National Coalition of STD Directors

The 340B Drug Pricing Program:
Frequently Asked Questions (FAQs)

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Note: This information is provided by NCSD for general information purposes and does not constitute legal advice. These FAQs are designed for Ending the HIV Epidemic (EHE) and other 318 grantees and subgrantees, which include, but are not limited to, state and local health departments and private non-profit clinics that receive PCHD grants (NOFO 19-1901) for the prevention and treatment of STDs.

Topics

General

Q: What is the 340B Program?
A: The 340B Drug Pricing Program (the "340B Program") is a federal program that requires manufacturers to provide drugs at a discount to certain safety net providers (referred to as, "covered entities"). The 340B Program was enacted in 1992 to help eligible safety net providers "stretch scarce Federal resources as far as possible reaching more eligible patients and providing more comprehensive services." (H.R. Rep. 102-384(II)) Estimates in savings on drug costs range from 20–50 percent. The 340B Program is codified in Section 340B of the Public Health Service Act. The Office of Pharmacy Affairs (OPA), located in the Health Resources and Services Administration (HRSA), is the federal agency charged with administering and overseeing the 340B Program.

Q: What are the benefits of participating in the 340B Program?
A: The biggest benefit is the savings on drug costs, which allows 318 grantees and subgrantees to expand their formularies to include more costly therapeutic options,

such as Bicillin LA, Azithromycin, and Isoniazid oral tablets. Any revenue generated from the cost of the drug and what a 340B covered entity is reimbursed (referred to as the "spread") enables covered entities to serve more patients and provide more comprehensive services as intended by the 340B Program. It also helps covered entities cover the cost of providing uncompensated care to uninsured and under-insured individuals and, in many states, cover the cost of providing services to Medicaid patients.

Q: Why would a manufacturer participate in the 340B Program and have to give discounts to 340B covered entities?

A: If a manufacturer wants its products covered by Medicaid (and most do), it must agree to: (1) pay rebates on drugs used by Medicaid beneficiaries and (2) give discounts on drugs to 340B covered entities. The Medicaid drug rebate formula is set forth in statute and is calculated using a manufacturer's average manufacturer price or AMP (the average price paid to the manufacturer by wholesalers for drugs distributed to retail community pharmacies) and best price (for brand name drugs). The rebate formula is designed to ensure that Medicaid gets the best price for a drug that a manufacturer has offered to any other purchaser. Importantly, a state may not collect a rebate on a drug that is purchased at a 340B price. This would result in an illegal duplicate discount – where a manufacturer pays a discount upfront to a covered entity and a rebate to the state on the same unit of drug.

Q: How is 340B pricing established?

A: The 340B ceiling price is the maximum amount a drug manufacturer can charge a 340B covered entity enrolled in the 340B Program. The 340B ceiling price is a statutory formula based on the same components as the Medicaid drug rebate formula (AMP from the preceding quarter for the smallest unit of drug minus the Unit Rebate Amount). A manufacturer may offer pricing that is lower than the 340B statutory ceiling price and many do.

Q. What if a manufacturer refuses to sell me drugs at a 340B price or charges me more than the 340B ceiling price?

A: Manufacturers are required by law to sell drugs at or below the 340B ceiling price to covered entities. A covered entity can check the 340B Ceiling Price Database in the Office of Pharmacy Affairs Information System (OPAIS) to see if it is being overcharged for a drug. If a covered entity discovers that it is being overcharged, it should first see if the manufacturer or wholesaler will fix the pricing and refund the covered entity for any overcharged amounts. If the covered entity verifies an overcharge and is unable to resolve it with the manufacturer or wholesaler, it should follow the dispute resolution process. You can learn more about the Administrative Dispute Resolution Process here.

Eligibility and Registration

Q: How do I know if my site is eligible for 340B pricing?

A: The entities eligible for 340B pricing are set forth in statute and generally include certain federally funded grantees, federally qualified health centers and look-alikes, and safety net hospitals. Recipients of funding authorized under Section 318 of the

Public Health Service Act are eligible for 340B pricing, including EHE and PCHD (STD) grantees and subgrantees. The full list of eligible entities may be found here.

Q: Can the receipt of in-kind contributions (e.g., lab testing kits, medications etc.) through Section 318 of the Public Health Service Act (PHSA) qualify an entity for participation in the 340B Drug Pricing Program?

A: Yes. An entity receiving in-kind contributions through Section 318 of the PHSA may qualify for the 340B Program. It is common for 318 grantees and subgrantees to receive in-kind contributions, which may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

Q: My state gives me drugs to treat patients with STDs. Is this an in-kind contribution and would it make my site eligible for 340B?

A: It is not uncommon for a state with a 318-funded PCHD grant (NOFO 19-1901) to purchase drugs, such as drugs to treat STDs, and distribute them to their local health departments and contracted providers. This would be an acceptable 318 funded in-kind contribution and would confer 340B eligibility for each subrecipient. In this case, each site receiving the medications from the state should register as a covered entity in OPAIS to receive its own unique 340B ID. Once a site has its own 340B ID, it may purchase drugs other than those that the state has provided to expand its formulary and offer more medication options for its patients. These arrangements are referred to as a "combined purchasing and distribution" arrangement and should be approved in advance by HRSA. *See* https://www.340bpvp.com/resource-center/340b-tools (click on "Grantees" and scroll to the "Operational and Purchasing" section for more information).

Q: If I am a recipient of 318 funding or in-kind contributions, how do I start to get the 340B discounted pricing on drugs?

A: Although a 318 grantee or subgrantee may be eligible to participate in the 340B Program, it must register for the 340B Program before manufacturers will sell 340B discounted drugs. The Office of Pharmacy Affairs manages the OPA Information System (OPAIS) where eligible entities can register for 340B status. Once a 318 grantee or subgrantee registers for the 340B Program through the OPAIS portal, its name will be listed in the system, however, PCHD grantees and subgrantees (NOFO 19-1901) must have their registration confirmed by their jurisdiction's STD program director. All covered entities must ensure that the information in OPAIS is updated.

Q: Once I have registered all eligible sites in OPAIS, when do the drug discounts begin?

A: The Office of Pharmacy Affairs has designated the first two weeks of every quarter for registering newly eligible entities in OPAIS. Once registration is complete, 318 grantees and subgrantees will receive a 340B identification number that begins with STD followed by several numbers (e.g., STDXXXX). Manufacturers or distributors will verify a covered entity's 340B ID before allowing it to purchase 340B drugs at the beginning of the following quarter. The designated registration periods and start dates for discounted drugs are as follows:

- January 1 – 15 registration for a start date of April 1,
- April 1 – 15 registration for a start date of July 1,
- July 1 – 15 registration for a start date of October 1, and
- October 1 – 15 registration for a start date of January 1.

Q: Where can I purchase 340B drugs?

A: 340B grantees can purchase 340B drugs directly from a manufacturer or wholesaler or through a group purchasing organization (GPO), such as Apexus, HRSA's contracted prime vendor. A 340B grantee can participate in more than one GPO.

Q. My site has two different 318 grants -- a PCHD grant (NOFO 19-1901) and an EHE grant (NOFO 20-2010). Do I need to register twice in OPAIS under each federal grant and NOFO number?

A. You are not required to register under both grants; however, you have the option to do so. There are important considerations when making the decision regarding which grant to register under or whether to register under multiple designations (e.g., two 318 grants, or a combination of a 318 grant or Ryan White or some other grant etc.). You will want to register and purchase your 340B inventory under the grant that gives you the broadest authority in terms of eligible patients. Registering under multiple designations could help prevent a gap in eligibility should you lose one of your 318 grants (or other 340B eligible grants); however, it will involve additional administrative and inventory management processes (e.g., multiple accounts to keep updated in OPAIS; multiple recertifications; ensuring inventory purchased under different 340B ID accounts are kept separate etc.).

Q: What if my site loses its 318 grant?

A: If a covered entity loses its 318 grant, it immediately should stop purchasing 340B drugs and submit a termination request in OPAIS. The covered entity will have to indicate the date and the circumstances under which it lost its grant (e.g., contract expired, site closure etc.) and the last date 340B drugs were purchased. The covered entity should contact the manufacturers of any remaining product to discuss how it should be handled. Some options may include transferring the inventory to another 340B qualified site (which may require HRSA's approval), credit/rebill, or the return or destruction of the product. Covered entities should keep auditable records of what was done with leftover 340B drugs.

Recertification

Q. What is the "recertification" process and do I have to recertify all of my 340B-qualified sites?

A: Every year, each covered entity is required to "recertify" eligibility and compliance with all 340B Program requirements. The "recertification" process requires the covered entity's Authorizing Official to do two things: (1) ensure that the information in the 340B covered entity database (OPAIS) and the Medicaid Exclusion File is accurate (***Note: changes to information in these databases should be updated on an ongoing basis, not just during recertification***), and (2) certify compliance with all 340B Program requirements. The Authorizing Official listed in OPAIS will receive a notification about the time period for the recertification process. Therefore, it is

essential that the individual designated as the "Authorizing Official" for each of your 340B eligible sites is accurate or updated if necessary before the recertification process begins.

Q: Who should I list as the Authorizing Official?
A: The Office of Pharmacy Affairs (OPA) defines an Authorizing Official (AO) as follows:
The Authorizing Official is someone who represents and confirms that they are fully authorized to legally bind the covered entity into a relationship with the Federal Government and has knowledge of the practices and eligible programs at that site. This would be the person responsible, and whom the Federal Government would reach out to, for requests of compliance, integrity evaluations, and audits. For many entities this is the grantee of record or the Clinic Director based upon Federal funding streams.

For sites qualifying for 340B through the CDC's PCHD Program (NOFO 19-1901), the Authorizing Official was typically someone from the state or local STD division or health department. This practice is no longer recommended for liability reasons. Instead, it is preferred that the "Authorizing Official" be someone who is employed by and can legally bind the site delivering health care services. For many covered entities, the Authorizing Official is usually the CEO, CFO, or COO.

Q: Who should I list as the Primary Contact (PC) and can it be the same person as the Authorizing Official?
A: The Primary Contact is a secondary point of contact for the covered entity. While the primary contact will receive information from HRSA, this person has no legal authority to bind the covered entity. The PC can help the AO update records in OPAIS as a part of recertification or as needed; however, only the AO can submit the changes to HRSA for approval or attest to the covered entity's compliance. The PC should be someone other than the AO.

Q: How should I prepare for recertification?
A: To prepare for the 340B recertification process, 318 grantees and subgrantees should check who is currently listed as the Authorizing Official for each site listed in the OPA Information System (OPAIS). If you want to change the name of the Authorizing Official, you must update the contact information in OPAIS with the new official's name and contact information prior to the beginning of the recertification period. Once the change has been approved by OPA, you may make additional changes to your records online and complete the recertification process.

Patient Eligibility and Prevention of Drug Diversion

Q: Which patients can get 340B priced drugs?
A: The 340B Program prohibits the sale or transfer of a drug purchased at the 340B discounted price to persons who are not "patients" of the covered entity – this is referred to as drug diversion. In other words, only "patients" as defined by guidance can receive 340B priced drugs. An individual is considered a "patient" of the covered

entity for the purposes of the 340B Program only if:

1. The covered entity maintains records of the individual's health care;
2. The individual receives health care services from a professional who is employed by or works under contract or other arrangement with the covered entity; and
3. The individual receives a service or range of services consistent with the grant funding that made the covered entity eligible for 340B discounted drugs.

An individual is not considered a "patient" if the ***only*** health care service 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. For 318 PCHD grantees, an individual must receive a healthcare service that is consistent with the scope of that grant. NCSD recommends that at a minimum, a patient should receive a sexual health history and review of STD risk factors at every visit. That patient should then receive any STD testing and treatment warranted, per CDC STD guidelines, from that sexual health history. For 318 EHE grantees, an individual must receive a health care service that is consistent with screening, preventing, or treating HIV or other STDs. For more information on the definition of a patient, see Federal Register Notice, "Patient and Entity Eligibility," October 24, 1996.

