system or an Accountable Care Organization does not make the entire larger organization eligible for the 340B Program or automatically qualify all of the individuals receiving services from the larger organization as patients of the covered entity for 340B Program purposes.

Likewise, if covered entity eligibility is limited to a distinct part of a hospital, HHS will not list the hospital as a covered entity unless the hospital is otherwise eligible and registers for the 340B Program. For example, if a covered entity hemophilia treatment center (HTC) is part of a hospital, HHS will not list the hospital as a covered entity for the 340B Program unless otherwise eligible and registered as such.

A non-hospital covered entity is listed by HHS under each of its eligible entity types, and is able to purchase and use 340B drugs under each of its eligible entity types, if the covered entity registers accordingly. For example, a covered entity site with the same address that is eligible as sexually transmitted disease (STD) and TB clinics will register and be listed with a 340B identification number for both STD and TB entity types.

If a hospital is eligible for the 340B Program as more than one hospital entity type, HHS will only list the entity as one hospital type. HHS will change the entity type under which a hospital is listed if the hospital:

- terminates the previous registration,
- submits a new registration during regular enrollment periods as set forth by HHS, and
- abides by the statutory requirements of the new covered entity type.

HHS will list contract pharmacies that have written agreements with the new entity type if the entity registers these pharmacies as part of its new registration. HHS lists covered entities on the public 340B database on the condition that the entity will immediately update the public 340B database information or submit updates to HHS for any changes to any portion of its covered entity database record, including changes in its child site or contract pharmacy and authorized shipping address information.

The PHSA does not include pharmacies as an entity type that is eligible to participate in the 340B Program.

HHS lists in-house pharmacies owned and operated by the covered entity as an authorized shipping address (*i.e.*, the "ship-to" field in the public 340B database) if 340B drugs will be shipped there directly for use by the covered entity.

HHS also lists contract pharmacies registered by a covered entity to dispense 340B drugs to eligible patients of the covered entity.

HHS lists central fill pharmacies or repackaging firms as an authorized shipping address for a covered entity.

Termination: HHS lists covered entities on its public 340B database on the condition that the covered entity will regularly review and update its information on the database.

Upon loss of eligibility of a parent site, child site, or termination of any contract pharmacy arrangement, the covered entity must immediately notify HHS and stop purchasing and using 340B drugs at the terminated site(s).

HHS requests that the covered entity provide:

- the reason for the loss of eligibility,
- the effective date for the loss of eligibility, and
- the date of the last 340B drug purchase for a terminated covered entity, child site, or contract pharmacy.

A covered entity is liable to manufacturers for repayment for the 340B discounts on any drugs purchased for itself, any child site, or any contract pharmacy when the covered entity was ineligible for the 340B Program for any reason.

HHS is proposing to clarify when a covered entity can re-enroll in the 340B Program once removed for violation of an eligibility requirement, including the requirement not to use a group purchasing organization. A covered entity removed from the 340B Program would be able to re-enroll in the 340B Program during the next regular enrollment period after it has satisfactorily demonstrated to HHS that it will comply with all statutory requirements moving forward and has completed, or is in the process of offering repayment to affected manufacturers as necessary. HHS is seeking comments on what type of information a covered entity would submit to HHS to demonstrate compliance to re-enroll in the 340B Program. For example, if removed for violation of the group purchasing organization prohibition, a hospital could demonstrate it has set up appropriate purchasing accounts and, if applicable, software programmed to allocate drug purchases to the correct purchasing accounts; it could also submit policies and procedures directing proper purchase allocations and a self-audit report confirming correct purchasing. Or, hospitals that lost eligibility based on DSH percentage, but subsequently won an appeal to have the DSH percentage changed, could submit documentation of the appeal.

Annual Recertification: Sections 340B(d)(2)(B)(i) and (ii) of the PHSA require the development of procedures for covered entities to update 340B Program database information annually, and for HHS to verify the accuracy of this information.

HHS will list covered entities on its public 340B database that annually certify the accuracy of their database information and their compliance with 340B Program statutory requirements.

HHS reviews and verifies this information through HHS Operating Divisions, where appropriate, and will terminate a covered entity from the 340B Program if it is ineligible by informing the entity and noting this in the public 340B database.

By certifying compliance with all 340B Program requirements, a covered entity attests that it:

- employs effective business practices to ensure and monitor ongoing compliance, including self-audits where appropriate;
- maintains accurate 340B database information; and
- notifies HHS in the event the entity is no longer eligible for the 340B Program or has violated any 340B Program requirement, subject to HHS audit.

A covered entity may voluntarily terminate its 340B Program participation (or the participation of a child site or contract pharmacy arrangement) during the annual recertification process or at any other time.

When a covered entity removes itself, its child site, or contract pharmacy arrangement from the 340B Program, the covered entity is expected to provide an explanation and documentation of the termination, the timing of the termination, and the date the covered entity has ceased or plans to cease purchasing and using 340B drugs under the 340B Program. Failure to provide this information will be considered in any determination regarding the covered entity's liability to manufacturers, and if the organization seeks to re-enroll as a covered entity.

A covered entity removed for failure to recertify would be able to re-enroll for the 340B Program during the next regular enrollment period after the covered entity has demonstrated to HHS its ability to comply with all 340B Program requirements.

Group Purchasing Organization (GPO) Prohibition for Certain Covered Entities: To be eligible for the 340B Program, disproportionate share hospitals (DSH), children's hospitals, and freestanding cancer hospitals in the 340B Program are subject to the GPO prohibition in section 340B(a)(4)(L)(iii) of the PHSA, which states that to be eligible, these hospital covered entities do not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." Section 340B(b)(2)(A) defines "covered outpatient drug" as the definition in section 1927(k) of the Social Security Act (42 U.S.C. 1396r–8(k)).

Section 340B of the PHSA does not limit GPO participation for inpatient drug purchases. A GPO may only be used by one of the affected covered entities to purchase drugs dispensed to inpatients or to purchase drugs which do not meet the definition of covered outpatient drug.

This prohibition extends to any pharmacy owned or operated by these covered entities, and takes effect as of the start date of enrollment in the 340B Program. The prime vendor program established pursuant to section 340B(a)(8) of the PHSA is not considered a GPO subject to this prohibition. During registration for the 340B Program, the authorizing official registering a DSH, children's hospital, or freestanding cancer hospital attests it will comply

with the statutory GPO prohibition. These hospitals also attest to compliance with this prohibition during the annual recertification process.

Exceptions The proposed guidance clarifies specific situations which would not violate the GPO statutory prohibition.

- First, the proposed guidance clarifies that a GPO account may be used at an off-site outpatient facility (*i.e.*, not at the same physical address of the 340B hospital covered entity) of a 340B covered entity which is not participating in the 340B Program or listed on the public 340B database. HHS is proposing that an off-site outpatient facility which is not participating or listed on the public 340B database, is able to access outpatient drugs through a GPO as long as that facility has a purchasing account separate from that of any 340B enrolled site, and that facility ensures GPO purchased drugs are never provided to outpatients of the hospital or other child sites enrolled in the 340B Program.
- Second, the proposed guidance clarifies that 340B eligibility can be maintained when GPO drugs are provided to an inpatient whose status is subsequently changed to outpatient by a third party, such as an insurer or a Medicare Recovery Audit Contractor, or a hospital review, provided there is sufficient documentation of the patient's change of status.
- Finally, HHS is proposing to recognize an exception to the GPO prohibition for hospitals that cannot access a drug at the 340B price or at wholesale acquisition cost (WAC) to prevent disruptions in patient care. HHS will consider a hospital in compliance with the statute if a hospital covered entity that resorts to using a GPO for covered outpatient drugs in this circumstance documents the facts surrounding the purchase and provides HHS with the name of drug in question, the manufacturer, and a brief description of the attempts to purchase the drug at the 340B price and the WAC price prior to purchasing the drug through a GPO.

Under no circumstances may the specific situations noted in these exceptions be used to circumvent the GPO prohibition to supply GPO- purchased covered outpatient drugs to parts of the hospital subject to the GPO prohibition.

Drug Replenishment Models: A large number of hospitals use replenishment models to operationalize the 340B Program. HHS clarified its position in a February 2013 Policy Release No. 2013–1, *Statutory Prohibition on Group Purchasing Organization Participation*. Just as a hospital subject to the GPO prohibition may not purchase covered outpatient drugs using a GPO for use with 340B- ineligible outpatients, a hospital that orders drugs based on actual prior usage cannot tally 340B-ineligible outpatient use for drug orders on a GPO account. A covered entity may be found in violation of the statutory GPO prohibition if a replenishment model or split billing software is used in a manner contrary to the statute. Pursuant to section 340B(a)(5)(C) of the PHSA, covered entities

using replenishment models should maintain records demonstrating that the replenishment model and associated software is used in a manner that complies with the statute. Part C of this proposed guidance provides further information on drug replenishment models.

Use of Previously-Purchased GPO Drugs: Newly enrolled covered entities subject to the GPO prohibition must stop purchasing covered outpatient drugs through a GPO before the first day the covered entity is listed on the public 340B database as eligible to purchase 340B drugs ("start date"). However, if a covered entity has GPO-purchased covered outpatient drugs remaining in inventory on or after the covered entity start date for the 340B Program, those drugs may be used until expended.

Violations of the Statutory GPO Prohibition: HHS is aware that manufacturers and covered entities may currently work together to identify and correct errors in GPO purchasing within 30 days of the initial purchase through a credit and rebill process as a standard business practice. HHS encourages manufacturers and covered entities to continue this practice. This collaboration necessitates a covered entity's frequent monitoring of compliance to identify GPO purchasing errors within 30 days of the erroneous purchase.

Under this proposed guidance, HHS proposes to extend the notice and hearing process, as described in Part H, to covered entities found in violation of the GPO prohibition.

As part of the notice and hearing process, the covered entity could demonstrate that the GPO violation was an isolated error as opposed to a systematic violation.

If the covered entity were to demonstrate the GPO violation was an isolated incident and the covered entity is currently in compliance, the covered entity will be permitted to remain in the 340B Program upon submission of a corrective action plan.

If, after notice and hearing, the covered entity's GPO violation was determined not to be isolated, the covered entity would be deemed ineligible for the 340B Program as of the date of the violation and immediately removed.

A covered entity removed from the 340B Program would be required to offer repayment to affected manufacturers for any 340B drug purchase made after the first date of violation of the GPO prohibition.

If a parent site were deemed ineligible by HHS due to GPO prohibition violation, the parent site, all child sites, and all contract pharmacy arrangements would be removed from the 340B Program.

In the case of a violation that HHS determines is isolated to a child site, the child site would be removed from the 340B Program. The parent site may be able to remain in the

340B Program if it can demonstrate that the GPO prohibition violation was isolated to the child site and that the parent site did not violate the GPO prohibition.

GPO participation cannot be limited to a child site if the parent site also purchases drugs on the same account as the child site.

Part B—Drugs Eligible for Purchase Under 340B: Pursuant to section 340B(a) of the PHSa, a manufacturer participating in the 340B Program must offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price. The term covered outpatient drug is defined in section 1927(k)(2) of the Social Security Act and is limited by paragraph (3) which states:

"The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (*and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug*):

- (A) Inpatient hospital services;
- (B) Hospice services;
- (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
- (D) Physicians' services;
- (E) Outpatient hospital services;
- (F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded;
- (G) Other laboratory and x-ray services; and
- (H) Renal dialysis.

Such term also does not include any such drug for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication." (Section 1927(k)(3) of the Social Security Act). (*emphasis added*)

HHS published guidance on May 7, 1993, which stated that a covered outpatient drug does not include any drug, biological product, or insulin that meets this limiting definition (58 FR 27289, 27291).

HHS published additional guidance on May 13, 1994, which further clarified that, in the settings identified in the limiting definition,

- "if a covered drug is included in the *per diem* rate (*i.e.*, bundled with other payments in an all- inclusive, a per visit, or an encounter rate), it will not be included in the [340B Program].
- However, if a covered drug is billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program." (59 FR 25110, 25113).

The limiting definition includes two parts which, if both are met, exclude a drug, biological product, or insulin mentioned in section 1927(k)(2) of the Social Security Act as a covered outpatient drug.

- First, the drug is "provided as part of, or as incident to and in the same setting as" the services listed in section 1927(k)(3) and
- second, the payment for such service may be made under Title XIX of the Social Security Act and not as direct reimbursement for the drug.

This guidance proposes that a drug that satisfies both conditions will not qualify as a covered outpatient drug in the 340B Program.

Further, the limiting definition in section 1927(k)(3) to exclude covered outpatient drugs for purposes of the 340B Program 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, a drug provided as part of a hospital outpatient service which is billed to any other third party or directly billed to Medicaid would still qualify as a covered outpatient drug.

Covered entities that purchase drugs through the 340B Program which do not meet the definition of covered outpatient drug would be subject to repayment to affected manufacturers.

Hospital covered entities subject to the GPO prohibition in section 340B(a)(4)(L)(iii) of the PHSA must ensure that drugs that meet the definition of covered outpatient drug described in section 1927(k) of the Social Security Act are purchased using the correct accounts to comply with the GPO prohibition.

A covered entity must maintain auditable records pursuant to section 340B(a)(5)(C) of the PHSA which pertain to compliance with this provision.

