

Orphan Drug Exclusion:

340B hospitals subject to the orphan drug exclusion (i.e., critical access hospitals,

free-standing cancer hospitals, sole community hospitals and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act. Please choose one of the following:

- I. The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.
- II. The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drugs exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used and will not use a Group Purchasing Organization (GPO) to purchase those drugs if the hospital is a free-standing cancer hospital.

Certify Decertify Cancel



Authorizing Official

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Make Primary Contact Information same as Authorizing Official

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HHS Privacy Policy Notice

I.S. Department of Health and Human Services (HHS) lealth Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) - 340B Program

April 30, 2012 3:31 PM ET Questions, Comments, or Suggestions Email Us: ask@hrsa.gov Call Us: 1 - 800 - 628 - 6297

Edit

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 section 340B(a)(4)(L)(iii) if applicable the Group Purchasing Organization prohibition 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; The covered entity will comply 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, the prohibition against transferring drugspurchased under 340B to anyone other than a patient of the entity, and the exclusion of orphan drugs for critical access hospitals, sole community hospitals and rural referral centers.
- (4) the covered entity maintains auditable records demonstrating compliance with the requirements described in paragraph (3) above;
- (5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described in (3) 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 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 the payment of interest and/or removal from the list of eligible 340B entities.

Signature of Authorizing Official:	Date: