

Covered Entities Guide for Public Users

Downloading the Orphan Drug Selection File

This guide describes how to download and review the **Orphan Drug Selection File**. This file page enables drug manufacturers and wholesalers to identify which hospitals will purchase orphan drugs under the 340B program.

Hospitals subject to the orphan drug exclusion are:

- Free Standing Cancer (CAN)
- Critical Access (CAH)
- Sole Community (SCH)
- Rural Referral Centers (RRC)

Eligible 340B hospitals are responsible for ensuring that orphan drugs purchased through the 340B program are not sold, transferred or used for the rare condition or disease for which the orphan drugs are designated.

To download the **Orphan Drug Selection File**, follow these steps:

- 1) Click **Covered Entities** in the menu bar to see the **Download Orphan Drug Selection File** option and select, or click **Download Orphan Drug Selection File** option in the **Covered Entities** section of the home page.

The **Download Orphan Drug Selection File** page displays.

Download Orphan Drug Selection File

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.

The files available below allow 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 340B 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.

Prior quarters' files will remain available for future use.

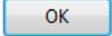
For purchases made during the selected quarter:

04/01/2014 - 06/30/2014
 04/01/2014 - 06/30/2014
 01/01/2014 - 03/31/2014
 10/01/2013 - 12/31/2013

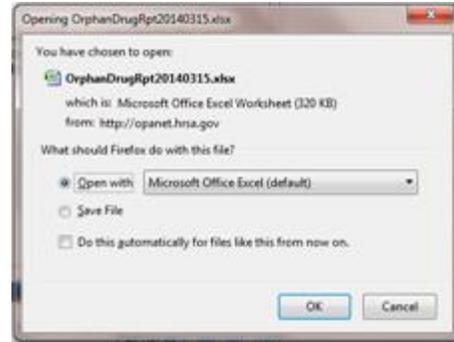
2) Select the quarterly time period in which the drug purchases were made.

3) Click .

- 4) When the dialog box opens asking if you want to open the report with an Excel spreadsheet, click



The **Orphan Drug Report** for the quarter you selected displays.



1	Entity T	340B ID	CE ID	Medica	NPI Nu	Entity N	Entity S	City	State	Start Date	Term Dat
2	340S	340S012	6514	31000086	NULL	LEXINGTON - FAYETT	LEXINGTO	KY		00:00.0	00:00
3	340S	340S015	2359	10006412C	NULL	MARION C SCHOOL H	INDIANAF	IN		00:00.0	00:
4	340S	340S018	15052	2902504	NULL	FAMILY HEALTH CEN	KALAMAZ	MI		00:00.0	00:00
5	340S	340S025	15679	3.76E+08	NULL	HEALTH START, INC	ST. PAUL	MN		00:00.0	00:0
6	BL	BL031700	18268	1.01E+12	NULL	CENTERVI J. A. YABL	FREDERIC	PA		00:00.0	NULL
7	BL	BL051711C	39264	5569406	NULL	East Ohio Respirato	Martins Fe	OH		00:00.0	NULL
8	BL	BL80206X	3924	3616802	NULL	NATIONAL JEWISH M	DENVER	CO		00:00.0	NULL
9	CAH	CAH01130	448	20408	NULL	COLBERT (DBA/RED I	RED BAY	AL		00:00.0	NULL
10	CAH	CAH01130	448	4791150S	NULL	COLBERT (DBA/RED I	RED BAY	AL		00:00.0	NULL
11	CAH	CAH01130	38581	1.18E+09	NULL	St. Vincent's Blount	Oneonta	AL		00:00.0	NULL
12	CAH	CAH02130	14718	HS06IP	NULL	WRANGELL MEDICAL	WRANGEL	AK		00:00.0	00:00
13	CAH	CAH02130	14718	HS06SB	NULL	WRANGELL MEDICAL	WRANGEL	AK		00:00.0	00:00
14	CAH	CAH02130	14718	HS06LT	NULL	WRANGELL MEDICAL	WRANGEL	AK		00:00.0	00:00
15	CAH	CAH02130	14718	HS06OP	NULL	WRANGELL MEDICAL	WRANGEL	AK		00:00.0	00:00
16	CAH	CAH02130	14718	NULL	1.52E+09	WRANGELL MEDICAL	WRANGEL	AK		00:00.0	00:00
17	CAH	CAH02131	6530	HS15OP	NULL	SOUTH PENINSULA H	HOMER	AK		00:00.0	NULL
18	CAH	CAH03130	4469	20058	NULL	NORTHERN COCHISE	WILLCOX	AZ		00:00.0	NULL

- 5) Search for a covered entity the same as you would search any Microsoft Excel document. To search for a covered entity using the 340B Database search see [Searching for a Covered Entity](#).

(Back to [Getting Started Guide for Public Users](#).)

Other Covered Entities Guides

[Searching for a Covered Entity](#)

[Viewing a Covered Entity Record](#)

[Using Advanced Search Features](#)

[Exporting Search Results Data](#)

[Downloading the Medicaid Exclusion File](#)

[Registering a Covered Entity / Outpatient Facility](#)

[Submitting a Change Request](#)

[Terminating a Covered Entity](#)

[Covered Entity Daily Report](#)