In accordance with section 340B(a)(1) of the PHSA, a manufacturer may not condition the sale of a covered outpatient drug on covered entity compliance with this provision. Remedies for violations would be imposed under the enforcement provisions of the 340B Program, but manufacturers may not unilaterally deny sales based on such violations.

Part C—Individuals Eligible to Receive 340B Drugs

Section 340B(a)(5)(B) of the PHSA prohibits covered entities from reselling or transferring drugs purchased under the 340B Program to individuals who are not patients of the covered entity.

HHS is proposing a clarified definition of patient for purposes of the 340B Program. In its clarification of what constitutes a violation of section 340B(a)(5)(B) of the PHSA, HHS also is proposing its interpretation of section 340B(a)(5)(D) of the PHSA. Section 340B(a)(5)(D) of the PHSA states a covered entity violating section 340B(a)(5)(B) of the PHSA shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug.

The sale or transfer of 340B drugs to an individual not meeting the criteria in this section of the proposed guidance is considered diversion. HHS has proposed a number of guidances that have addressed the definition of a patient.

The current guidance, issued in 1996, outlined a three-part test which state that an "individual is a 'patient' of a covered entity only if:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

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.

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." (61 FR 55157–8, October 24, 1996).

The development of this proposed guidance is meant to address the diverse set of 340B covered entities, and was informed by 340B Program audits, through which HHS has learned more about how the definition of patient is applied in different health care settings.

Under this proposed guidance, an individual will be considered a patient of a covered entity, on a prescription-by- prescription or order-by-order basis, if all of the following conditions are met:

1. *The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database.*

HHS interprets the statute such that a 340B eligible patient receives a health care service from the covered entity, and the covered entity is medically responsible for the care provided to the individual.

An individual who sees a physician in his or her private practice which is not listed on the public 340B database or any other non-340B site of a covered entity, even as follow-up to care at a registered site, would not be eligible to receive 340B drugs for the services provided at these non-340B sites.

The use of telemedicine involving the issuance of a prescription by a covered entity provider is permitted, as long as the practice is authorized under State or Federal law and the drug purchase otherwise complies with the 340B Program.

An individual will not be considered a patient of the covered entity if 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. Access to an individual's records by a covered entity, by itself, does not make the individual a patient of that covered entity.

2. *The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.*

Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships that would meet this standard.

Simply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B Program purposes.

If a patient is referred from the covered entity for care at an outside provider and receives a prescription from that provider, the drug in question would not be eligible for a 340B discount at that covered entity. However, when the patient returns to the covered entity for ongoing medical care, subsequent prescriptions written by the covered entity's providers may be eligible for 340B discounts.

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 be considered a patient of a covered entity if the health care service received results in a drug order or prescription. The use of telemedicine, telepharmacy, remote, and other health care service arrangements (e.g., medication therapy management) involving the issuance of a prescription by a covered entity is permitted, as long as the practice is authorized under State or Federal law and otherwise complies with the 340B Program.

An individual would not be considered a patient of a covered entity whose only relationship to the individual is the dispensing or infusion of a drug. The dispensing of or infusion of a drug alone, without a covered entity provider-to-patient encounter, does not qualify an individual as a patient for purposes of the 340B Program. However, if the covered entity infuses a drug and meets all other criteria as defined in this section, an individual may be classified as a patient for purposes of 340B.

4. *The individual's health care is consistent with scope of the Federal grant, project, designation, or contract.*

In the case of a covered entity with 340B eligibility based on receipt of a Federal grant, Federal project, Federal designation, or Federal contract, individuals will be considered patients only if they are receiving health care at a covered entity site from a covered entity provider which is consistent with the health care service or range of services designated in the Federal grant, project, designation, or contract.

These criteria extend to each child site of a covered entity. If a child site's scope of grant, project, or contract is more limited than that of the parent site, individuals will be considered patients if they are receiving health care at the child site which is consistent with the health care service or range of services delegated to the child site. For example, if a child site of an FQHC is limited in its scope of grant to treating pediatric individuals, then only individuals receiving pediatric care meeting the limitations specified in the child site scope of grant would be eligible to receive 340B drugs.

A covered entity registered as one of the hospital covered entity categories is not subject to this limitation. However, a hospital that is only enrolled in the 340B Program on the basis of a Federal grant, contract, or project is subject to this limitation. For example, a hospital that is not enrolled as one of the hospital covered entity types may instead receive a grant for a family planning project. In this case, the hospital cannot access 340B drugs for patients receiving care outside of those facilities and outside the scope of the Federal family planning project.

With respect to Indian Tribes or Tribal Organizations whose 340B Program eligibility arises solely from the Indian Self-Determination and Education Assistance Act, Public Law 93–638 (ISDEAA), use of 340B drugs is limited to those individuals that the tribe or tribal organization is authorized to serve under its ISDEAA contract, in accordance with the requirements in Section 813 of the Indian Health Care Improvement Act.

5. *The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.*

Section 340B(a)(1) of the PHSA establishes the 340B Program as a drug discount program for covered entities furnishing covered outpatient drugs. Therefore, an individual cannot be considered a patient of the entity furnishing outpatient drugs if his or her care is classified as inpatient.

An 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.

The covered entity should maintain auditable records documenting any changes in patient status due to insurer determinations.

The outpatient status of individuals who are self-pay, uninsured, or whose care is provided by the hospital covered entity's charity care program, would be determined by the covered entity's documented, auditable policies and procedures. We expect that most such policies include categorizing a patient as inpatient or outpatient based on how the services would have been billed to Medicare or another third party payer, if such patient were eligible.

6. *The individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.*

An individual will be considered a patient if he or she has an established relationship such that the covered entity maintains auditable health care records that demonstrate the covered entity has a provider-to-patient relationship for the health care service that results in the order or prescription and that the covered

entity retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to an individual.

Records: Pursuant to section 340B(a)(5)(C) of the PHSA, which requires covered entities to permit audits of records directly pertaining to compliance, covered entities must maintain records that demonstrate that all of the criteria above were met for every prescription or order resulting in a 340B drug being dispensed or accumulated through a replenishment model.

Eligibility for Covered Entity Employees: The 340B Program does not serve as a general employee pharmacy benefit or self-insured pharmacy benefit. HHS guidance has always specified, and this proposed guidance continues to make explicit, that only individuals who are patients of the covered entity are eligible for drugs purchased through the 340B Program. Employees of covered entities do not become eligible to receive 340B drugs solely by being employees, but by being a patient as defined in this guidance. Covered entities that solely have financial responsibility for employees' health care, and contract with prescribing health care professionals loosely affiliated or unaffiliated with the covered entity, would not meet the level of responsibility for health care services as outlined in this guidance. A covered entity would be acting primarily as the insurance provider for these individuals and not as the health care provider of these individuals. For 340B Program purposes, there is a fundamental difference between the individuals for whom the covered entity provides direct health care services and meets all criteria in this section and employees for whom a covered entity only provides insurance coverage.

AIDS Drug Assistance Program (ADAP): HHS proposes to reaffirm its long standing position that 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.

Emergency Provisions: HHS proposes to recognize the unique circumstances that arise during a public health emergency declared by the Secretary and to allow certain flexibilities for demonstrating that an individual is a patient of a covered entity in these situations (e.g., limited medical documentation or a site not listed in the 340B database). A covered entity is expected to maintain auditable records pertaining to the effective dates and alternate methods to be used during the Secretarial-declared public health emergency.

Drug Inventory/Replenishment Models: Covered entities use replenishment models to manage drug inventory, including 340B drugs, which is permissible if the covered entity remains in compliance with all 340B requirements. For example, a 340B covered entity that sees many different types of patients (e.g., inpatients, 340B-eligible outpatients, and other outpatients) would tally the drugs dispensed to each type of patient and then replenish the drugs used by reordering from the appropriate accounts.

Some covered entities use software, referred to as accumulators, to track drug use for each patient type. The accumulator software would indicate which drugs are available to reorder on various accounts. In this example, the covered entity counts the units or amounts received by each 340B eligible patient. Once the covered entity has dispensed enough of a certain drug to equal an available package size, the covered entity could reorder that drug at the 340B price.

Once drugs are received in inventory, the drugs lose their identity as 340B drugs, inpatient GPO drugs, or outpatient non-340B/non-GPO drugs. Each 340B drug order placed should be supported by auditable records demonstrating prior receipt of that drug by a 340B-eligible patient.

If the covered entity improperly accumulates or tallies 340B drug inventory, even if it is prior to placing an order, the covered entity has effectively sold or transferred drugs to a person who is not a patient, in violation of section 340B(a)(5)(B) of the PHSA.

A similar violation would occur if the recorded number of 340B drugs does not match the actual number of 340B drugs in inventory, if the covered entity maintains a virtual or separate physical inventory.

HHS is aware that manufacturers and covered entities currently work together to identify and correct errors in purchasing within 30 days of the initial purchase through a credit and rebill process. HHS encourages manufacturers and covered entities to continue this practice. This collaboration requires a covered entity's frequent monitoring of compliance to identify purchasing errors within 30 days of the erroneous purchase and communicating with the manufacturer.

On occasion covered entities have attempted to retroactively look back over long periods of time at drug purchases not initially identified as 340B eligible, sometimes looking back at drug purchases over several years. Covered entities then attempt to re-characterize these purchases as 340B eligible and then purchase 340B drugs on the basis of these previous transactions. This practice is sometimes referred to as "banking."

Covered entities are responsible for requesting 340B pricing at the time of the original purchase. If 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.

Regular reviews of 340B drug inventory ensure that any inventory discrepancy is accounted for and properly documented to demonstrate that 340B drugs are not diverted. A covered entity should follow standard business procedures to return unused or expired 340B drugs and appropriately account for waste of 340B drugs (e.g., discards after expiration dates).

Policies and procedures regarding 340B drug inventory discrepancies, and how the covered entity will reconcile any discrepancy in 340B drugs, can assist in meeting this standard. Without this information documented in auditable records, a covered entity would not be able to demonstrate that drug inventory discrepancies have not resulted in diversion.

Repayment: Covered entities must comply with section 340B(a)(5)(D) of the PHSA, which assigns liability to a covered entity if it violates the diversion prohibition in section 340B(a)(5)(B) of the PHSA. Covered entities are expected to work with manufacturers regarding repayment within 90 days of identifying the violation.

A manufacturer retains discretion as to whether to request repayment based on its own business considerations, provided that, when exercising its discretion, the manufacturer complies with applicable law, including the Federal anti-kickback statute (42 U.S.C. 1320a-7b(B)). For example, a manufacturer may prefer not to accept payments below a *de minimis* amount or to process repayments owed through a credit/rebill mechanism. Manufacturers should bear in mind the potential impact of such decisions on CMS price reporting requirements.

A covered entity must notify HHS and each affected manufacturer of diversion and is expected to document notification attempts in auditable records. The covered entity is responsible for reporting a summary of its corrective actions taken to HHS for transparency, compliance, and audit purposes (see Part H).

Part D—Covered Entity Requirements

Prohibition of Duplicate Discounts: Under section 340B(a)(1) of the PHSA, manufacturers are required to provide a discounted 340B price to a covered entity for a covered outpatient drug. Under section 1927 of the Social Security Act, manufacturers must generally provide a rebate to a State for a covered outpatient drug provided to a Medicaid patient. However, section 340B(a)(5)(A)(i) of the PHSA prohibits duplicate discounts whereby a State obtains a rebate on a drug provided to a Medicaid patient when that same drug was discounted under the 340B Program.

While Medicaid drug rebates were previously limited to Medicaid fee-for-service (FFS) drugs, section 2501(c) of the Affordable Care Act amended the Social Security Act, extending Medicaid drug rebate eligibility to certain Medicaid Managed Care covered outpatient drugs.

Section 2501(c) further amended the Social Security Act to specify that covered outpatient drugs dispensed by Medicaid Managed Care Organizations (MCOs) are not subject to a rebate if also subject to a discount under section 340B of the PHSA.

Fee for Service: Pursuant to section 340B(a)(5)(A)(ii) of the PHSA, HHS established the 340B Medicaid Exclusion File as the mechanism to prevent duplicate discounts. The 340B Medicaid Exclusion File is posted on the public 340B database to enable 340B covered entities, States, and manufacturers to determine whether a covered entity purchases 340B drugs for its Medicaid FFS patients.

Under this proposed guidance, a covered entity will be listed on the public 340B database if it notifies HHS at the time of registration whether it will purchase and dispense 340B drugs to its Medicaid FFS patients (carve-in) and bill the State, or whether it will purchase drugs for these patients through other mechanisms (carve-out). A covered entity electing carve-in will then have their Medicaid billing number, National Provider Identifier (NPI), or both listed on HHS' 340B Medicaid Exclusion File.

Covered entities must provide any Medicaid billing number/NPIs they use to bill Medicaid for 340B drugs for listing on the 340B Medicaid Exclusion File if they intend to bill Medicaid at any associated sites registered with the 340B Program.

Covered entities that wish to bill Medicaid for their non-340B eligible sites should work with their state to receive a different NPI number for that purpose.

Medicaid Managed Care: The covered entity may make a different determination regarding carve-in or carve-out status for MCO patients than it does for FFS patients. An entity can make different decisions by covered entity site and by MCO, but must provide to HRSA identifying information of the covered entity site, the associated MCO, and the decision to carve-in or carve-out. This information may be made available on a 340B Medicaid Exclusion file. HRSA seeks comments on the utility of this billing information for other stakeholders, as well as the format through which it is made public.

