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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding Section 340B of the Public Health Service Act

Registration Period

AGENCY: Department of Health and Human Services, Health Resources and Services Administration.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing this notice to inform stakeholders of the revised deadlines for registration of new covered entities and for adding outpatient facilities and contract pharmacy arrangements to the 340B Drug Pricing Program (340B Program).

DATES: Effective Date: October 1, 2012.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C-03, Rockville, MD 20857, or by telephone at 301-594-4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 340B(a)(4) of the Public Health Service Act (PHS) Act (42 U.S.C. 256b) lists the various types of organizations eligible to participate in and purchase discounted drugs under the 340B

Program. For a complete list of eligible entities, visit the OPA web site at <http://www.hrsa.gov/opa.introduction.htm>. Eligibility for participation in the 340B Program is limited to the categories of entities specified in this section of the statute. Section 340B(a)(9) of the PHS Act requires the Secretary to notify participating manufacturers of the identity of those entities that meet the definition of covered entity under 340B(a)(4). HRSA published final guidelines on the participation of outpatient facilities in the Federal Register at 59 Fed. Reg. 47884 (Sept. 19, 1994). HRSA published final guidelines on the utilization of Contract Pharmacy Arrangements in the *Federal Register* at 75 Fed. Reg. 10272 (March 5, 2010).

II. Registration Deadlines

This notice replaces all previous 340B Program guidance documents addressing the deadline and enrollment period for the 340B Program registration of new covered entities, addition of outpatient facilities and contract pharmacies, including any individual correspondence issued by HRSA on the subject.

(A) Registration Period for New Covered Entities and for the Addition of Outpatient Facilities

The registration period for 340B Program registration of new covered entities and the addition of outpatient facilities shall be limited to the following: January 1 - January 15 for an effective start date of April 1; April 1 - April 15 for an effective start date of July 1; July 1 - July 15 for an effective start date of October 1; and October 1 - October 15 for an effective start date of January 1.

In situations where the 15th falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day. Covered entities will not be able to submit registrations outside of these date parameters listed above except when the Secretary has declared a Public Health Emergency.

In addition to the complete on-line registration, any required supporting documentation must be submitted on the same day as on-line registration is completed. Incomplete packages will not be considered. For more information on what constitutes a complete package, visit the Office of Pharmacy Affairs (OPA) web site at www.hrsa.gov/opa.

(B) Registration Period for Contract Pharmacies

The registration period for 340B Program registration of contract pharmacies shall be limited to the following: January 1 - January 15 for an effective start date of April 1; April 1 - April 15 for an effective start date of July 1; July 1 - July 15 for an effective start date of October 1; and October 1 - October 15 for an effective start date of January 1.

In situations where the 15th falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day. The contract pharmacy registration process is not complete unless the registration form has been completed in its entirety and the original, signed copy is received by OPA.

Signed contract pharmacy registration forms are due to OPA within 15 days from the time online registration was completed. Incomplete packages will not be considered. For more information on what constitutes a complete package, visit the OPA web site at www.hrsa.gov/opa.

(C) Other Deadlines

Deadlines for forms other than those listed above are not affected by this notice. For example, change requests are not affected by this notice and will be processed as they are received.

DATED: July 17, 2012

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

Administrator

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