

340B Drug Pricing Program Orphan Drug Exclusion Final Rule

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Health Resources and Services Administration
Healthcare Systems Bureau
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August 8, 2013



Legislative History

- Section 2302 of the Health Care and Education Reconciliation Act excluded from the definition of covered outpatient drug those drugs used for a rare disease or condition designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (Orphan Drug exclusion).
- Section 340B(e) of the Public Health Service Act
- Only applies to Free-standing Cancer Hospitals, Rural Referral Centers, Sole Community Hospitals, and Critical Access Hospitals
- Notice of Proposed Rulemaking: Published May 20, 2011 – public comments received
- Final Rule: Published July 23, 2013
- Final rule effective October 1, 2013



Purpose of the Orphan Rule

- Details how the orphan drug exclusion will be implemented
- Provide clarity in the marketplace
- Maintain the 340B savings and interests of the newly eligible covered entities
- Protect financial interests of orphan drug manufacturers
- Clarify the orphan drug exclusion is consistent with the FDA's interpretation and oversight of the FFDCA.



Who does the rule apply to?

- Critical Access Hospitals
- Free-standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals



What is an Orphan Drug?

- A drug is designated by the FDA as “a drug for a rare disease or condition” pursuant to section 526 of the FDCA at the request of the sponsor, if FDA finds that the drug is being or will be investigated for a rare disease or condition
- If approved by FDA, the approval will be for that disease or condition. 21 U.S.C. 360bb(a)(1).
- The orphan drug designation provides a number of incentives for the development of the orphan drug for the particular disease or condition.



What orphan drugs are excluded?

- The orphan drug rule excludes from the 340B Program those drugs when used for the indication for which they received an orphan designation but not when the drug is used for indications independent of that designation.
- The 340B Program will publish on its public web site FDA's section 526 list of drugs as of the first day of the last month of each quarter, to govern purchases beginning on the first day of the following quarter.