While the proposed use of a 340B Medicaid Exclusion File would identify the covered entity billing practices used for MCO patients, HHS encourages covered entities, States, and Medicaid MCOs to work together to establish a process to identify 340B claims.

- First, covered entities should have mechanisms in place to be able to identify MCO patients.
- Second, covered entities and States should continue to work together on various methods to prevent duplicate discounts on Medicaid MCO drugs.

Currently, covered entities report using Bank Identification Numbers, Processor Control Numbers, and National Council for Prescription Drug Programs (NCPDP) codes, among other methods, to identify Medicaid MCO patients and 340B claims. In some cases, States may require covered entities to follow additional steps to prevent duplicate

discounts, including use of certain modifiers and codes which identify individual claims as associated with 340B drugs and therefore not eligible for rebate. Such billing instructions are beyond the scope of the 340B Program.

340B Medicaid Exclusion File Changes: After enrollment, a covered entity can change its election to purchase and dispense 340B drugs for Medicaid FFS and/or MCO patients by notifying HHS. While changes to how a covered entity uses 340B drugs for its Medicaid FFS and MCO patients can be submitted at any time, the changes are only effective on a quarterly basis. A covered entity should ensure the changes are correctly reflected on the 340B Medicaid Exclusion File prior to implementation to permit full transparency for the State, MCO, and manufacturers, thus ensuring the avoidance of duplicate discounts. HHS is seeking comments regarding alternative mechanisms to supplement the 340B Medicaid Exclusion File to allow covered entities to take a more nuanced approach to purchasing, for example, only using 340B drugs for Medicaid FFS and MCO patients when appropriate for service delivery but maintaining practices that prevent the statutorily prohibited duplicate discounts.

HHS seeks information about current state arrangements that could be adapted for use as Federal standards for these supplements or alternatives.

Contract Pharmacy: Risk of duplicate discounts can increase with certain drug purchasing and distribution systems, including covered entity contract pharmacy arrangements. Therefore, in accordance with the statutory requirement under 340B(a)(5)(B)(ii) to establish a mechanism to prevent duplicate discounts, HHS will examine those systems and determine if adjustments have to be made to the system to prevent duplicate discounts.

Due to these heightened risks of duplicate discounts, when a contract pharmacy is listed on the public 340B database it will be presumed that the contract pharmacy will not dispense 340B drugs to Medicaid FFS or MCO patients.

If a covered entity wishes to purchase 340B drugs for its Medicaid FFS or MCO patients and dispense 340B drugs to those patients utilizing a contract pharmacy, the covered entity will provide HHS a written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts.

Once approved, HHS will list on the public 340B database a contract pharmacy as dispensing 340B drugs for Medicaid FFS and/or MCO patients.

Repayment: HHS and approved manufacturer 340B Program audits include the review of covered entity compliance with the duplicate discount prohibition. If the information provided to HHS does not reflect the covered entity's actual billing practices, the covered entity can be found in violation of the duplicate discount prohibition and may be required

to repay manufacturers if duplicate discounts have occurred due to the inaccurate information.

In the event that a covered entity is unable to use a 340B drug for a Medicaid FFS or MCO patient in a particular instance, it should have a mechanism in place to notify the State Medicaid agency and MCO. HHS encourages States, MCOs, and covered entities to work together to ensure records are accurate and auditable.

Maintenance of Auditable Records: Section 340B(a)(5)(C) of the PHSA requires a covered entity to permit the Secretary and certain manufacturers to audit covered entity records that pertain to the entity's compliance with 340B Program requirements. Documentation of compliance would include records of contract pharmacies used by covered entities to dispense 340B drugs. Failure to maintain the records necessary to permit such auditing is failure to meet the requirements of section 340B(a)(5) of the PHSA. A covered entity's failure to maintain auditable records is grounds for losing eligibility to participate in the 340B Program.

340B Program stakeholders have requested a standard for records retention, and HHS agrees that it is important, especially in assisting covered entities and manufacturers in preparing for audits and understanding the time and scope limitations of 340B Program audits. Therefore, HHS is proposing a record retention standard for all 340B Program records for a period of not less than 5 years, which HHS believes appropriately balances the need for a covered entity to document its compliance with 340B Program requirements and the covered entity's effort and expense required to maintain records for an extended period of time. This standard would also apply to records pertaining to all child sites and contract pharmacies. In the case of termination, a terminated covered entity or associated site is expected to maintain records pertaining to compliance with 340B statutory requirements for five years after the date of termination.

If during an audit, HHS finds a pattern of failure to comply with 340B Program statutory requirements, this provision does not preclude HHS from accessing existing records prior to the 5-year period for its review. In accordance with the statute, a covered entity's failure to provide required records is grounds for termination from the 340B Program.

This guidance further clarifies associated repayment to manufacturers, as well as restrictions on when an entity can re-enroll in the 340B Program. However, HHS proposes to use discretion for those entities whose failure to retain records is non-systematic. A non-systematic recordkeeping violation would occur if the covered entity generally has available records but cannot produce a certain specific record demonstrating compliance with a 340B Program requirement.

For example, if a covered entity can generally produce 340B records for patient eligibility, but cannot produce a record for a particular patient who received a 340B drug, the drug purchase would be presumed to be in violation of section 340B(a)(5)(B) of the PHSA

(diversion) and the entity may be liable for repayment to the manufacturer; however, the covered entity would not be removed from the 340B Program.

Any failure to retain records that prevents the auditing of compliance would constitute a violation under section 340B(a)(5)(C) of the PHSA. This systematic failure could result in a determination of ineligibility and the covered entity may be liable for repayment to manufacturers for periods of ineligibility. Prior to removal, a covered entity would be entitled to notice and hearing pursuant to this guidance regarding removal from the 340B Program for failure to meet a statutory 340B Program eligibility requirement. A covered entity removed for systematic failure to maintain records would be able to re-enroll in the 340B Program during the next regular registration period after the covered entity has demonstrated to HHS its ability to comply with all 340B Program requirements, including the requirement to maintain auditable records.

Part E—Contract Pharmacy Arrangements

Section 340B(a)(4) of the PHSA specifies the types of entities eligible to participate in the 340B Program, but does not specify how a covered entity may provide or dispense such drugs to its patients. The diverse nature of eligible entity types (*e.g.*, FQHCs, rural referral centers, disproportionate share hospitals) has resulted in a variety of drug distribution systems.

Under the 340B Program, 340B drugs may not be diverted to non-patients, duplicate discounts must be prevented, and a covered entity must have auditable records pertaining to its compliance with these requirements. Covered entities must ensure that all drug distribution arrangements with third parties to provide or dispense 340B drugs to patients meet 340B Program statutory requirements.

In 1996, HHS issued guidance recognizing covered entity use of contract pharmacy arrangements, which are permitted under State law, to dispense 340B drugs. The 340B statute does not prohibit the use of contract pharmacies. The guidance permitted covered entities to use a single contract pharmacy arrangement in addition to any in-house covered entity pharmacy service and outlined other requirements (61 FR 43549, August 23, 1996).

Beginning in 2001, HHS permitted certain covered entities to conduct Alternative Methods Demonstration Projects (AMDP) to use and develop multiple contract pharmacy arrangements to access 340B drug pricing.

HHS issued revised guidance in 2010 which permitted a covered entity to use multiple contract pharmacy arrangements, to include multiple contract pharmacy locations (75 FR 10772, March 5, 2010). Congress intended the benefits of the 340B Program to accrue to participating covered entities. **Each covered entity should carefully evaluate its**

relationships with contract pharmacies (*i.e.*, cost/benefit analysis) to make certain that the relationship benefits the covered entity and is in line with the intent of the Program.

A covered entity may contract with one or more licensed pharmacies to dispense 340B drugs to the covered entity's patients, instead of or in addition to an in-house pharmacy. If permitted under applicable State and local law, a covered entity may contract with one or more pharmacies on behalf of its child sites, or a child site may contract directly with a pharmacy. A covered entity may contract with a pharmacy location (or pharmacy corporation to include multiple pharmacy locations) as an individual covered entity and for its child sites.

The contracts establishing these arrangements are expected to meet the standards identified in this proposed guidance and all applicable Federal, State, and local laws. A covered entity contracting with a pharmacy to dispense 340B drugs should be aware of the Federal anti-kickback statute and how such provisions could apply to arrangements with contract pharmacies. HHS will continue its policy of referring cases of suspected violations of the anti-kickback statute to the HHS Office of Inspector General (OIG). A covered entity whose 340B eligibility is based on the receipt of a Federal grant, Federal project, Federal designation, or Federal contract must also ensure that no grant, project, designation, or contract conditions are violated in its contract pharmacy arrangements.

Registration: The 340B registration deadlines and effective dates, announced in the *Federal Register*, apply to all changes in the covered entity's list of contract pharmacies, whether initially registering a contract pharmacy agreement or adding contract pharmacy locations to an existing contract with a pharmacy organization. A contract pharmacy is not an eligible 340B covered entity and therefore does not receive a 340B identification number.

HHS only lists contract pharmacy locations on a covered entity's 340B database record once a written contract exists between the covered entity and contract pharmacy and the covered entity registers those arrangements. The written contract should include all locations of a single pharmacy company the covered entity plans to use and all child sites that plan to use the contract pharmacies.

The written contract should also set forth the requirements contained in this proposed guidance. Pursuant to 340B statutory auditing requirements, the contract should be available to HHS upon request.

To further strengthen 340B Program integrity, registration of a contract pharmacy will only be accepted from a covered entity. Pursuant to section 340B(a)(5)(B) of the PHSA, which prohibits covered entities from reselling or otherwise transferring drugs to persons who are not patients of the covered entity, a parent covered entity may contract with a pharmacy only on its own behalf as an individual covered entity and for its child sites.

Groups or networks of covered entities may not register or contract for pharmacy services on behalf of their individual covered entity members.

Under this proposed guidance, required documentation for registration would include a series of compliance requirements and a covered entity's attestation regarding its arrangement with the contract pharmacy.

Manufacturers and wholesalers are required to ship only to the authorized shipping addresses listed for the covered entity in the public 340B database. The contract pharmacy may only provide 340B drugs to patients of the covered entity after the contract pharmacy's start date in the public 340B database.

Likewise, the contract pharmacy location must cease dispensing 340B drugs on behalf of the covered entity on or before the date that contract pharmacy location is terminated.

Any changes to existing contract pharmacy arrangements should be reflected on the covered entity record in the public 340B database and requested by submitting an online change request form.

A covered entity can request additional contract pharmacy locations under a public health emergency declared by the Secretary. Special registration instructions and requirements would be published on the HRSA Office of Pharmacy Affairs Web site (www.hrsa.gov/opa).

Compliance With Statutory Requirements: Through audits of covered entities' arrangements with contract pharmacies, HHS has observed that not all covered entities have sufficient mechanisms in place to ensure their contract pharmacies' compliance with all 340B Program requirements. To ensure compliance with 340B statutory requirements, HHS is proposing compliance mechanisms for covered entities that contract with pharmacies to dispense 340B drugs.

The covered entity would retain complete responsibility for contract pharmacy compliance with 340B Program requirements. If noncompliance is occurring within contract pharmacy arrangements, it is essential that any issues be promptly identified and corrected. HHS is proposing standards for audit and quarterly reviews to ensure that compliance efforts related to contract pharmacies result in the early identification of problems, implementation of corrections, and the prevention of future compliance issues.

The 2010 contract pharmacy guidance recommended annual audits of contract pharmacies; this proposed guidance further clarifies the expectations of this recommendation. HHS believes that covered entities that do not regularly review and audit contract pharmacy operations are at an increased risk for compliance issues. An annual audit of each contract pharmacy location will provide covered entities a regular opportunity to review and reconcile pertinent 340B patient eligibility information at the

contract pharmacy and help prevent diversion. Conducting these audits using an independent auditor will ensure the pharmacy is following all 340B Program requirements.

Additionally, as a separate compliance mechanism, the covered entity should compare its 340B prescribing records with the contract pharmacy's 340B dispensing records at least quarterly to ensure that neither diversion nor duplicate discounts have occurred.

A covered entity should correct any instances of diversion or duplicate discounts found during either the annual audit or quarterly review and report corrective action to HHS. A patient is not required to use the covered entity's in-house pharmacy, where such service exists, or a covered entity's contract pharmacy to receive a prescription drug. A drug manufacturer would not be required to offer the covered entity a 340B priced-drug when a 340B-eligible patient chooses to have a prescription filled at a non-contract pharmacy or a contract pharmacy location not listed on the covered entity's 340B database record.

Diversion, Duplicate Discounts, and Removal From the 340B Program: HHS may remove a contract pharmacy location from the 340B Program if HHS finds that the contract pharmacy is not complying with 340B Program requirements. A covered entity is liable for diversion or duplicate discounts which occur at any of the covered entity's contract pharmacy locations, including potential repayments to manufacturers.

