340B Drug Pricing Program: Participation, Eligibility and Program Integrity
HOSPITALS
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Healthcare Systems Bureau
Office of Pharmacy Affairs
340B Program: Overview and Benefits

• Provides discounts on outpatient drugs to certain safety-net covered entities

• Average savings of 25-50%

Savings may be used to:

- Reduce price of pharmaceuticals for patients
- Expand services offered to patients
- Provide services to more patients

• Estimated 7 billion dollars in 340B drug purchases last year

• Manufacturers that participate in Medicaid must also participate in the 340B Program
Permits eligible safety net providers “to stretch scarce Federal Resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

340B Database

- Entities are not eligible for the program unless listed in the 340B database with an active ID
- The 340B Database is the primary source for Covered entities/Manufacturers/Wholesaler/OPA
- Each clinic/site must have a specific 340B ID
- Wholesalers will not ship discounted drugs unless it is an exact match to the 340B database
- Information is updated daily
- Includes the Medicaid Exclusion File
- Online registration available for all applicants
Program Integrity

Program integrity performed through 4 primary routes

• Enhanced initial Registration/Certification
• Annual Recertification
• Program Audits
• Self Disclosures and Reported Compliance allegations
Recertification

- Required by Statute (PHS Act/ACA)
- Ensure program integrity, compliance, transparency and accountability
- Ensure accuracy of covered entity information in the 340B database
- It is the covered entity’s responsibility to ensure the accuracy of the information in the 340B database
- Ensure the accuracy of the Contract pharmacies listed in the database
- Recertification is the primary mechanism for annually capturing covered entities updated information
2014/Current 340B Program Recertification Process all Covered Entities

- Covered Entity (Self Certifies Participation)
- OPA completes recertification
Changes to recertification

- All entities with an active 340B ID and without a future termination date are required to recertify on the listed start date.

- Move to local level Recertification by having the listed Authorizing Official (AO) for the parent hospital perform recertification for the parent and all child sites.

- Verifications can be cross referenced via CMS data.

- Determination of Whom should be listed or continue to be listed as the Authorizing Official based upon “C” Suite requirements.
• Keys to successful recertification?
  ➢ Verify contact information is up to date in the 340B Program database prior to recertification
  ➢ Submit 340B Program change form to update entity information prior to recertification [http://opanet.hrsa.gov/op/CRPublicSearch.aspx](http://opanet.hrsa.gov/op/CRPublicSearch.aspx)
  ➢ Monitor 340B Program webpage and your email prior to recertification
  ➢ Do not mistake submission of a 340B change form for performing recertification
  ➢ Review Recertification Users Guide (updates directly prior to recertification initiation)

1. Ensure all information in 340B Database is accurate and prepared for recertification via online change request forms or paper forms as necessary. 

2. All Entities currently listed in the database will be required to recertify Annually no matter the length of time of listed participation (except those sites with a pending termination date).

3. An Email with user name and Password will “only” be emailed to the Authorizing Official listed for the parent covered entity. Advanced notification and all general communications will be sent to the Primary Contact Also

4. Authorizing Official for the Parent will be required to recertify for Parent and all Outpatient Facilities/satellite sites/sub-grantees/sub-contractors and contract pharmacies associated with the covered entity.
5. The Authorizing Official will be required to certify and update any information that is not complete. As the database has progressed throughout time, more requirements have been added and additional information may be required to be entered by Authorizing Official.

6. Once Authorizing Official has completed any additional program updates they will “Certify” that their information is true, accurate, and that the covered entity will be in compliance with all program requirements through the Attestation language.

7. HRSA/OPA will review certifications and determine to Accept All, Accept Partial, Reject All proposed changes to the database.

8. HRSA/OPA will Recertify or Decertify the Covered Entity.

9. The Authorizing Official (unless changes during the process) will receive a completion notification and will have the ability to review the Covered Entities history tab for recertification completion.
Covered Entity Attestation

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. Failure to recertify may be grounds for removal from the 340B Program.

