340B Drug Pricing Program: Participation, Eligibility and Program Integrity

Hospitals

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Overview

• 340B Program
• Program Integrity
• Recertification
• Resources
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

- Manufacturers that participate in Medicaid must also participate in the 340B Program
Intent of 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.”

• Entities are not eligible for the 340B Program unless listed in the 340B database
• The 340B Database is the primary record for Covered entities/Manufacturers/Wholesaler/OPA
• Each hospital/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
• Online registration available for all applicants
• [URL: http://opanet.hrsa.gov/opa/default.aspx]
Program Integrity

Program integrity performed through five primary routes:

- Enhanced initial Registration
- Annual Recertification
- Program Audits
- Self Disclosures and allegations
- Bureau Site Visit Questionnaire
Recertification

- Required by Statute (PHS Act/ACA) for all entity types
- 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 information in the 340B database
- Ensure the accuracy of the Contract pharmacies listed in the database
Who can or should be listed as the Authorizing Official?

• The AO is someone who is 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 the Federal Government turns to at the entity about compliance, integrity evaluations, and HRSA audits.

• For hospitals, it is required that someone at the CEO/CFO/President/Vice President level perform this role.
340B Recertification Keys

Keys to successful recertification
• Verify contact information is up to date in the 340B Program database prior to recertification
• Submit 340B Program online change requests to update entity information prior to recertification
http://opanet.hrsa.gov/opa/CRPublicSearch.aspx
• Monitor 340B Program webpage and your email prior to recertification
• Do not mistake submission of a 340B online change request for performing recertification
• Review recertification Users Guide (updates prior to the start of recertification and contained in the advanced notification)
340B Recertification Steps

1. Ensure all information in 340B database is accurate and if needed, make changes prior to recertification via http://opanet.hrsa.gov/opa/CRPublicSearch.aspx

2. All entities currently listed in the 340B database will be required to recertify annually (except those sites with a pending termination date)

3. An email with the user name and password will “only” be emailed to the AO listed for the covered entity. Advanced notification and all general communications will also be sent to the Primary Contact

4. The AO is required to recertify the covered entity and verify contract pharmacy information associated with the covered entity is accurate
5. Once the AO has completed all program updates they will “Certify” the information is true, accurate, and the covered entity will be in compliance with all program requirements.

6. HRSA/OPA will review certifications and determine to accept All, accept partial, or reject all proposed changes to the database.

7. HRSA/OPA will recertify or decertify the covered entity.

8. The AO (unless changed during the process) will receive a completion email notification and have the ability to review the covered entities history tab for recertification completion.
Recertification Steps cont.

• When recertifying qualifying data such as DSH % and cost reporting period, the most recently filed Medicare Cost Report (MCR) should be used.

• Once qualifying data is certified for the parent, all child sites are automatically updated.

• If a mistake is made entering qualifying data, you will be required to submit your most recently filed MCR to OPA for review.

• It is highly recommended to have your MCR available during recertification to ensure accuracy of qualifying data.
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 Authorizing Official, I certify on behalf of the covered entity that:

(1) all information listed in the 340B Program database for the covered entity is complete, accurate, and correct;

(2) the covered entity meets 340B Program eligibility requirements;

(3) the covered entity will comply with all requirements of Section 340B of the Public Health Service Act and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion (section 340B(a)(5)(A) and (B) of the Public Health Service Act;
(4) the covered entity maintains auditable records pertaining to compliance with the requirements described in paragraph (3) above, pursuant to section 340B(a)(5)(C) of the Public Health Service Act;

(5) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines;
(6) the covered entity acknowledges its responsibility to contact OPA as soon as possible if there is any change in 340B eligibility and/or breach by the covered entity of any of the foregoing; and

(7) the covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) 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 removal from the list of eligible 340B entities.
Recertification Lessons Learned/Helpful

• The purpose of recertification is to verify and update covered entity information and attest to compliance.

• PO Boxes are only authorized for an entity’s billing address. PO Boxes listed in the Main Address or Shipping Address will be removed during hospital recertification.

• It is highly recommended that entities print the recertification user guide for assistance. (contained within the advanced notification)

Recertification Lessons
Learned/Helpful Hints Continued

• When communicating with HRSA/Apexus for questions of any nature- please provide your covered entity’s 340B ID or answers to your questions will be delayed or returned.

• It is recommended that the AO and Primary Contact be two separate personnel

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

• Entities will not be able to view changes in the general database until OPA has signed off on the entity’s recertification. Entities will be given roughly four weeks to perform recertification; failure to perform recertification during this period will result in removal from the program
Recertification Lessons Learned/Helpful Hints Continued

- Entities that wait until the last days of recertification may experience delays in technical assistance.
- Once a covered entity selects to certify all of its sites, the entity will lose the ability to log in and adjust its record.
- Use only the latest username and password to log into the entity’s record.
- Usernames and Passwords are sent from 340b.recertification@hrsa.gov, please verify your spam filters are set to allow communication from this address.
• Once recertification has started, only change requests for AO’s shall be processed.

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

Prime Vendor Program (PVP)

- Primary resource for 340B Program information and technical assistance.
- No cost to participate
- Drug price negotiation services
- Multiple wholesale distributor agreements
- Favorable discounts on other pharmacy related products/service
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

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?
Contact Information

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