Part F—Manufacturer Responsibilities

Pharmaceutical Pricing Agreement: A manufacturer that has entered into a Medicaid Drug Rebate Agreement pursuant to section 1927(a) of the Social Security Act (42 U.S.C. 1936r–8(a)) is required, pursuant to section 1927(a)(5), to enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary as described in section 340B(a) of the PHSA. Under the PPA, a manufacturer must offer all covered outpatient drugs, as defined in section 1927(k) of the Social Security Act, from each of the manufacturer's labeler codes to covered entities participating in the 340B Program at no more than the statutory 340B ceiling price.

A manufacturer that is not subject to a Medicaid Drug Rebate Agreement may voluntarily enter into a PPA for all of its covered outpatient drugs, as defined in section 1927(k) of the Social Security Act. The PPA incorporates 340B Program statutory obligations and records a manufacturer's agreement to abide by them. By executing the PPA when it enrolls in the 340B Program, a manufacturer agrees to all 340B Program statutory requirements, including statutory and regulatory changes that occur after execution of the PPA.

In the event of a transfer of ownership of the manufacturer, the PPA is automatically assigned to the new owner. In addition, the following expectations apply to participating manufacturers:

- (a) For a manufacturer whose 340B Program participation is required by virtue of its participation in the Medicaid Drug Rebate Program, sign a PPA within 30 days of enrolling in the Medicaid Drug Rebate Program;
- (b) submit timely updates to its 340B database record and PPA to ensure that any new covered outpatient drug is added to the 340B Program;
- (c) maintain auditable records demonstrating 340B Program compliance for no less than five years and provide such records when requested; and
- (d) permit HHS to audit manufacturer compliance.

Termination: If a manufacturer withdraws from the Medicaid Drug Rebate Program, the manufacturer may continue to participate in the 340B Program voluntarily. If a manufacturer withdraws from the Medicaid Drug Rebate Program, HHS will presume continued participation in the 340B Program unless and until the manufacturer advises HHS otherwise. A manufacturer that has voluntarily entered into a PPA and does not participate in the Medicaid Drug Rebate Program may terminate its PPA by notifying HHS during the annual recertification process or at any other time, in accordance with the terms of the PPA.

When a manufacturer voluntarily participating in the 340B Program requests 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 covered outpatient drugs under the 340B Program.

A manufacturer that terminates a PPA should maintain auditable 340B Program records for 5 years after the termination pertaining to compliance with all 340B Program statutory requirements during the time that the manufacturer had a PPA. Refunds and credits specified under this proposed guidance may still be imposed on a terminated manufacturer for 340B drugs sold above the ceiling price during the time that the manufacturer had a PPA in effect.

Obligation To Offer 340B Prices to Covered Entities: Pursuant to section 340B(a)(1) of the PHSA, a manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the 340B ceiling price to a covered entity listed on the public 340B database.

For manufacturers signing their first PPA by virtue of participating in the Medicaid Drug Rebate Program, the effective date for 340B pricing for covered outpatient drugs to any covered entity is 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 inclusion 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 new drugs approved, the effective date for 340B pricing for the new drug is the date the drug is first available for sale.

Pursuant to section 340B(a)(1) of the PHSA, a manufacturer shall rely on the information in the public 340B database to determine whether the manufacturer must offer the 340B price and not base its offer on a covered entity's assurance of compliance with the 340B Program. HHS will continue to provide communications and Web site notices to manufacturers to alert them to covered entity additions or deletions in the public 340B database that occur during a calendar quarter due to special circumstances (e.g., additions to covered entity sites because of a public health emergency declared by the Secretary; termination of a covered entity site).

Limited Distribution of Covered Outpatient Drugs: Certain covered outpatient drugs may be required to be dispensed by specialty pharmacies (e.g., drugs approved with a risk evaluation and mitigation strategy (REMS) pursuant to section 505–1 of the Federal Food, Drug, and Cosmetic Act). As a result, certain manufacturers may use a restricted network of certified specialty pharmacies, which do not fall under the terms of a contract pharmacy agreement or wholesaler contract for the distribution of drugs to a covered entity. Other covered outpatient drugs may become intermittently limited in supply due to manufacturing issues, supply chain problems, or other issues. The manufacturer may develop a limited distribution plan when a covered outpatient drug must be handled in a special manner (e.g., special refrigeration), or when the available supply of a covered outpatient drug is not adequate to meet market demands. 340B Program pricing requirements apply to such sales.

Pursuant to section 340B(a)(1) of the PHSA, which requires manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price," the plan will be reviewed by HHS to ensure that the manufacturer is treating 340B covered entities the same as all non-340B providers.

To reduce the potential for disputes and ensure that limited distribution plans are transparent to all stakeholders, HHS is proposing that a manufacturer notify HHS in writing of any limited distribution plan prior to implementation. HHS proposes that the plan include the following information: a description of product information (drug name, dosage, form, and NDC) and details of a non-discriminatory practice for restricted distribution to all purchasers, including 340B covered entities, which includes each of the following components:

- (1) An explanation of the product's limited supply or special distribution requirements and the rationale for restricted distribution among all purchasers;
- (2) an assurance that manufacturers will impose these restrictions equally on both 340B covered entities and non-340B purchasers;

- (3) specific details of the drug allocation plan, including a mechanism that allocates sales to both covered entities and non-340B purchasers with no previous purchase history of the restricted drug;
- (4) the dates the restricted distribution begins and concludes; and
- (5) a plan for the notification of wholesalers and 340B covered entities of the restricted plan.

HHS may publish all submitted limited distribution plans on the 340B Web site. If HHS has concerns about the plan, it will work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the 340B Web site. Covered entities that have concerns regarding the manner in which a particular plan is implemented are first encouraged to resolve them in good faith with manufacturers. Where such issues are not resolved, covered entities should contact HHS for appropriate action or involvement of other federal agencies (e.g., Office of Inspector General, Department of Justice) to bring the issue to resolution.

Additional Discounts Permitted: Pursuant to section 340B(a)(10) of the PHSA, a manufacturer may choose to sell a covered outpatient drug below the ceiling price to a covered entity. Such pricing is voluntary and need not be offered to all covered entities.

Procedures for Issuance of Refunds and Credits: Pursuant to section 340B(d)(1)(B) of the PHSA, this proposed guidance establishes clarity around the procedures for issuing refunds and credits in the event that there is an overcharge. HHS also outlines its proposed oversight of this process to ensure that refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data as well as exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

If a manufacturer charges a covered entity more than the 340B ceiling price, the manufacturer must refund or credit that covered entity an amount equal to the price difference between the sale price and the correct 340B price for that drug, multiplied by the units purchased. A refund or credit may also be necessary in the case of a drug price restatement by manufacturers. This refund or credit is expected to occur within 90 days of the determination by the manufacturer or HHS that an overcharge occurred.

Multiple price calculations will be required if the 340B price changed during the affected period of overcharges. 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.

The covered entity may choose to have the manufacturer apply a credit to its account rather than receive a refund of any incorrect payment. If a covered entity fails to act to accept a direct repayment (e.g., cash a check) within 90 days of a manufacturer's refund

and the repayment amount is undisputed by the covered entity, the covered entity has waived its right to repayment.

Pursuant to section 340B(d)(1)(B)(ii) of the PHSA, a manufacturer must submit to HHS, along with the price recalculation information, an explanation of why the overcharge occurred, how the refund will be calculated, and to whom refunds or credits will be issued.

Manufacturer Recertification: The 2010 amendments to section 340B(d)(1)(A) of the PHSA provide for improvements in manufacturer compliance with 340B Program pricing requirements. Pursuant to this authority, HHS is proposing a manufacturer recertification process. Under this proposed guidance, HHS will list manufacturers as participating in the 340B Program if they annually review and update 340B database information. A manufacturer should provide HHS with any changes to 340B database information as changes occur. HHS may also request additional documentation to verify the information provided. HHS understands that manufacturers may transfer ownership and control of labeler codes or NDCs after signing a PPA. Annual recertification for manufacturers with a PPA will ensure that all stakeholders have the most up- to-date information regarding the covered outpatient drugs subject to the 340B price, particularly for manufacturers that have voluntarily entered into a PPA that do not participate in the Medicaid Drug Rebate Program. This process is designed to prevent pricing violations and improve the accuracy of the public 340B database.

Part G—Rebate Option for AIDS Drug Assistance Programs

HHS proposes to continue the long- standing practice of providing the option for AIDS Drug Assistance Programs (ADAPs) to participate in the 340B Program through a rebate model. Section 340B(a)(1) of the PHSA provides that the amount paid to a manufacturer for covered outpatient drugs takes into account any rebate or discount, as provided by the Secretary. The ADAP rebate option has been operational since 1998, after a proposed notice sought comment on the option (62 FR 45823 (August 29, 1997)), and a final notice was published in the *Federal Register* (63 FR 35239 ((June 29, 1998))).

This proposed guidance would continue the policy of allowing ADAPs to access 340B prices on covered outpatient drugs either through a direct purchase option (*i.e.*, at the 340B ceiling price), a rebate after the purchase, or a combination of both mechanisms ("hybrid").

HHS expects ADAPs seeking to pursue the rebate mechanism to take three actions.

- First, the ADAP is expected to inform HHS during the registration process whether it will participate using direct purchase, a rebate option, or both.
- Second, the ADAP is expected to make a qualified payment, as defined in this proposed guidance.

- Third, the ADAP is expected to submit claims-level data to a manufacturer in support of each qualified payment to receive a rebate from that manufacturer. ADAPs will be expected to submit claims-level data to manufacturers to support the ADAPs' rebate requests. HHS will provide subsequent guidance regarding the data to be provided in support of rebate requests. Data elements may include: The ADAP name and state, medication name/label name, medication national drug code, the package size, the date of dispensing, the ADAP payment for the medication (to include the amount paid to the dispensing pharmacy as a payment, copayment, or deductible), an assurance that the claim is not for a drug subject to a Medicaid rebate, and, when applicable, an assurance that the ADAP paid the patient's health insurance premium (which, in turn, paid for the medication).

HHS welcomes public comment regarding this proposed data submission, especially regarding the suitability of the claims-level data elements mentioned above for ADAP submission to manufacturers for purposes of receiving a rebate.

Qualified Payment: Under this proposed guidance ADAPs make a qualified payment of covered outpatient drugs in two circumstances.

- First, the ADAP purchase of a covered outpatient drug at a price greater the 340B ceiling price constitutes a qualified payment.
- Second, the ADAP purchase of the ADAP client's insurance, in addition to the ADAP payment of the copayment, coinsurance, or deductible, constitutes a qualified payment for a covered outpatient drug. Section 2615(a) of the PHSA allows ADAPs to use a portion of their grant funds to purchase health insurance policies that, at a minimum, include at least one drug in each class of core antiretroviral therapeutics from the HHS Clinical Guidelines for the Treatment of HIV/AIDS, and coverage for other essential medical benefits.

After the implementation of the rebate option for ADAPs, Congress further specified under the Ryan White CARE Act Amendments of 2000, Public Law 106– 345, that certain statutory requirements imposed by title XXVI of the PHSA must be met by ADAPs when purchasing health insurance policies. Section 2616(f) of the PHSA indicates that such health insurance coverage must include a full range of therapeutics to treat HIV/AIDS, including measures for the prevention and treatment of opportunistic infections, and that the costs of the health insurance must not exceed the costs of otherwise providing the therapeutics.

ADAP funds may be used to cover any costs associated with the health insurance policy, including copayments, coinsurance, deductibles, and premiums. Therefore, it is the view of HHS that the use of ADAP funds to make a qualified payment as outlined above, after the ADAP has engaged in the necessary cost-effectiveness analysis demonstrating that the costs of the health insurance do not exceed the costs of otherwise providing the

therapeutics, constitutes a purchase of necessary drugs for ADAP clients that is consistent with the statutory eligibility for State- operated AIDS drug purchasing assistance programs and the statutory provision allowing the program to purchase the drugs through an insurance mechanism rather than a direct purchase.

Recognizing this mechanism gives full effect to both statutes: Section 340B of the PHSA and the Ryan White HIV/AIDS Program statute. After careful analysis, HHS has determined that the payment by the ADAP of a copayment, coinsurance, or deductible, in the absence of also paying for the health insurance premium, is too attenuated within the context of the 340B Program to constitute a "purchase." Therefore, implementation of this proposed guidance would result in manufacturers, upon request of the ADAP, providing rebates only when the ADAP purchases drugs directly, or when the ADAP purchases health insurance, through payment of the health insurance premium, and pays the copayment, coinsurance, or deductible that covers the drug purchases at issue.

HHS recognizes that ADAPs can cover the cost of health insurance (e.g., premiums, co-pays, co-insurance, deductibles, etc.) to ensure access to HIV medications and care. Therefore, we are seeking comments on how this policy may impact those practices. In addition, HHS recognizes that the proposed guidelines regarding the types of payments that will qualify a drug purchase by an ADAP for a 340B rebate (section (b) of Part G) present unique challenges that may require changes to program practices, to an ADAP's drug payment processes, or to State law. Therefore, to allow for the development of systems and any other necessary changes in order to make qualified payments on behalf of an ADAP client for those states utilizing the rebate option, HHS is proposing to delay the effective date of section (b) of Part G, defining qualified payment, for 12 months after the publication date of the final guidance.

To ensure that particular drugs have been paid for by the ADAP's purchased health insurance, HHS is proposing that the ADAP document the transaction, as demonstrated by the ADAP's payment of a copayment or deductible, or such other auditable evidence that links the drug purchase at issue to the ADAP's purchased insurance policy. In this situation, the rebate would be paid regardless of how the ADAP expenditure compares to the 340B ceiling price for the drug. While this proposed guidance is subject to comment and finalization, HHS encourages ADAPs and drug manufacturers to work together to minimize any disruptions in current rebate practices.

Multiple 340B Discounts and Rebates: HHS is aware that ADAP clients may also be patients of other covered entities. Therefore, pursuant to the 340B statute, HHS proposes that no covered entity may obtain 340B pricing (either through a rebate or through a direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price. All covered entities, including ADAPs, must ensure that drugs that have been purchased at or below the ceiling price for a patient of a covered entity are not also subject to any additional 340B discounts. Nothing in this proposed guidance prohibits a manufacturer from voluntarily extending additional discounts or rebates on 340B drugs.

Audits: Pursuant to section 340B(a)(5)(C) of the PHSA, an ADAP participating in the 340B Program, whether through the rebate option, direct purchase option, or both, is subject to a 340B Program audit by HHS, as detailed in Part H of this proposed guidance.

Obligation To Provide Rebates: Pursuant to a manufacturer's obligation under section 340B(a)(1) of the PHSA to charge no more than the ceiling price for covered outpatient drugs (taking into account any rebate or discount, as provided by the Secretary), a manufacturer with a PPA would pay a rebate on a claim submitted for a qualified payment for a covered outpatient drug to an ADAP registered for the 340B Program under the rebate option or the hybrid option.

Rebate Amount: The question has arisen as to the determination of the appropriate level of rebates in cases where the ADAP paid the health insurance premium and the copayment, coinsurance, or deductible. In formulation of this proposed guidance, HHS considered a percentage rebate whereby an ADAP would be entitled to a percentage of the rebate on a dispensed drug contingent on the percentage of the total cost of the drug borne by the ADAP. Upon review of the approach, HHS concluded that this mechanism would be so operationally burdensome as to be inoperable. Percentage calculations would entail increased administrative costs and require access to pricing information about the total amounts paid and total cost of the drug that may not be available to ADAPs. The accounting requirements of such an approach would decrease the efficiency and effectiveness of the program even if the necessary information were readily available.

This proposed guidance specifies that the rebate owed to the ADAP is equal to the Medicaid drug rebate amount described in section 1927(c) of the Social Security Act. In accordance with section 340B(a) of the PHSA, requiring that "the amount to be paid ... to manufacturers ... for covered outpatient drugs ... does not exceed" the 340B ceiling price, the rebate option is equivalent to the direct purchase option.

HHS supports an approach that allows for a rebate for drugs where ADAPs have directly expended funds to purchase a covered outpatient drug for an eligible patient. Under this approach, the ADAP is entitled to a rebate for each of the units purchased with a direct payment of ADAP funds. In cases involving health insurance coverage, the ADAP is entitled to a rebate on each unit of covered outpatient drugs when it has paid for the ADAP client's health insurance and the drug copayment, coinsurance, or deductible. This approach avoids additional unnecessary accounting requirements that would be required in percentage-of-cost approaches. Manufacturers are expected to maintain records that provide sufficient documentation to determine the correct rebate amounts to be paid to ADAPs as part of auditable records.

Part H—Program Integrity

HHS Audit of a Covered Entity: Under section 340B(a)(5)(C) of the PHSA, HHS has the authority to audit (acting in accordance with procedures established by the Department) covered entities to monitor their compliance with the statutory prohibition of duplicate discounts (section 340B(a)(5)(A) of the PHSA) and diversion (section 340B(a)(5)(B) of the PHSA). The audits permit HHS to assess a covered entity's compliance with the 340B Program.

These audits also help HHS and participating covered entities identify and mitigate program risk as well as identify best practices regarding compliance. HHS reserves the right to refer matters to other Federal agencies as appropriate. A covered entity participating in the 340B Program is subject to audit by HHS to determine whether it is complying with 340B statutory requirements. Pursuant to section 340B(a)(5)(C) of the PHSA, HHS must be provided access to all records pertaining to compliance, including those of any child site or pharmacy which is under contract with the covered entity. Failure to provide records can result in termination from the 340B Program. To reduce burden on covered entities, HHS will ensure that only one 340B Program audit of a covered entity is conducted or ongoing at any time. HHS will notify the covered entity of its intent to audit for 340B compliance.

Pursuant to authority vested in HHS to maintain an accurate and up-to-date list of covered entities (section 340B(d)(2)(B) of the PHSA), HHS will review covered entity eligibility and 340B database information as part of an audit. HHS may audit the parent covered entity site, any child site, and any pharmacy under contract with that covered entity. Additionally, HHS may audit other 340B identification numbers associated with the parent or child site. An HHS audit may include either an on-site review, an off-site review of documentation requested by HHS, or both.

To the extent possible, HHS will perform a 340B Program audit at a time and in a manner which minimizes disruption to the covered entity's operations and maximizes the ability to conduct a thorough 340B Program review. HHS may make public any final audit findings.

Notice and Hearing for Noncompliance: Pursuant to section 340B(a)(5)(D) of the PHSA, HHS is proposing a notice and hearing process under which a covered entity has the opportunity to respond to adverse audit findings and other instances of noncompliance or to respond to the proposed loss of 340B Program eligibility. The notice and hearing process will be conducted based on the written submissions of the involved parties. HHS proposes to initiate the notice and hearing process by providing written notice to a covered entity of a proposed finding of noncompliance with specific 340B Program requirements. This notice will be sent to the covered entity's authorizing official as listed on the public 340B database and specify a 30- day response deadline. The covered entity responds in writing to each issue of noncompliance, providing details and documentation where appropriate. Failure to respond by the deadline specified will be

construed as the covered entity's agreement with the specific allegations of noncompliance included in the notice. HHS will then proceed to make final findings of noncompliance and to take appropriate actions.

If a covered entity anticipates the inability to respond by a particular deadline, it is expected to request an extension. HHS will consider such requests on a case-by-case basis. HHS will review all documents and information submitted by the covered entity regarding its position on the covered entity's noncompliance.

HHS will issue a final written notice with its final determination regarding noncompliance. In the case of HHS's 340B Program audits, the initial notice and final notice will include a 340B Program audit report. If a final determination of noncompliance is made, the covered entity may have to submit a corrective action plan as outlined in this proposed guidance. If HHS's final determination of noncompliance includes a finding that the covered entity is no longer eligible for the 340B Program (e.g., the latest filed Medicare cost report showing a disproportionate share adjustment percentage below the threshold, loss of grant funding, lack of auditable records, GPO violation), it will be removed from the 340B Program.

The entity is responsible for repayment to affected manufacturers for 340B drug purchases made after the date the entity first violated a statutory requirement.

Corrective Action Plan for 340B Program Noncompliance: If a covered entity submits a corrective action plan that addresses all findings of noncompliance, HHS may determine that the covered entity can continue to participate in the 340B Program. A corrective action plan should include, at minimum:

- The correction of each finding of noncompliance,
- the implementation of measures to prevent future occurrences of noncompliance,
- plans to make offers of repayment to affected manufacturers for discounts improperly received or
- to work with State Medicaid offices regarding duplicate discounts, if applicable, and
- a timeline for corrective actions to be taken.

HHS will work with a covered entity to specify the time frame for the submission of the corrective action plan based on the scope of the findings and will determine if the submitted corrective plan is acceptable.

HHS may verify a covered entity's compliance with its HHS-approved corrective action plan at any time. A corrective action plan and its subsequent implementation are considered auditable records and should be maintained as such. Failure of an entity to correct compliance issues or submit a corrective action plan may result in further HHS action, including termination from the 340B Program.

Manufacturer Audit of a Covered Entity: Under section 340B(a)(5)(C) of the PHSA, a drug manufacturer participating in the 340B Program is authorized to audit a covered entity's compliance with the statutory prohibitions against duplicate discounts and diversion of 340B drugs (sections 340B(a)(5)(A) and (B) of the PHSA).

The statute does not permit a manufacturer to audit covered entity's compliance with 340B Program eligibility requirements (*e.g.*, GPO prohibition, disproportionate share adjustment percentage), although a manufacturer may refer such issues to HHS for its review.

A manufacturer should work in good faith with a covered entity to resolve any concerns related to duplicate discounts and diversion of 340B drugs before requesting HHS approval to audit the covered entity.

Reasonable Cause: This section proposes a "reasonable cause" standard, by which a manufacturer, prior to audit, documents to HHS's satisfaction that a reasonable person could conclude, based on reliable evidence, that a covered entity, its child sites, or contract pharmacies may have violated either section 340B(a)(5)(A) or (B) of the PHSA.

Examples of reasonable cause include, but are not limited to:

- (1) Significant changes in quantities of specific drugs ordered by a covered entity without adequate explanation by the covered entity;
- (2) significant deviations from national averages of inpatient or outpatient use of certain drugs without adequate explanation by the covered entity; and
- (3) evidence of duplicate discounts provided by manufacturers or State Medicaid agencies.

A covered entity's refusal to respond to manufacturer questions related to 340B drug diversion and duplicate discounts may also be construed as reasonable cause.

Procedures and Audit Work Plan: To ensure that the audits pertain to compliance with the prohibitions against duplicate discounts and diversion, HHS proposes that a manufacturer submit an audit work plan for HHS approval prior to conducting such an audit.

The manufacturer may consult with HHS on its grounds for reasonable cause prior to submitting documentation or a work plan.

HHS will review the reasonable cause documentation and the scope of the audit work plan.

HHS may limit the scope of the audit to ensure that the audit is conducted with the least possible disruption to the covered entity.

If HHS has concerns regarding the audit work plan, it may require manufacturers to revise certain audit procedures.

Audit Standards: General standards for manufacturers conducting a 340B Program audit include

- the use of an independent certified public accountant to perform the audit in accordance with Government Auditing Standards,
- the protection of confidential patient information, and
- a total audit duration of not more than 1 year.

Pursuant to section 340B(a)(5)(C) of the PHSA, a covered entity must provide records pertaining to compliance of the covered entity, child sites, and any related contract pharmacy with the prohibition against duplicate discounts and diversion.

Failure of a covered entity to provide auditable records within 30 days of the request is a violation of section 340B(a)(5)(C) of the PHSA.

A covered entity and manufacturer must continue to meet all 340B Program requirements during an audit.

At the completion of the audit, the auditors prepare a final audit report and submit it to HHS.

The cost of the audit shall be borne by the manufacturer.

HHS Audit of a Manufacturer and its Contractors: Section 340B(d)(1)(B)(v) of the PHSA authorizes HHS to audit a manufacturer or wholesaler to ensure 340B Program compliance.

In this guidance, HHS is proposing standards for audits of a manufacturer or wholesaler that manufactures, processes, or distributes covered outpatient drugs in the 340B Program.

The HHS audit may include either an on-site review, an off-site review of documentation requested by HHS, or both.

HHS will notify the manufacturer of its intent to audit for 340B Program compliance.

HHS audits all relevant records retained by the manufacturer or any of its contractors (such as wholesalers) to assess its compliance with 340B Program requirements.

Failure to provide or give access to records or respond to requests for information within HHS-specified time frames may result in further action by HHS or referral for investigation

(e.g., United States Department of Justice or the HHS OIG). HHS may make public any final audit findings.

Notice and Hearing Regarding Audit Findings: After the conclusion of the audit, if HHS determines that a manufacturer has violated the 340B Program, the manufacturer will be provided opportunity for notice and hearing. HHS will send the manufacturer written notification of any audit findings and will notify the manufacturer of the deadline to respond with its agreement or disagreement with each proposed finding. If a manufacturer fails to respond to the proposed findings within the required deadlines and fails to request an extension, HHS will conclude the manufacturer has concurred with all findings. HHS will review any documentation submitted in making a final determination and will advise the manufacturer of its final determination in written audit findings, and request corrective action, as needed. HHS will notify CMS and other government agencies of these actions, as appropriate.

Corrective Action Plan: A manufacturer's corrective action plan is expected to include correction of past instances of noncompliance, implementing measures to prevent future occurrences, refunds of overpriced 340B drugs to affected covered entities pursuant to this proposed guidance, when applicable, and a timeline for corrective actions to be completed. HHS will specify the time frame for the submission of this corrective action plan and determine if the submitted corrective plan is acceptable. HHS will also determine when an audit is closed. HHS may verify a manufacturer's compliance with its HHS-approved corrective action plan at any time.

III. Proposed Guidance

Definitions

- **340B identification number** is the unique identifier HHS provides to a covered entity participating in the 340B Program.
- **Associated site** is a health care delivery site which is not located at the same physical address as a non-hospital covered entity, but is part of and delivers outpatient services for the non-hospital covered entity. An associated site, once enrolled in the 340B Program, is referred to as a child site.
- **Authorized billing address** is the covered entity address designated for 340B billing purposes in the covered entity's 340B database record. The authorized billing address is designated in the public 340B database by the "bill to" field.
- **Authorized shipping address** is a covered entity address designated for receiving 340B drugs. Authorized shipping addresses which are part of the covered entity are termed "ship to" in the covered entity's 340B database entry. A registered contract pharmacy is an authorized shipping address.
- **Authorizing official** is an individual who can legally bind a covered entity to contract, such as a chief executive officer, chief operating officer, chief financial officer, or program manager, who attests to the covered entity's 340B Program compliance.