Q: Can I dispense 340B priced drugs to an individual who has private insurance?
A: Yes, payer status is not a determining factor for 340B patient eligibility. Regardless of an individual's insurance status (Medicaid, Medicare, private insurance, uninsured), an individual must meet the three-pronged 340B definition of a "patient" in order to be eligible to receive 340B drugs (see question above).

Q: May 340B covered entities fill prescriptions for their own employees?
A: Yes, but only if the employee meets the three-pronged 340B definition of a patient (see question above).

Q: For 318 grantees, does testing meet the patient definition requirement that a patient receive a service consistent with the grant funding?
A: Yes, testing would satisfy the patient definition health care services requirement. The patient must meet all of the other 340B patient requirements to receive 340B drugs (see question above).

Eligible Drugs

Q: Is a 318 grantee or subgrantee limited to using or prescribing drugs that address the services or range of services for which 318 grant funding was received?
A: The 340B Program does not limit the drugs a covered entity can purchase or prescribe; however, 340B drugs may only be given to individuals who are patients of the covered entity (an individual must meet the three-pronged 340B patient definition to be eligible for 340B drugs). Grantees and subgrantees should check their grants or contracts for any limitations on how grant funds may be used – for example, in some cases, grant funds may not be used to purchase 340B drugs, but other funds may be used to purchase them.

Q. May 340B drugs be used for refills?
A: Yes, as long as the refill(s) were prescribed as part of the health care service provided by the covered entity and documented along with the initial prescription for prevention or treatment in the patient's medical record. For example, a covered entity could dispense 340B priced PrEP or HSV medication (e.g., Zovirax, Famvir, and Valtrex) refills provided that the individual meets the 340B definition of a patient and the initial prescription and refills are documented in the patient's medical record. Please refer to your state law for any regulations regarding the refilling of prescriptions.

Q. Can physician/clinician-administered drugs, such as the Bicillin shot, be purchased at a 340B price?
A: Yes, physician/clinician-administered drugs may be purchased by covered entities at a 340B price, but they may only be dispensed to individuals meeting the 340B definition of a patient. A covered entity can participate in the 340B Program solely to purchase its physician/clinician administered drugs if it does not have an in-house pharmacy or contract pharmacy arrangement.

Q. May 340B drugs be used for individuals who are partners of patients being treated for an STD?
A: Yes. Medications prescribed for partners of 340B eligible patients being treated for an STD can be purchased at the 340B price because it is considered treatment for the underlying patient to prevent re-infection.

Q: Can I purchase vaccines at a 340B price?
A: Vaccines are not considered a covered outpatient drug and, therefore, are ineligible for 340B pricing. However, group purchasing organizations (GPOs), including Apexus' 340B Prime Vendor, are often able to negotiate a discounted rate for vaccines and other products outside of the 340B Program as a part of their contracted services. You should check with the 340B Prime Vendor or any other GPO you participate in to ask about discounted pricing on vaccines.

Q: Can I use a repackager for expedited partner therapy (EPT) or other drugs? If so, do I have to register the repackager as a 340B contract pharmacy?
A: A covered entity may use a repackager for 340B drugs, however, it is essential that you check your state pharmacy laws to ensure compliance with any requirements (for example -- some states require a licensed pharmacist or pharmacy to do the repackaging). You do not need to register the repackager as a contract pharmacy if: (1) the covered entity retains ownership and title to the 340B drugs; (2) the covered entity does not sell or transfer its 340B drugs to the repackager; and (3) the repackager does not dispense the 340B drugs. If the repackager will be dispensing, you should consult the 340B Prime Vendor for guidance regarding contract pharmacy registration requirements.

Q: Can you prescribe HIV prevention medications under STD/318 340B designation?
A: Yes. The 340B Program does not limit the drugs a covered entity can purchase or prescribe as long as they are given to individuals who meet the patient definition under the grant associated with the 340B designation (see question above). Routine

STD counseling and screening is consistent with prescribing practices for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) and would qualify the individual to receive PrEP or PEP at the 340B discounted price.

Q: Are PrEP injectables eligible for 340B discounts?

