340B Drug Pricing Program

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Orphan Drugs Exclusion

On May 23, 2014, the U.S. District Court for the District of Columbia issued a ruling in Pharmaceutical Research and Manufacturers of America v. US Department of Health and Human Services (HHS) (Civil Action No. 13-1501) that vacated the orphan drug regulation on the grounds that HHS lacks the statutory authority to engage in such rulemaking. However, the Court did not invalidate HRSA's interpretation of the statute. HHS/HRSA continues to stand by the interpretation described in its published final rule, which allows the 340B covered entities affected by the orphan drug exclusion to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation. HRSA is continuing to post updated Orphan Drug Designation Lists, found below, as well as the Orphan Selection File, found on the 340B database, in order to assist all 340B stakeholders in complying with HRSA's policy.

340B hospitals subject to the orphan drug exclusion (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.

Orphan Drug Final Rule (PDF - 266 KB) *07/23/2013*

Orphan Drug FAQs

Orphan Drug webinar slides (PDF - 205 KB) *08/08/2013*

Orphan Drug Designation List

The following Orphan Drug Designation List was updated and developed using the methodology referenced below and should be used to govern the quarter July 1 – September 30, 2014 (see "About the Orphan Drug List").

Orphan Drug List Governing July 1 - September 30, 2014 spreadsheet (XLS - 250 KB)

Orphan Drug List Governing July 1 - September 30, 2014 (PDF - 1,596 KB)

Archived List

Archived Orphan Drug List Governing April 1 - June 30, 2014 spreadsheet (XLS - 241 KB)

Program Integrity

340B Drug Pricing Program covered entities must ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements.

Covered entities are subject to audit by manufacturers or the federal government. Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts obtained.

Learn more: **Program Integrity**

Archived Orphan Drug List Governing April 1 - June 30, 2014 (PDF - 823 KB)

Archived Orphan Drug List Governing January 1 - March 31, 2014 spreadsheet (XLS - 229 KB)

Archived Orphan Drug List Governing January 1 - March 31, 2014 (PDF - 786 KB)

About the Orphan Drug List

The list is developed by HRSA and updated quarterly. It is based upon specific fields captured from the list of orphan drug designations provided by the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD). The list posted should be the source used by 340B stakeholders to ensure compliance with the orphan drug exclusion. Covered entities may need to conduct additional analyses of the drugs provided on this list to determine the appropriate orphan drugs to exclude from the 340B Program.

HRSA recognizes that orphan drug designation sponsors listed on the FDA orphan drug list may not be the current manufacturer for an orphan drug. The sponsor listed reflects the latest information reported by the sponsor to the FDA OOPD. HRSA encourages 340B stakeholders to work, in good faith, to resolve any potential disputes that may result from the use of this list. HRSA will continue to improve the list that is posted on a quarterly basis to ensure covered entities have the information they need to comply with the orphan drug exclusion.

HRSA uses the following methodology to develop the list:

- Source: FDA OOPD list of orphan drugs
- Search Results: All designations
- Output Format: Download Excel File
- HRSA only included orphan drugs with a status of “Designated” and “Designated/Approved.”
- HRSA only used the following fields: row number, generic name, trade name, designation date, orphan designation, contact company/sponsor.

Orphan Drug Selection File

The 340B program database allows drug manufacturers and wholesalers to identify affected hospitals that will purchase orphan drugs under the 340B Program and will maintain auditable records to demonstrate compliance with the orphan drug exclusion (Orphan Drug Participation = Yes), or that cannot or do 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 (Orphan Drug Participation = No).

The database takes a snapshot of affected hospitals’ elections at 12:01am ET on the 15th day of the month prior to the start of each calendar quarter, irrespective of weekends or holidays. Covered entities may request changes to their election at any time but changes take effect quarterly and only then if approved by OPA before the time of the snapshot.

To access current or past quarters’ files, follow the ‘Download Orphan Drug Selection File’ link from the database home page.