- **Carve-in** refers to the purchase and dispensing of 340B drugs to a covered entity's Medicaid patients.
- **Carve-out** refers to the purchase and dispensing of non-340B drugs to a covered entity's Medicaid patients.
- **Child site** is a non-hospital covered entity associated site or a hospital covered entity outpatient facility with 340B Program eligibility derived from an enrolled parent site, and that is enrolled in the 340B Program and is listed on the public 340B database.
- **CMS** is the Centers for Medicare & Medicaid Services.
- **Contract pharmacy** means a pharmacy not owned by the covered entity, but under contract with and listed on the covered entity's 340B database record.
- **Disproportionate share hospital (DSH)** is a hospital covered entity registered for the 340B Program under section 340B(a)(4)(L) of the PHSA.
- **Group purchasing arrangement** is any arrangement, other than the Prime Vendor Program, created to leverage the purchasing power of multiple entities to obtain discounts from manufacturers, distributors, and other vendors based on collective buying power.
- **Group purchasing organization (GPO)** is an entity that contracts with purchasers, such as hospitals, nursing homes, and home health agencies, to aggregate purchasing volume and negotiate final prices with manufacturers, distributors, and other vendors.
- **Hospital covered entity**, within the 340B Program, means a covered entity registered for the 340B Program as one of the covered entity types described in section 340B(a)(4)(L), (M), (N), or (O) of the PHSA.
- **In-house pharmacy** means a pharmacy that is owned by, and a legal part of, the 340B covered entity.
- **Medicaid Drug Rebate Program and Medicaid Drug Rebate Agreement** mean, respectively, the program described in section 1927 of the Social Security Act and a signed agreement between the Secretary and the manufacturer, to implement the provisions of section 1927 of the Social Security Act.
- **Non-hospital covered entity** is a covered entity which is registered for the 340B Program as one of the covered entity types described in sections 340B(a)(4)(A) through (K) of the PHSA.
- **Parent site** is a covered entity which has met the eligibility criteria for participation specified in section 340B(a)(4) of the PHSA, is enrolled in the 340B Program, and is listed on the public 340B database.
- **Prime Vendor Program** is a program established by the Secretary pursuant to section 340B(a)(8) of the PHSA for price negotiation, distribution facilitation, and other activities in support of the 340B Program.
- **Rebate percentage** is an amount (expressed as a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple

source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

- **Replenishment** is a process by which a covered entity reorders drug inventory based on actual prior drug usage.
- **State** has the meaning set forth in 42 U.S.C. 201(f).
- **Wholesale acquisition cost (WAC)** has the meaning set forth in 42 U.S.C. 1395w-3a(c)(6)(B).

Part A—340B Program Eligibility and Registration

Section 340B(a)(4) of the Public Health Service Act (PHSA) (42 U.S.C. 256b(a)(4)) lists the entity types eligible to participate in the 340B Program and further requires that such entities must meet the requirements of section 340B(a)(5) of the PHSA. An entity participating in the 340B Program is referred to as a covered entity. There are two main categories of covered entities:

- (1) Non-hospital covered entities described in sections 340B(a)(4)(A) through (K) of the PHSA and
- (2) hospital covered entities described in sections 340B(a)(4)(L) through (O) of the PHSA.

Non-Hospital Covered Entities

(a) Eligibility. A non-hospital entity will be listed on the public 340B database if it registers and establishes that it receives a qualifying Federal grant, Federal contract, Federal designation, or Federal project as defined in sections 340B(a)(4)(A) through (K) of the PHSA. HHS will assign a unique 340B identification number to represent each entity type for which a non-hospital covered entity registers and demonstrates eligibility, and list the entity accordingly on the public 340B database.

(b) Associated site eligibility. An associated site which is authorized to provide health care services through the scope of a Federal grant, Federal project, Federal designation, or Federal contract of a covered entity as defined in section 340B(a)(4)(A)–(K) of the PHSA may be eligible to participate in the 340B Program. Once registered for the 340B Program, the associated site will be referred to as a child site. The child site will be listed on the public 340B database, and can purchase and use 340B drugs, if the Departmental division which oversees such grant, project, designation, or contract verifies the eligibility. HHS will list on the public 340B database all sites associated with multiple covered entities under each covered entity type.

(c) Loss of eligibility. A non-hospital covered entity and its child sites are immediately ineligible for the 340B Program upon closing of the covered entity or

upon loss of the parent covered entity's qualifying Federal grant, Federal project, Federal designation, or Federal contract. The entity may be liable to impacted manufacturers for 340B drug purchases made when the entity was ineligible for the 340B Program, and this information may be made available to the public. Additionally, a child site will lose eligibility in the following scenarios:

- (1) Termination of the grant, project, designation, or contract of a child site.** A child site immediately loses eligibility for the 340B Program, separately from the parent covered entity, if the child site no longer qualifies under the parent covered entity's grant, project, designation, or contract.

- (2) A child site registered through multiple statutory sections.** If a child site loses eligibility for one of the multiple covered entity types for which it is registered, it may continue purchasing and using 340B drugs only for the registered covered entity type(s) which remains eligible for the 340B Program.

Hospital Covered Entities

(a) Eligibility. HHS will list hospital covered entities on its public 340B database if the entity establishes that it meets the eligibility requirements in section 340B(a)(4)(L), (M), (N), or (O) of the PHSA. A hospital which qualifies for the 340B Program as more than one of the statutorily-defined hospital types may only register as one hospital covered entity type. A hospital covered entity must comply with all 340B Program requirements for the hospital covered entity type for which it registered. If a hospital covered entity qualifies as another covered entity type, the hospital covered entity may change its covered entity type by registering as a different covered entity type during a regular registration period. The hospital covered entity will only be eligible under the new covered entity type as of the start date listed on the public 340B database for the new 340B identification number. HHS interprets the provisions in section 340B(a)(4)(L), (M), (N), or (O) of the PHSA in the following manner:

- (1) Government owned or operated.** In accordance with section 340B(a)(4)(L)(i) of the PHSA, HHS will consider a hospital eligible for the 340B Program 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 in Internal Revenue Service filings and acknowledgements, if applicable, or other documentation from Federal entities; or operated through an arrangement where the State or local government is the sole operating authority of a hospital.

- (2) Governmental powers.** In accordance with section 340B(a)(4)(L)(i) of the PHSA, HHS will consider a hospital eligible for the 340B Program on the basis of being "formally granted governmental powers by a unit of State or local

government" if HHS 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 State or local 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.

(3) Contract with a State or local government. In accordance with section 340B(a)(4)(L)(i) of the PHSA, HHS will consider a hospital 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 benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title" 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). The signed certification indicates that a contract is currently in place between the private, non-profit hospital and the State or local government to provide health care services to low-income individuals who are not entitled to Medicare or Medicaid. For the purposes of the 340B Program, such contract should create enforceable expectations for the hospital for the provision of health care services, including the provision of direct medical care.

(4) Disproportionate share adjustment percentage. For hospitals qualifying through sections 340B(a)(4)(L)(ii) and 340B(a)(4)(O) of the PHSA, HHS will review a hospital's most recently filed Medicare cost report to ensure the hospital meets the statutorily required disproportionate share adjustment percentage. A disproportionate share hospital (section 340B(a)(4)(L) of the PHSA), children's hospital (section 340B(a)(4)(M) of the PHSA), or freestanding cancer hospital (section 340B(a)(4)(M) of the PHSA) may alternatively seek eligibility as a hospital as described in section 1886(d)(5)(F)(i)(II) of the Social Security Act. A children's hospital which is not required to file a Medicare cost report may provide, in a time frame determined by HHS, a statement from a qualified independent auditor certifying that the auditor performed an audit on the records of the children's hospital, that the auditor is familiar with Federal rules and regulations relevant to its findings, and found that the hospital would meet the criterion in section 340B(a)(4)(L)(ii) of the PHSA.

(b) Off-site outpatient facility eligibility. A hospital covered entity as defined in section 340B(a)(4)(L), (M), (N), or (O) of the PHSA may have one or more off-site outpatient facilities or clinics that deliver outpatient services for the hospital. Off-site outpatient facilities and clinics will be listed on the public 340B database, and may purchase or use 340B drugs for eligible patients, if the most recently filed Medicare cost report lists each facility or clinic on a line that is reimbursable under Medicare, and demonstrates that the services provided at the facility or clinic have associated outpatient Medicare costs and

charges. For a children's hospital which does not file a Medicare cost report, HHS will list an off-site outpatient facility if the parent hospital authorizing official submits a signed statement which certifies the requested outpatient facility:

- (1) Is an integral part of the children's hospital whose patients meet the requirements of this guidance; and
- (2) Would be correctly included on a reimbursable line with associated Medicare outpatient costs and charges on a Medicare cost report, if filed.

(c) Loss of eligibility. A hospital covered entity and its child sites are immediately ineligible upon closing of the hospital or upon change of ownership or contract status which results in the hospital failing to qualify under 340B(a)(4)(L)(i) of the PHSa. A hospital which qualifies for the 340B Program on the basis of a disproportionate share adjustment percentage will lose eligibility immediately upon filing of a Medicare cost report for which the disproportionate share adjustment percentage falls below the statutory threshold. A hospital which qualifies for the 340B Program as described in section 1886(d)(5)(F)(i)(II) of the Social Security Act will lose eligibility immediately upon filing of a Medicare cost report for which the hospital does not meet the requirements of section 1886(d)(5)(F)(i)(II) of the Social Security Act. A children's hospital which does not file a Medicare cost report will lose eligibility for the 340B Program immediately upon an annual independent audit which results in a disproportionate share adjustment percentage less than or equal to 11.75. Additionally, a registered child site will lose eligibility in the following scenarios:

- (1) Immediately upon closing of the clinic or facility or when sold or transferred to any entity.
- (2) 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.
- (3) For hospitals subject to the GPO prohibition, immediately upon use of a GPO for covered outpatient drugs as specified in this guidance.

Registration and Termination

(a) Registration. Sections 340B(d)(2)(B)(i), (ii), and (iv) of the PHSa require HHS to maintain a single, universal, and standardized identification system listing participating covered entities. HHS publishes and regularly updates this list of covered entities and their registered associated sites on the public 340B database. The registered covered entity is listed as the "parent" site and the registered off-site outpatient facility or associated site is listed as the "child" site. If an authorizing official submits a registration that demonstrates eligibility for the 340B Program, the covered entity is listed on the public 340B database, assigned a unique 340B identification number, and is able to purchase and use 340B drugs for their eligible patients. The inclusion of a covered entity within a larger organization does not make the entire organization eligible for the 340B Program.

HHS will not list a pharmacy on its public 340B database nor assign it a 340B identification number, as a pharmacy is not an eligible covered entity under the PHSA. HHS will list a covered entity-owned and operated pharmacy as an authorized shipping address for the parent and any child sites. HHS may provide a special registration opportunity for entities during a public health emergency declared by the Secretary. The geographic scope and time period limitations of the Secretary's public health emergency notice will govern limits for this special registration.

(b) Termination. HHS lists covered entities on its public 340B database on the condition that the covered entity will regularly review and update 340B database information. Upon loss of eligibility of a parent site, child site, or termination of any contract pharmacy arrangement, the covered entity must immediately notify HHS and stop purchasing and using 340B drugs. HHS requests that the covered entity provide information pertaining to the reason for the loss of eligibility, the effective date for the loss of eligibility, and the date of the last 340B drug purchase for a terminated covered entity, child site, or contract pharmacy. A covered entity is liable to manufacturers for repayment for the 340B discounts on any drugs purchased for itself, any child site, or any contract pharmacy when the covered entity was ineligible for the 340B Program for any reason. A covered entity removed from the 340B Program would be able to re-enroll to the 340B Program during the next regular enrollment period after it has satisfactorily demonstrated to HHS that it will comply with all statutory requirements moving forward and is in the process of offering repayment to affected manufacturers, if necessary.

Annual Recertification

In order to continue to be listed as an eligible covered entity and purchase 340B drugs, a covered entity annually recertifies that the covered entity, its child sites, and its contract pharmacy arrangements meet all 340B Program eligibility and compliance requirements. This recertification shall be carried out in a manner and time frame specified by HHS. If a covered entity cannot attest to compliance or is no longer eligible, the covered entity shall cease purchasing and using 340B drugs and terminate its listing and that of any child site, or associated contract pharmacy arrangement which is no longer eligible or for which compliance cannot be attested. A covered entity which voluntarily terminates its listing and that of any child site, or any contract pharmacy arrangement from the 340B Program, is expected to provide information and documentation for voluntary termination and whether it purchased 340B drugs during a period of ineligibility. The covered entity is responsible for repayment to manufacturers in the amount of the discounts for 340B Program drug purchases made after the date the covered entity or child site became ineligible for the 340B Program. HHS may review submissions during recertification or at any time to determine if the covered entity remains eligible and may remove the covered entity from the public 340B database for failure to meet 340B Program eligibility requirements.

Group Purchasing Organization Prohibition for Certain Covered Entities

Covered entities subject to the group purchasing organization (GPO) prohibition in section 340B(a)(4)(L)(iii) of the PHSA shall not obtain any covered outpatient drugs (including covered outpatient drugs given to non- 340B patients) through a GPO or other group purchasing arrangement on or after the start date of enrollment in the 340B Program, including any pharmacy owned or operated by the covered entity, except in circumstances described in paragraph (a) of this section. Violations of the statutory prohibition concerning the use of GPOs are addressed in paragraph (d) of this section. A prime vendor program established pursuant to section 340B(a)(8) of the PHSA is not considered a GPO or group purchasing arrangement under this section. Inclusion of off-site outpatient facilities and clinics in the entity's 340B database record demonstrates that these facilities and clinics are subject to the GPO prohibition.

(a) Exceptions. A GPO used to obtain covered outpatient drugs in the following situations and off-site outpatient facilities and clinics will not be considered in violation of the statutory GPO prohibition.

- (1) An off-site outpatient clinic of a 340B hospital covered entity if the outpatient clinic is located at a separate physical address from the 340B parent covered entity, is not participating in the 340B Program or listed on the public 340B database, and purchases drugs through a separate account from the 340B parent covered entity;
- (2) A GPO-purchased drug provided to an inpatient who, upon subsequent review (e.g., insurer, Medicare Recovery Audit Contractor, or hospital review), results in the designation of that patient as an outpatient for payment purposes; and
- (3) A hospital which can only access a covered outpatient drug through a GPO account. In such case, the hospital is expected to document attempts to purchase the drug at the 340B price and wholesale acquisition cost price and report the circumstances to HHS, including drug name, manufacturer, and summary of attempts made to acquire the drug.

(b) Drug replenishment models. A covered entity electing to use a replenishment model should be able to clearly demonstrate through auditable records that the replenishment model, along with any associated software, is used in a manner that complies with the statute.

(c) Use of previously-purchased GPO drugs. A covered entity subject to the GPO prohibition must cease purchasing or obtaining covered outpatient drugs through a GPO before the first day the covered entity is listed on the public 340B database as eligible to purchase 340B drugs. A covered entity subject to the GPO prohibition with GPO-

purchased covered outpatient drugs remaining in inventory on the effective date of enrollment in the 340B Program may use those drugs until expended.

(d) Violations of the statutory prohibition on use of GPOs. The 340B statute makes compliance with the GPO prohibition a condition of eligibility. Therefore, a covered entity found in violation of the GPO prohibition will be considered ineligible and removed from the 340B Program after a notice and hearing process as described in Part H. However, if a covered entity can demonstrate the violation is an isolated error, HHS may allow the covered entity to continue 340B Program participation under a corrective action plan. A covered entity found in violation must offer to repay affected manufacturers for any 340B drug purchase made after the date of the first GPO violation.

If a GPO prohibition violation occurs at a parent site, and the parent site is terminated from the 340B Program, all child sites registered through the parent covered entity will be removed from the 340B Program. If the GPO prohibition violation can be limited to certain child sites, only those child sites where the violation occurred will be removed, but repayment for periods of ineligibility must be offered. GPO violations by child sites may only be limited if the child site has auditable records which show that the child site:

- (1) Is located in a building separate from the parent site and other child sites; and
- (2) All drug purchasing for the sites occur using separate purchase accounts from the parent site and other child sites.

(e) Re-enrollment in the 340B Program. A covered entity removed from the 340B Program for a GPO prohibition violation would be able to re-enroll during the next regular registration period after it has satisfactorily demonstrated to HHS that it will comply with the GPO prohibition going forward and is in the process of offering repayment to affected manufacturers.

Part B—Drugs Eligible for Purchase Under the 340B Program

A covered outpatient drug, as defined in section 1927(k)(2) and (3) of the Social Security Act, is eligible for purchase under the 340B Program. For purposes of the 340B Program, only drugs bundled for and receiving such bundled reimbursement under Title XIX of the Social Security Act described in section 1927(k)(3) will be considered excluded from the definition of covered outpatient drug.

Part C—Individuals Eligible To Receive 340B Drugs

(a) Criteria. Section 340B(a)(5)(B) of the PHSA prohibits covered entities from reselling or otherwise transferring a 340B drug to a person who is not a patient of the entity. HHS interprets this section to include all patients that meet all of the following criteria on a prescription-by-prescription or order- by-order basis:

- (1) The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database;
- (2) The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider.
- (3) An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.
- (4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract;
- (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; and
- (6) The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.

(b) Exceptions.

(1) AIDS Drug Assistance Program. 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.

(2) Public health emergency declared by the Secretary. If normal health care operations are disrupted due to a public health emergency declared by the Secretary, a covered entity may request, and HHS may authorize, a covered entity to temporarily follow alternate patient eligibility criteria. A covered entity must maintain auditable records that document the alternate patient eligibility criteria used and the exact dates for which alternate patient eligibility criteria are in effect.

(c) Replenishment. To avoid a violation of the statutory prohibition on diversion, a covered entity that utilizes a drug replenishment model may only order 340B drugs based on actual prior usage for eligible patients of that covered entity as defined by this guidance.

(d) Repayment. If a 340B drug is found to have been diverted to an individual who is not a patient of the covered entity contrary to the statutory prohibition on diversion, the covered entity is responsible for offering repayment to all affected manufacturers. A covered entity is also responsible for any repayment for 340B drugs diverted from a child site or through its contract pharmacy arrangements.

(e) Corrective action requirement. A covered entity should notify HHS of its corrective actions regarding diversion, including any manufacturer agreements on repayment. *Part*

D—Covered Entity Responsibilities

Prohibition of Duplicate Discounts: Section 340B(a)(5)(A)(i) of the PHSA prohibits duplicate discounts whereby a State obtains a rebate on a drug provided to a Medicaid fee-for-service or managed care organization patient when that same drug was discounted under the 340B Program.

(a) 340B Medicaid Exclusion File. Pursuant to section 340B(a)(5)(A)(ii) of the PHSA, which requires HHS to create mechanisms to ensure duplicate discounts do not occur, HHS has established the 340B Medicaid Exclusion File as the mechanism to prevent duplicate discounts. The 340B Medicaid Exclusion File is posted on HHS's public Web site to enable 340B covered entities, States, and manufacturers to determine whether a covered entity purchases 340B drugs for its Medicaid patients.

(1) Medicaid Fee-for-Service. HHS lists 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. The listing of a covered entity's Medicaid provider number or NPI on the Medicaid Exclusion File means that all drugs billed to Medicaid FFS under the Medicaid provider number are purchased through the 340B Program. 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.

(2) Medicaid Managed Care. The covered entity may choose whether to use 340B drugs for its Medicaid Managed Care Organization (MCO) patients. The covered entity may make differing selections by covered entity site and managed care organization so long as such distinction is made available to HHS. This information may be made available publicly through an Exclusion File or other mechanism. In

addition, a covered entity should have mechanisms in place to identify Medicaid MCO patients.

(b) Change requests. A covered entity may make changes to its use of 340B drugs for Medicaid FFS or MCO patients after initial registration for itself or its child sites during HHS-specified timeframes. A covered entity must inform HHS of the change prior to being implemented.

(c) Contract pharmacy. Unless otherwise noted on the public 340B database, contract pharmacies will not dispense 340B drugs for Medicaid FFS or MCO patients. If a covered entity wishes to purchase 340B drugs for its Medicaid FFS or MCO patients and dispense 340B drugs utilizing a contract pharmacy, the covered entity will provide a written agreement for HHS approval with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts.

(d) State notification. In the event that a covered entity is unable to use a 340B drug for a Medicaid FFS or MCO patient in a particular instance, it is expected to document the reason and have a mechanism in place to notify the State Medicaid agency or MCO.

(e) Repayment. In accordance with section 340B(a)(5)(D) of the PHSA, if the information provided to HHS does not reflect the covered entity's actual billing practices, the covered entity may be found in violation of the duplicate discount prohibition and would be required to repay rebate amounts to manufacturers if duplicate discounts have occurred due to the inaccurate information.

Maintenance of Auditable Records

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. 340B Program records must be made available to HHS at any time and to certain manufacturers pursuant to an audit. If an entity, any child site, or any contract pharmacy terminates its 340B Program participation, an entity must maintain applicable auditable records for 5 years after the date of termination.

(a) Failure to maintain records. If a covered entity cannot produce records pertaining to compliance with any specific 340B Program requirement during an audit or pursuant to a request from HHS, the covered entity could be presumed to be out of compliance with that 340B Program requirement and subject to the penalty applicable to the requirement. If a covered entity systematically fails to maintain auditable records, which is a statutory eligibility requirement, or fails to provide them as requested by HHS or a manufacturer authorized to conduct an audit, the covered entity will be removed from the 340B Program after a notice and hearing process as described in this guidance. A covered entity deemed

ineligible and removed from the 340B Program for failure to maintain auditable records would be liable for repayment to manufacturers for periods of ineligibility.

(b) Re-enrollment in the 340B Program. A covered entity that has been removed from the 340B Program for failure to maintain auditable records may re-enroll for the 340B Program during the next regular registration period after it has demonstrated to HHS its ability to comply with all 340B Program requirements, including the ability to maintain auditable records.

Part E—Contract Pharmacy Arrangements

Regardless of the availability of an in-house pharmacy, a covered entity may contract with one or more licensed pharmacies to dispense 340B drugs to eligible patients of the covered entity (as defined in this guidance) provided the arrangement is in accordance with all other statutory 340B Program requirements and applicable Federal, State, and local laws, including the Federal anti-kickback statute (42 U.S.C. 1320a-7b(B)). In the case of a covered entity whose 340B Program eligibility is based on a Federal grant, Federal contract, Federal designation or Federal project, any contract pharmacy arrangement must comply with all grant, contract, or project requirements. A covered entity may 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 may contract directly with a pharmacy if not prohibited by Federal, State, or local law.

(a) Registration. Once listed on the public 340B database, the contract pharmacy may provide 340B drugs to eligible patients of the covered entity (defined in this guidance). HHS 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. As the covered entity maintains responsibility for compliance with 340B statutory requirements, a covered entity is the only party that may submit a contract pharmacy registration, certify a contract pharmacy, make changes to the contract pharmacy arrangements listed on the public 340B database, and verify that all public and non-public information in the 340B database regarding its contract pharmacies is accurate. A covered entity may request additional contract pharmacy locations under a public health emergency declared by the Secretary for the geographic area and time period specified in the declaration, provided all other 340B Program requirements are met. HHS may remove a contract pharmacy from the 340B Program if HHS finds that the contract pharmacy is not complying with 340B Program requirements. The covered entity is responsible for offering repayment in the amount of the 340B discount to a manufacturer for 340B drugs dispensed by a contract pharmacy that has not adhered to 340B Program requirements.

(b) Compliance with statutory requirements. A covered entity must follow all 340B statutory requirements when utilizing a contract pharmacy, including, but not limited to:

(1) Prevention of diversion. The covered entity and contract pharmacy are expected to have a system in place to verify the patient's eligibility for each 340B drug dispensed by the contract pharmacy and must prevent diversion as prohibited in section 340B(a)(5)(B) of the PHSA.

(2) Prevention of duplicate discounts. A covered entity's contract pharmacy may not dispense 340B drugs to Medicaid patients of the covered entity unless the covered entity has submitted information to HHS regarding the arrangement and has systems in place with the State Medicaid agency and contract pharmacy to ensure duplicate discounts cannot occur.

(3) Contract pharmacy oversight. The covered entity is expected to conduct quarterly reviews and annual independent audits of each contract pharmacy location; the results of these reviews are included in the records' requirements of section 340B(a)(5)(C) of the PHSA. Any 340B Program violation detected through quarterly reviews or annual audits of a contract pharmacy should be disclosed to HHS. Covered entities are subject to the applicable penalties for instances of duplicate discounts and diversion.

Part F—Manufacturer Responsibilities

Pharmaceutical Pricing Agreement Pursuant to the statutory requirements of section 340B(a)(1) of the PHSA, a manufacturer that has entered into a Medicaid Drug Rebate Agreement pursuant to section 1927(a) of the Social Security Act must also enter into a pharmaceutical pricing agreement (PPA) pursuant to section 340B(a) of the PHSA. Under the PPA, a manufacturer must offer all covered outpatient drugs, as defined in section 1927(k) of the Social Security Act, from each of the manufacturer's labeler codes to covered entities participating in the 340B Program at no more than the statutory 340B ceiling price. A manufacturer that does not have a Medicaid Drug Rebate Agreement may voluntarily enter into a PPA. By signing the PPA, a manufacturer agrees to comply with all 340B Program statutory requirements, including statutory and regulatory changes that occur after execution of the PPA. In the event of a transfer of ownership of the manufacturer, the PPA is automatically assigned to the new owner. The following expectations apply to participating manufacturers:

- (1) For a manufacturer whose 340B Program participation is required by virtue of its participation in the Medicaid Drug Rebate Program, sign a PPA within 30 days of enrolling in the Medicaid Drug Rebate Program;
- (2) Submit timely updates to its 340B database record and PPA such that any new covered outpatient drug is added to the 340B Program;

- (3) Maintain auditable records demonstrating 340B Program compliance for no less than 5 years and provide such records to HHS when requested; and
- (4) Permit HHS to audit manufacturer compliance.

A manufacturer that has voluntarily signed a PPA with the Secretary may terminate its 340B Program participation at any time in accordance with the terms of the PPA. When a manufacturer voluntarily participating in the 340B Program requests 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 covered outpatient drugs under the 340B Program.

Obligation To Offer 340B Prices to Covered Entities Pursuant to section 340B(a)(1), a manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed on the public 340B database. The public 340B database provides information to allow manufacturers to determine if a covered entity is participating in the 340B Program or for any changes to eligibility.

(a) Effective date. For manufacturers signing their first PPA by virtue of participating in the Medicaid Drug Rebate Program, the effective date for 340B pricing for existing covered outpatient drugs to any covered entity is 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 inclusion 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.

(b) No conditioning of sales. In accordance with section 340B(a)(1) of the PHSA, a manufacturer is required to offer 340B drugs to each covered entity if it is available to any other purchaser at any price. Manufacturers may not condition the offer of the 340B ceiling price on a covered entity's assurance of compliance with 340B Program requirements.

(c) Limited distribution plan. A manufacturer using a specialty pharmacy or a restricted distribution network, or needing to limit distribution due to potential or actual shortages, is expected to notify HHS in writing prior to implementation of such limited distribution plan. HHS may publish plans on the 340B Web site. HHS will work with manufacturers if there are concerns regarding the plan prior to making public. A manufacturer's limited distribution plan is expected to include each of the following components:

- (1) An explanation of the product's limited supply or special distribution requirements and the rationale for restricted distribution among all purchasers;

- (2) An assurance that the manufacturers will impose these restrictions equally on both 340B covered entities and non-340B purchasers;
- (3) Specific details of the drug distribution plan, including a mechanism that allocates sales to both covered entities and non-340B purchasers with no previous purchase history of the restricted drug;
- (4) The dates the alternative distribution begins and concludes; and
- (5) A plan for notification of wholesalers and 340B covered entities of the restricted plan.

(d) Additional discounts permitted. A manufacturer may choose to sell a covered outpatient drug below the 340B ceiling price to a covered entity. Such pricing is voluntary and need not be applied to all 340B covered entities.

Procedures for Issuance of Refunds and Credits

Pursuant to section 340B(d)(1)(B)(ii) of the PHSA, which requires HHS to establish procedures for manufacturers to issue refunds, a manufacturer must refund or credit a covered entity when there is an overcharge in an amount equal to the price difference between the sale price and the correct 340B price for that drug, multiplied by the number of units. The refund or credit is expected occur within 90 days of the determination by the manufacturer or HHS that an overcharge occurred.

(a) Required information. A manufacturer must submit to HHS 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.

(b) Waiver. 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

A participating manufacturer should review and update 340B database information on an annual basis

Part G—Rebate Option for AIDS Drug Assistance Programs

A State AIDS Drug Assistance Program eligible to participate in the 340B Program under section 340B(a)(4)(E) of the PHSA may register for and participate in the 340B Program through this rebate option. 340B Program participation by an AIDS Drug Assistance Program via the rebate option or the hybrid option (participation in the 340B Program both through the direct purchase option and the rebate option) is subject to all the same applicable obligations, requirements, and duties imposed on other covered entities.

(a) Procedures for the AIDS Drug Assistance Program rebate option.

(1) Only an AIDS Drug Assistance Program registered under the rebate option or the hybrid option and listed on the public 340B database may request rebates pursuant to this section.

(2) An AIDS Drug Assistance Program is expected to make a qualified payment, as defined in paragraph (b) of this section, for an eligible patient, as defined in this guidance.

(3) An AIDS Drug Assistance Program is expected to submit claims-level data to manufacturers which document a qualified payment was made to support each request for a rebate.

(b) Qualified payment. A qualified payment by an AIDS Drug Assistance Program for a covered outpatient drug is:

(1) A direct purchase by the AIDS Drug Assistance Program of a covered outpatient drug at a price greater than the 340B ceiling price; or

(2) A payment by the AIDS Drug Assistance Program of the health insurance premiums that cover the covered outpatient drug purchases at issue and payment of a copayment, coinsurance, or deductible for the covered outpatient drug.

(c) Multiple 340B discounts and rebates. An AIDS Drug Assistance Program participating via the rebate option or hybrid option described in this section may not request a 340B rebate for a drug which was already purchased by another covered entity at or below the 340B ceiling price.

(d) Audits. An AIDS Drug Assistance Program participating in the 340B Program through the rebate option or hybrid option is subject to audit by HHS.

(e) Manufacturer rebates.

(1) Manufacturer obligation to offer rebates. Pursuant to a manufacturer's obligation under section 340B(a)(1) of the PHSA to charge no more than the ceiling price for covered outpatient drugs (taking into account any rebate or discount, as

provided by the Secretary), a manufacturer must pay a rebate for a covered outpatient drug to an AIDS Drug Assistance Program, which has registered for the 340B Program under the rebate option or hybrid option and has made a qualified payment for such covered outpatient drug.

(2) Amount of rebate. The rebate owed to an AIDS Drug Assistance Program for a qualified payment for a covered outpatient drug is equal to the rebate described in section 1927(c) of the Social Security Act, multiplied by the units of drug included in the rebate claim. *Part*

H—Program Integrity

HHS Audit of a Covered Entity

Pursuant to section 340B(a)(5)(C) of the PHSA, a covered entity participating in the 340B Program, including all its child sites and contract pharmacies, is subject to audit by HHS to determine if it is complying with all 340B Program requirements. HHS will ensure that only one 340B Program audit of a covered entity, its child sites, and contract pharmacies is in process at any given time, including a 340B Program audit by a manufacturer. HHS will notify the covered entity of its intent to audit. HHS will have the option to conduct an on-site review, a review of documentation submitted to HHS, or both.

(a) Provision of auditable records. At HHS's request, the covered entity shall provide or arrange for access to all specified records pertaining to 340B Program compliance on behalf of the parent covered entity site, its child sites, and its contract pharmacies by the deadline specified. Failure to provide records or respond to requests for information within HHS-specified deadlines may result in the penalties specified in this guidance for failure to maintain auditable records and termination from the 340B Program.

(b) Notice and hearing. HHS will initiate a notice and hearing process under which a covered entity has the opportunity to respond to adverse audit findings and other instances of noncompliance or to respond to the proposed loss of 340B Program eligibility. HHS initiates the process by providing written notice that will specify a 30-day response deadline. The covered entity responds in writing to each issue of noncompliance, providing supporting documentation as necessary, including but not limited to a revised or amended cost report accepted for filing. HHS will issue a final written notice with its final determination regarding noncompliance. If the final determination of noncompliance includes a finding that the covered entity is no longer eligible, HHS will determine the removal date. The covered entity is liable for repayment to affected manufacturers for purchases made after the date the entity loses its eligibility.

(c) Corrective action plans. HHS considers a covered entity in compliance with 340B statutory requirements if the entity has submitted a corrective action plan that documents the correction of any finding of noncompliance, explains measures taken to prevent future

occurrences of noncompliance, includes a plan to offer affected manufacturers repayment for discounts improperly received, if applicable, and states a timeline for corrective actions to take place. HHS will review corrective action plans and work with covered entities to revise submitted corrective action plans to appropriately address the required components. HHS may verify a covered entity's compliance with an HHS- approved corrective action plan at any time. Failure of an entity to submit a corrective action plan may result in further HHS action, including termination from the 340B Program.

(d) Public information. HHS may make the final audit results available to the public.

Manufacturer Audit of a Covered Entity Pursuant to section 340B(a)(5)(C) of the PHSa, a drug manufacturer participating in the 340B Program may audit the records of a covered entity, its child sites, and its contract pharmacies regarding compliance with the 340B Program requirements that prohibit duplicate discounts and diversion of the manufacturer's drugs if the manufacturer has reasonable cause to believe the entity is not complying with these requirements. Drug manufacturer concerns regarding the 340B Program eligibility of a covered entity or compliance with 340B Program requirements other than diversion and duplicate discounts may be referred to HHS for investigation. A covered entity must permit an HHS-approved audit to be conducted by the manufacturer's auditor.

(a) Adherence to 340B Program requirements. Until HHS makes a determination of a 340B Program violation, a manufacturer must continue to sell covered outpatient drugs at no more than the 340B ceiling price to the covered entity, and the covered entity must continue to comply with all 340B Program requirements. Alleged noncompliance, the filing of a manufacturer audit work plan, or the conduct of an audit do not affect the statutory obligations of the manufacturer or the covered entity.

(b) Procedures for requesting and conducting an audit. The manufacturer shall follow the steps below in requesting and conducting an audit.

(1) Initial notification to the covered entity. The manufacturer notifies the covered entity in writing if it believes the covered entity has violated the prohibition concerning duplicate discounts or diversion (section 340B(a)(5)(A) or (B) of the PHSa) 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 written notification.

(2) Submission of basis for reasonable cause and audit work plan. If the manufacturer cannot resolve the matter through good faith negotiations with the covered entity, the manufacturer may submit its grounds for reasonable cause with supporting documentation and evidence of its attempt to resolve the matter with the covered entity, and its audit work plan to HHS.

(3) HHS review. HHS will review the request, all submitted documentation, and the audit work plan. HHS will notify a manufacturer of any concerns regarding the audit work plan or the manufacturer's basis for reasonable cause and may require revision of certain audit procedures.

(4) Covered entity audit requirements. A covered entity subject to manufacturer audit must provide access to records demonstrating compliance with sections 340B(a)(5)(A) and (B) of the PHSA within the scope of the audit. The covered entity is also responsible for arranging access to or directly providing child site and contract pharmacy records relevant to the audit.

(5) Audit scope. The scope of the audit is limited to drugs provided by that manufacturer which should not include a review of auditable records exceeding the 5-year record retention standard. Manufacturers must protect proprietary information of the covered entity at all times.

(6) Patient confidentiality. Patient confidentiality must be observed throughout the audit process and in the final audit report, in accordance with HIPAA requirements at 45 CFR parts 160, 162, and 164.

(7) Post-audit. The manufacturer submits the final audit report to the covered entity and the covered entity shall provide its response to the manufacturer on the audit report's findings and recommendations within 30 days of receipt of the audit report. A covered entity's failure to respond shall be considered as the covered entity's agreement with the audit findings. If the covered entity agrees with the audit report findings and recommendations either in full or in part, the covered entity shall include in its response to the manufacturer a description of the actions planned or taken to address the audit findings and recommendations. When the covered entity does not agree with the audit report findings and recommendations, the covered entity shall provide its rationale for the disagreement to the manufacturer.

(8) Audit reports. The manufacturer submits copies of the final audit report and covered entity responses to HHS.

(9) Other Federal agencies. HHS may also refer findings to other Federal agencies, the HHS OIG, or other Departmental divisions, as appropriate.

(c) Manufacturer audit work plan. The manufacturer's audit work plan is expected to include the following elements:

(1) Audit objectives, scope, and methodology;

- (2) Skill and knowledge of the auditor's personnel including supervisors, and any intended use of consultants, experts, and specialists;
- (3) Tests and procedures to be used to assess a covered entity's system of internal controls;
- (4) Procedures to be used to determine the 340B purchases questioned as potential violations of section 340B(a)(5)(A) or (B) of the PHSA; and
- (5) Procedures to be used to protect patient confidentiality consistent with HIPAA requirements at 45 CFR parts 160, 162, and 164, and the covered entity's proprietary information.

HHS Audit of a Manufacturer and Its Contractors

Pursuant to section 340B(d)(1)(B)(v) of the PHSA, a manufacturer (or its contractors, including wholesalers) participating in the 340B Program may be subject to audit by HHS to determine whether it is complying with 340B Program requirements in statute, regulations, and the PPA. HHS will notify the manufacturer or wholesaler in writing of HHS's intent to audit for 340B Program compliance.

(a) Provision of auditable records. The manufacturer shall provide all requested records demonstrating 340B Program compliance on behalf of itself and any wholesaler or organization which performs 340B Program requirements or contracts for the manufacturer. Failure to provide records or respond to requests for information within the HHS-specified time frames may result in further action by HHS or referral for investigation.

(b) Notice and hearing. HHS will provide the manufacturer with written notice of any proposed audit findings and will request a response within 30 days. The manufacturer shall respond to HHS with its agreement or disagreement with each audit finding and provide documentation to support its disagreement within the specified deadline. The manufacturer will be deemed to agree with any audit finding the manufacturer does not specifically address or if the manufacturer fails to respond to the HHS notification of audit findings within the specified deadline. HHS will review all documentation, including documents submitted by the manufacturer, and advise the manufacturer or wholesaler of its final determination regarding audit findings. HHS will request a corrective action plan within a specified time to address findings, as needed. If 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.

(c) Corrective action plan. A corrective action plan is submitted within 30 days of receiving HHS's audit findings of noncompliance. This corrective action plan addresses each audit finding of noncompliance, documents the correction of all

findings of noncompliance, institutes measures to prevent future occurrences of noncompliance, offers affected covered entities repayment for instances of overcharging, if applicable, and states a timeline for corrective actions to occur. HHS will determine if the submitted corrective action plan is sufficient. HHS may verify a manufacturer's compliance with the HHS-approved corrective action plan at any time.

(d) Public information. HHS may make the final audit results available to the public.

Dated: August 14, 2015.

James Macrae, *Acting Administrator, Health Resources and Services Administration.* Approved: August 17, 2015.

Sylvia M. Burwell, *Secretary.*

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