A: Yes, physician/clinician-administered drugs may be purchased by covered entities at a 340B price, but they may only be dispensed to individuals meeting the 340B definition of a patient (see question above). A covered entity can participate in the 340B program solely to order PrEP injectables under a physician's license for direct administration to patients onsite, even if it does not have an in-house or contract pharmacy.

Medicaid and Prevention of Duplicate Discounts

Q: Can I dispense 340B priced drugs to Medicaid patients covered under my state's Medicaid fee-for-service (FFS) program?

A: Yes, but under two conditions. First, the individual must meet the three-pronged 340B definition of a patient. Second, all Medicaid and National Provider Identifier (NPI) numbers used to bill Medicaid for 340B drugs must be listed on the Medicaid Exclusion File (MEF) maintained by the Office of Pharmacy Affairs (OPA). States use the MEF to identify which covered entities are billing Medicaid using 340B drugs (referred to as "carving-in"). When registering an entity for the 340B Program, you must indicate in OPAIS whether it will use 340B priced drugs with Medicaid FFS patients qualifying for 340B. According to OPA, this is an all-or-nothing selection – in other words, you cannot choose to use 340B priced drugs for some Medicaid patients and not for others. Most State Medicaid agencies check the MEF to prevent manufacturers from paying duplicate discounts – where a manufacturer gives a covered entity a discount on the drug upfront and then is asked by a state Medicaid agency to pay a rebate on the same unit of drug.

Q: My 340B covered entity sites are carving-in (using 340B drugs with Medicaid fee-for-service patients) and have entered all of the Medicaid and NPI billing numbers in the Medicaid Exclusion File. When can they begin dispensing 340B drugs to Medicaid beneficiaries?

A: The Medicaid Exclusion File allows drug manufacturers, wholesalers, and state Medicaid agencies to identify covered entities that have chosen to use 340B priced products with Medicaid beneficiaries covered under a state's FFS program (called carving-in) for a given calendar quarter. The 340B OPAIS takes a snapshot of carve-in and -out decisions at 12:01 a.m. ET on the 16th day of the month prior to the start of each quarter (regardless of weekends or holidays). Covered entities may request changes to their decision at any time, but changes take effect quarterly and only then if approved by OPA before the time of the snapshot. It is extremely important that the information in the Medicaid Exclusion File is accurate. 340B products should not be dispensed to Medicaid FFS patients until each covered entity's information (e.g., applicable Medicaid and NPI billing numbers) has been uploaded into the MEF.

Q: We do not bill Medicaid fee-for-service; however, we use 340B drugs for these patients. How should we answer the question in OPAIS: "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?"
A: In this case, you should answer "no" to the Medicaid billing question since you are not billing Medicaid for 340B products.

Q: Can I dispense 340B priced products to patients covered under Medicaid managed care plans?
A: Yes, but under two conditions. First, the individual must meet the three-pronged 340B definition of a patient (see above). Second, you must work with your state and its Medicaid managed care plans and pharmacy benefit managers to ensure that the state knows which claims include a 340B priced product (this is to prevent the state from collecting an unauthorized rebate on a 340B drug). CMS issued guidance for states addressing ways to prevent duplicate discounts under Medicaid managed care. Some states have successfully navigated this (e.g., requiring the use of modifier codes), while others have not (e.g., having no policy in place, incorrectly relying on the Medicaid Exclusion File which is only supposed to be for Medicaid FFS patients, or forcing providers to use or not use 340B with all Medicaid managed care patients). Covered entities should be prepared to advocate with their state or managed care organizations to prevent policies that infringe upon a 340B provider's right to use or not use 340B drugs with Medicaid patients as a means for the state to prevent duplicate discounts.

Q: If my covered entity only bills 340B drugs to Medicaid managed care organizations (MCOs), how should I answer the Medicaid billing question in OPAIS that is used for the Medicaid Exclusion File?
A: You should answer "no" to the Medicaid billing question in OPAIS because it only applies to drugs billed under Medicaid fee-for-service. However, if your state uses the Medicaid Exclusion File to identify 340B drugs billed to Medicaid MCOs or their PBMs, then you should contact Apexus/340B Prime Vendor at 1-888-340-2787 or apexusanswers@340bpvp.com for technical assistance.

Q: Do I have to bill Medicaid the amount I paid for the 340B drug (referred to as billing at "actual acquisition cost" or "invoice")?
A: In 2016, CMS changed the rules regarding how Medicaid fee-for-service programs must reimburse providers for both 340B and non-340B drugs. The Final Rule requires Medicaid payment for a drug to be consistent with a state's determination of what it costs providers to acquire the product (referred to as "actual acquisition cost"). States have some flexibility in determining this amount for non-340B providers, which can be based on national or regional surveys of prices paid by retail community pharmacies or some other pricing benchmark. However, for 340B drugs, CMS is defines AAC as a provider's true acquisition cost (invoice amount) or the 340B ceiling price. You should check your state's policy regarding billing Medicaid for 340B products. *It is important to note that the AAC reimbursement limitation in CMS's Final Rule does not apply to physician/clinician administered drugs (See Q7 in CMS Guidance) or 340B drugs billed to Medicaid managed care plans or their pharmacy benefit managers; however, you should consult your state's policies or managed care contracts as many have adopted AAC or invoice reimbursement in those situations as well.*

Inventory Management

Q: Do I have to maintain a separate inventory of drugs purchased under the 340B Program to show that there is no diversion (meaning 340B drugs are sold or given to individuals who do not meet the 340B definition of patient)?
A: HRSA does not require separate physical inventories for 340B drugs. However, covered entities must have fully auditable purchasing and dispensing records that document compliance with all 340B requirements including the prohibition on drug diversion and duplicate discounts. Covered entities should also check with their state's board of pharmacy to determine if there are any state requirements regarding separate inventories.

Q. What do I need to do if one of my sites loses 340B eligibility? Can I still use leftover 340B drugs at that site or move it to another that still qualifies for 340B?
A: If you have a site that loses eligibility for 340B, you must notify HRSA by submitting a termination request. See HRSA's OPAIS User Guide for step-by-step instructions. You may not use any remaining 340B drugs at that site as of the date it lost eligibility or transfer the 340B inventory to another 340B qualified site without approval from HRSA. In general, HRSA does not allow the transfer of 340B inventory between (or within) sites with unique 340B identifiers. You should contact the manufacturers of any remaining product for guidance on how to handle leftover 340B inventory.

Q. Can I transfer 340B purchased inventory between my 340B qualified sites?
A. Each covered entity with a 340B ID is considered a separate entity for purposes of the 340B Program. HRSA assigns 340B IDs in order for stakeholders to confirm eligibility and appropriate shipment of 340B drugs. HRSA does not allow the sharing of 340B inventory across 340B IDs unless first approved by HRSA. HRSA will consider approval of inventory sharing between unique 340B IDs on a case-by-case basis. Grantees may submit a written request to HRSA to purchase 340B inventory through one account and distribute the inventory to multiple 340B IDs operating under the same federal grant (this is referred to as a "Grantee Combined Purchasing and Distribution Request").

Q: Can I transfer 340B drugs to a site that is listed as a ship-to-address, but is not registered as a covered entity?
A: Yes, you can transfer 340B inventory to a shipping address that is associated with the covered entity, but that does not make that location eligible to use 340B drugs for any individuals receiving services there.

Compliance and Audits

Q. What if I discover that there has been drug diversion or instances of duplicate discounts at one of my 340B qualified sites?
A: You must notify impacted manufacturers if noncompliance is discovered during an internal audit or through some other means and try to resolve the issues directly with them. In addition, covered entities must notify HRSA in writing regarding any instances of a "material breach" of 340B Program requirements. Apexus, HRSA's

contractor to provide technical assistance, provides examples of how a covered entity can define a "material breach" triggering HRSA's self-disclosure requirements. Self disclosures should be submitted to: 340bselfdisclosure@hrsa.gov. Covered entities should have policies and procedures in place addressing when HRSA must be notified of non-compliance.