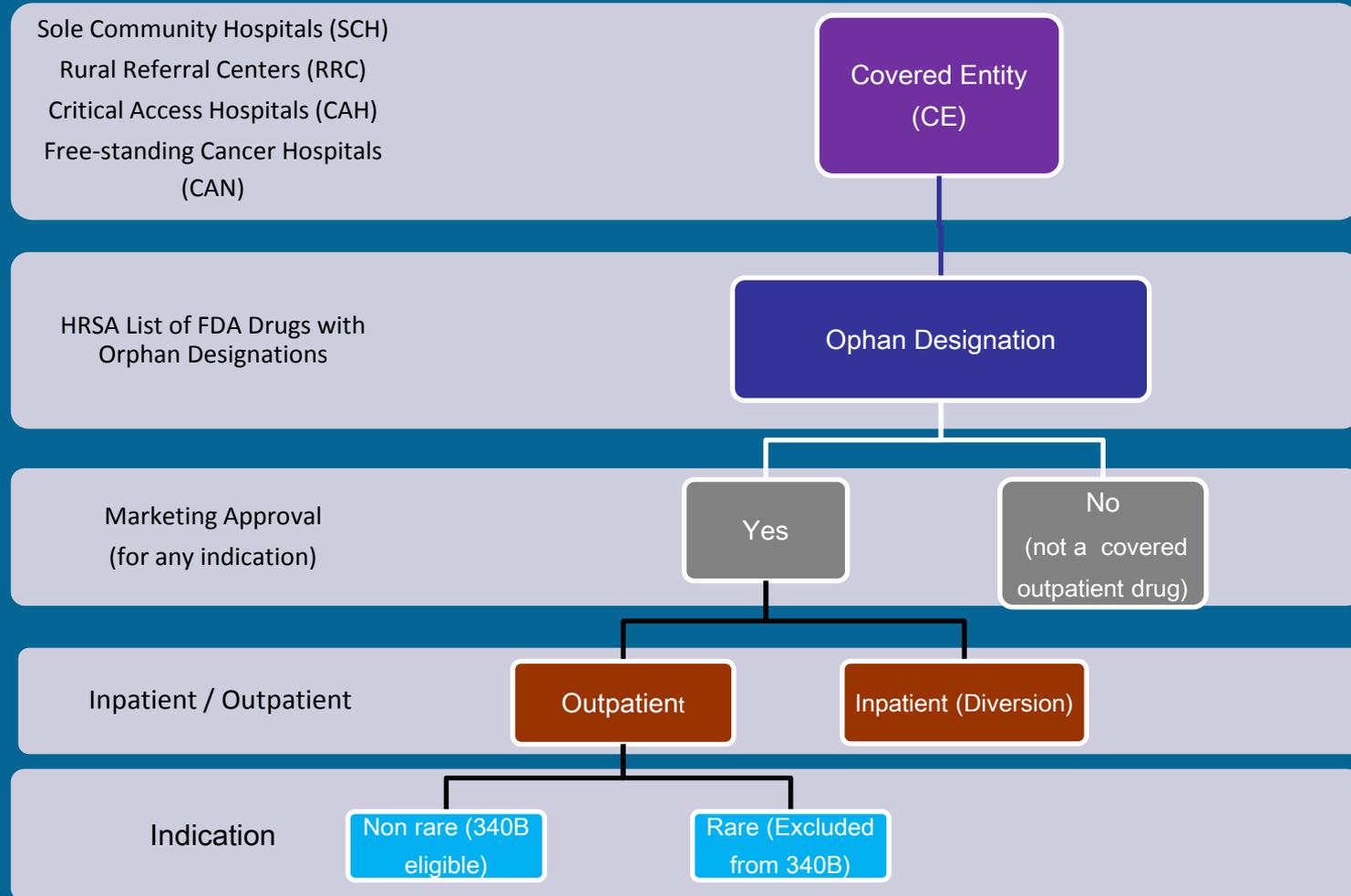


Covered Outpatient Drug

- A covered outpatient drug does not include orphan drugs that are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated under section 526 of the FFDCA.



Application of Exclusion



Opt in OR Opt out

- Covered entities (parent and child sites) are required to inform HRSA if they will opt in or opt out.
 - Opt In: The hospital will purchase orphan drugs under the 340B Program, can track by indication and will maintain auditable records to demonstrate compliance
 - Opt Out: The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drug exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used
- Manufacturers and wholesalers will be able to download current and archived quarterly opt-in/out files from the 340B database.



Example

HRSA is revising the example and will provide updated slides as soon as possible.



Group Purchasing Organization (GPO)

- An enrolled critical access hospital, rural referral center, or sole community hospital is not subject to the GPO Prohibition
 - These types of entities can use a GPO to purchase an orphan drug whether or not it is used for a rare disease or condition
- A free-standing cancer hospital must still comply with the prohibition against using a GPO for covered outpatient drugs.
 - When an orphan drug is used for the rare condition or disease for which that orphan drug was designated, it is not considered a covered outpatient drug for purposes of the 340B Program.
 - Therefore, a free-standing cancer hospital could use a GPO when an orphan drug is used for a rare disease or condition if it is able to track by indication, as these drugs are not considered covered outpatient drugs and the GPO prohibition only applies to covered outpatient drugs.

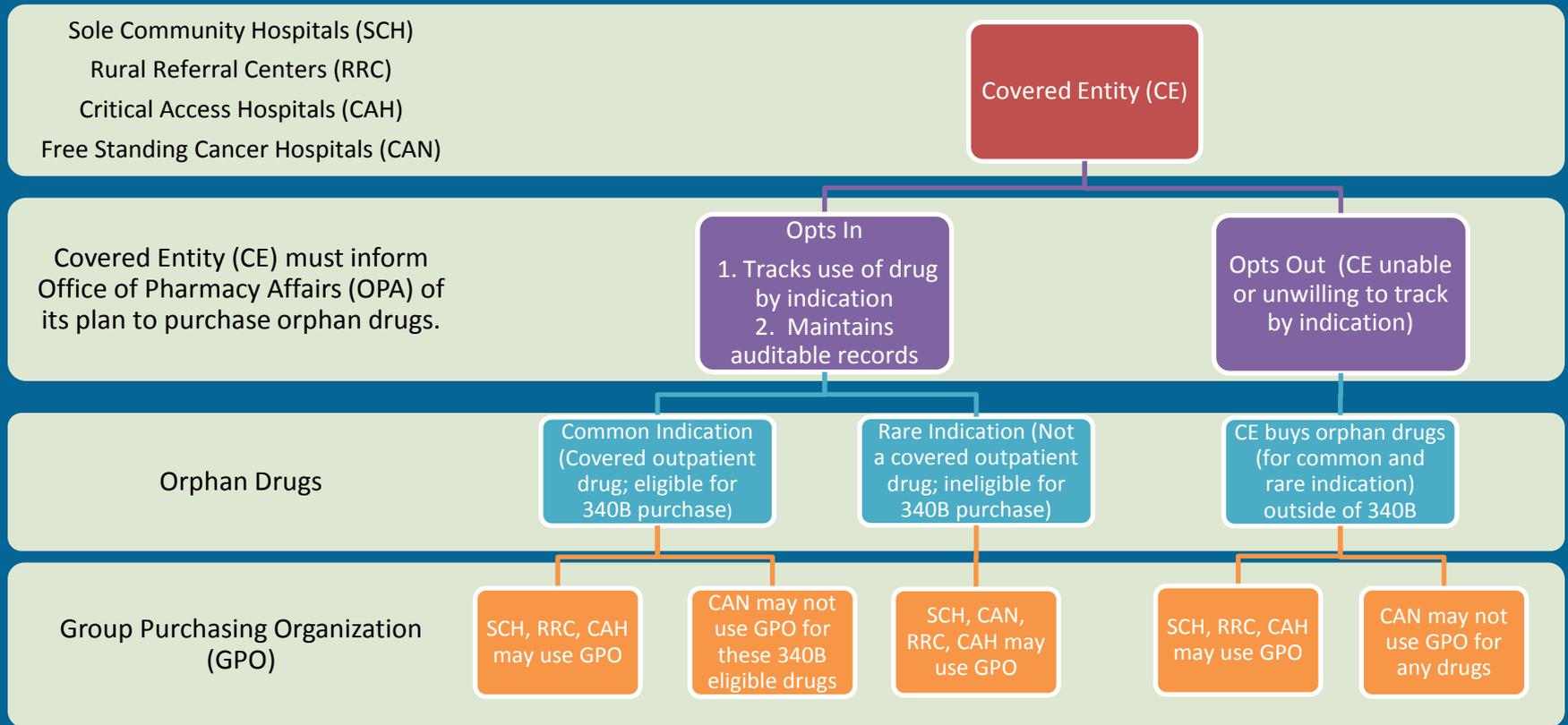


GPO cont'd

- When an orphan drug is used for a non-rare condition or disease, it is considered a covered outpatient drug and a free-standing cancer hospital cannot use a GPO.
- If the free-standing cancer hospital is unable to track by indication, it would not be able to demonstrate the difference between when an orphan drug is used for a rare disease or condition as compared to a non-rare disease or condition.
- Therefore, a free-standing cancer hospital that cannot track by indication must purchase all orphan drugs, regardless of indication, outside of the 340B Program and it is not permitted to use a GPO to purchase those orphan drugs because the hospital would be purchasing orphan drugs that are considered outpatient drugs through a GPO.



Options by Covered Entity Type



Registration, Annual Recertification, Change Request

- Covered entities (parent and child sites) are required to inform HRSA if they will opt in or opt out.
- Covered entity hospitals currently in the 340B Program will be required to inform HRSA during annual recertification (August 19) whether they will opt in or opt out in order complete recertification.
- Entities that newly register beginning October 1 must inform HRSA upon registration whether they will opt in or opt out.
- Covered entities may revise their selection at any time via an online change request in the 340B Program database; changes will be effective on the first day of the quarter following approval by OPA.



Form Language

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:

- The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.
- The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drug 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.



Records Requirement

- Covered entities for which this rule applies and that elect to purchase orphan drugs at 340B prices are required to keep auditable records to show the indication for which those drugs were ultimately used.
- Covered entities must provide those records upon HRSA's request or upon a government-approved manufacturer audit request that directly pertains to compliance with section 340B(e) of the PHSA.



Compliance

- Failure to comply will be considered diversion
- Entities (parent and child sites) must attest upon registration and on an annual basis that they are able to comply with the orphan drug exclusion
- HRSA will audit compliance with the orphan drug exclusion including a review of the covered entity's auditable records
- Manufacturers can audit a covered entity for compliance with the orphan drug exclusion
- Manufacturers cannot condition the offer of the 340B discount upon entity's assurance of compliance



340B Resources

HRSA's 340B Prime Vendor Program (PVP)

- Contract with Apexus
- Offer free call center and technical assistance
- www.340bpvp.com
- ApexusAnswers@340bpvp.com
- 340B University – educational opportunity
- Drug price negotiation services
- Multiple wholesale distributor agreements
- Favorable discounts on other pharmacy related products/service



Contact Information

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