The undersigned further acknowledges the 340B covered entity’s responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity that:

(1) all information listed on the 340B Program database for the covered entity is complete, accurate, and correct;
(2) the covered entity meets all 340B Program eligibility requirements, including (if applicable) section 340B(a)(4)(L)(iii) and the Statutory Prohibition on Group Purchasing Organization Participation Policy Release 2013-1, which ensures that the covered entity hospital does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement

(3) the covered entity is complying with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;

(4) the covered entity maintains auditable records demonstrating compliance with the requirements described above;

(5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described above;
(6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);

(7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and

(8) the covered entity acknowledges that if there is a breach of the requirements described above that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.
• The recertification process is a time for attestation to compliance, verification or update of covered entity data

• The next series of slides are reminders of common lessons learned and helpful hints for recertification above the initial steps to insuring your Authorizing Official and Primary Contact information is correct.

• OPA welcomes comments/recommendations on how to make the process more user friendly for all interested participants.
1. It is highly recommended that entities print off the recertification user guide for assistance in performing recertification, (updated quarterly prior to recertification and sent as part of the user name/password email template) http://opanet.hrsa.gov/OPA/Manuals/OPA%20Database%20Guide%20for%20Public%20Users%20-%20Recertification.pdf

2. When communicating with HRSA with questions of any nature- please add your covered entities 340B ID or answers to your questions will be delayed or returned

3. It is recommended that the Authorizing Official and Primary Contact person be two separate personnel. This allows for maximum communication in the case where those entities may have one person leave their position prior to recertification, preventing an entity from losing communication channels to HRSA OPA

4. Pharmacies are not authorized to have their own unique 340B ID.

5. Work with HRSA OPA to determine best suited Authorizing Official based upon grantee structure to include subgrantees
6. PO Boxes are only authorized for an entity’s billing address. PO Boxes listed via the Main Address or Shipping Address shall be removed during hospital recertification.

7. If an entity determines a site requires decertification—please be prepared to answer the following questions:
   
   A. The date that the reason for termination was effective;
   
   B. A brief description of the facts surrounding the reason for termination and how the effective date was determined; and
   
   C. The last day that 340B drugs were or will be purchased under the 340B ID

8. Entities will not be able to view changes in the general database until OPA has signed off on the entity’s recertification. This can be determined by viewing the dates tab (if recertified the recertification tab will hold a date of the first day of the next quarter) and history tab (will show exact date and time of HRSA OPA sign off).
10. Entities will be given a minimum of four weeks to perform recertification, failure to perform recertification during this period will result in removal from the program.

11. Entities that wait until the last days of recertification eligibility may receive reduced technical assistance.

12. Once a covered entity selects to recertify all of its sites, the entity will lose the ability to log in and adjust its record.

13. User names and passwords from an entity's last recertification are no longer valid and a new user name and password will be distributed with each recertification cycle. Once an entity has completed its portion of recertification the user name and password become a viewing only function and expire after 90 days.
14. Entities who have completed recertification and made an error or forgotten to add necessary updates should not submit additional change requests until the entities recertification has been signed off by HRSA OPA.

15. User name and Passwords are sent from 340b.recertification@hrsa.gov and HRSA@public.govdelivery.com please verify your spam filters are set to allow communication from this address

16. Once recertification has started only change requests for Authorizing Officials shall be processed. This allows HRSA OPA to get the newly listed Authorizing Official a user name and password to perform recertification in which the new Authorizing Official will be required to add their updated information.

17. Addition of a new field to collect Employer ID
Prime Vendor Program (PVP)

- No cost to participate
- Drug price negotiation services
  - Discounts on over 3500 covered drugs
  - Discounts average 15% below 340B ceiling prices
- Multiple wholesale distributor agreements
- Favorable discounts on other pharmacy related products/service
340B Resources

Office of Pharmacy Affairs (OPA)
Phone: 301-594-4353 or 1-800-628-6297
Web:  http://www.hrsa.gov/opa
      http://www.hrsa.gov/patientsafety
      340b.recertification@hrsa.gov

Prime Vendor Program (PVP)
Phone: 1-888-340-2787
Web:  http://www.340bpvp.com
ApexusAnswers@340bpvp.com
(PVP is primary resource for technical assistance of the 340b program recertification)
Questions?