Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: HHS is announcing the availability of an interpretive rule providing HHS's interpretation of section 340B(e) of the Public Health Service Act (PHSA), entitled "Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program." The interpretive rule states that section 340B(e) of the PHSA excludes drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Effective **[Insert date of publication in the Federal Register]**.

ADDRESSES: Submit written requests for single copies of the interpretive rule to the Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8W03A, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the interpretive rule.

FOR FURTHER INFORMATION CONTACT:

CDR Krista Pedley, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8W03A, Rockville, MD 20857, or by telephone at (301) 594-4353.

SUPPLEMENTARY INFORMATION:

I. Background

HHS is announcing the availability of an interpretive rule entitled "Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program." This interpretive rule explains how HHS interprets section 340B(e) of the PHSA. 42 U.S.C. 256b(e). This interpretive rule intends to: (1) provide clarity in the marketplace; (2) maintain the 340B Program savings for newly-eligible entities; and (3) protect the financial incentives for manufacturing orphan drugs designated for a rare disease or condition, as indicated in the Patient Protection and Affordable Care Act ("Affordable Care Act") (Public Law 111-148) and intended by Congress.

Earlier this year, after notice and comment rulemaking, HHS issued a final rule on this subject, "Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program" (78 FR 44016, July 23, 2013) (the "Rule"). The Rule was vacated by U.S. District Court for the District of Columbia on May 23, 2014, on the grounds that HHS does not have the authority to issue the Rule as a substantive rule. *PhRMA v. HHS*, No. 13-01501 (D.D.C. May 23, 2014). However, the decision did not invalidate HHS's interpretation of the orphan drug exclusion in the Rule.

Because there still is a need for HHS to clarify its interpretation of how the orphan drug exclusion in the 340B Program should be implemented to be consistent with section 340B(e) of the PHSA, HHS is making available an interpretive rule on this topic. In short, this interpretive rule clarifies that HHS interprets section 340B(e) of the PHSA as excluding drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for

the rare condition or disease for which the drug was designated under section 526 of the FD&C Act. This section of the PHSA does not exclude drugs that are transferred, prescribed, sold, or otherwise used for conditions or diseases other than for which the drug was designated under section 526 of the FD&C Act.

II. Electronic Access

Persons with access to the Internet may obtain the document at www.hrsa.gov/opa/programrequirements/interpretiverule/.

Dated: July 16, 2014.

Mary K. Wakefield, Ph.D., R.N.,

Administrator, Health Resources and Services Administration.

Dated: July 18, 2014.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2014-17409 Filed 07/21/2014 at 11:15 am; Publication Date: 07/23/2014]