Q. I received a notice from HRSA's Office of Pharmacy Affairs that my site is being audited. How do I prepare for this?
A: Since 2012, the Office of Pharmacy Affairs (OPA) has been conducting routine audits of 340B covered entities. These audits are part of the agency's attempts to improve its oversight of the Program as required under the Affordable Care Act. Each year, OPA has increased the number of audits for all covered entity types. Audit findings can be found here. The audits focus primarily on covered entity eligibility and prevention of duplicate discounts and drug diversion. OPA has recommended that covered entities have stand-alone policies and procedures that address 340B compliance. Sample policies and procedures for 318 grantees and subgrantees can be found here. Additional resources to prepare for an audit can be found here.

Contract Pharmacy

Q. What is a 340B contract pharmacy?
A: A 340B contract pharmacy is a contractual arrangement between a covered entity and a pharmacy (or multiple pharmacies) to distribute drugs to the covered entity's 340B eligible patients. Covered entities must register each contract pharmacy location in OPAIS, which can be done during the first two weeks of every quarter. Once approved by HRSA and listed in OPAIS, 340B drugs can be dispensed by the contract pharmacy to eligible patients at the beginning of the subsequent quarter. These arrangements are highly regulated, so it is essential that you look into the legal requirements before entering into any such contracts. More information on contract pharmacies can be found here.

Q: Do I have to have contracts with pharmacies to dispense 340B drugs?
A: No, covered entities choose how they will provide 340B pharmacy services to patients, subject to federal and state laws. Options may include providing in-house pharmacy dispensing services, administering drugs directly to patients, and/or contracting with retail or mail-order pharmacies.

Q: How would this type of arrangement benefit my health care delivery sites and patients?
A: 340B contract pharmacy arrangements may facilitate 340B participation for covered entities that are subject to restrictive state pharmacy dispensing laws, do not have in-clinic pharmacy capacity, or for those that want to supplement their in-clinic pharmacy services.

Q: Can 340B drugs be dispensed to Medicaid patients through a contract pharmacy?
A: 340B drugs may not be dispensed to Medicaid fee-for-service patients at a contract pharmacy unless an arrangement has been made between the state Medicaid agency, covered entity, and contract pharmacy to prevent duplicate

discounts. The covered entity must submit any such arrangement to HRSA's Office of Pharmacy Affairs for approval. HRSA will post approved arrangements in OPAIS. Although 340B drugs may be dispensed by contract pharmacies to Medicaid managed care patients, the covered entity must work with its Medicaid managed care organizations and pharmacy benefit managers to ensure the state knows when a 340B drug is dispensed so that it does not request an unauthorized rebate on that unit of drug.

Q: What is a ship-to bill-to arrangement?
A: This is an arrangement where a covered entity is billed and retains ownership for 340B product, but it is shipped by a manufacturer or wholesaler directly to a contract pharmacy which stores and then dispenses it to the covered entity's 340B eligible patients. A shipping address cannot be a P.O. Box.

Q: Do I have to register my in-house pharmacy as a contract pharmacy?
A: Not if the in-house pharmacy is owned and legally a part of the covered entity. In this case, the in-house pharmacy may be listed as a shipping address of the covered entity if it is in a different location than the address of the covered entity. If, however, the in-house pharmacy is a separate legal entity, it must be registered as a contract pharmacy and may not dispense 340B drugs until a written contract is in place and it has been listed in OPAIS.

Q: What kind of oversight of contract pharmacy arrangements does HRSA require?
A: Covered entities are responsible for ensuring that the contract pharmacy complies with all 340B requirements, including registration, maintenance of auditable records, and the prevention of diversion and duplicate discounts. The covered entity must have a contract with the pharmacy that addresses 340B requirements before registering the contract pharmacy in OPAIS. HRSA recommends that a covered entity hire an independent organization to perform annual audits of contract pharmacies and develop policies and procedures describing contract pharmacy compliance. More information on contract pharmacies can be found here.

About NCSD

National Coalition of STD Directors is a national organization representing health department STD directors, their support staff, and community-based organizations across 50 states, seven large cities, and eight US territories. NCSD advances effective STD prevention programs and services in every community across the country.

Contact

For more information or questions, please contact Stephanie Arnold Pang at sarnold@ncsddc.org.