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Bulletin

Docket No: INS 20-017-AB - Revised

To: Prescription Drug Manufacturers

From: Christopher R. Nicolopoulos, Esq., Commissioner CRN

Date: June 23, 2020

Re: HB 703, New High-Cost Prescription Drugs

On February 10, 2020, the legislature enacted HB 703 relative to new high-cost prescription drugs. The new law requires prescription drug manufacturers to notify the Insurance Department "if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program." RSA 318:68, I. The drug manufacturer must provide notice to the Department within 3 days of the release of the drug in the commercial market. *Id.* Notice must be provided in writing and should include the name of the drug manufacturer, name of the prescription drug, and the anticipated date of release. All notifications must be submitted to the Department electronically through email to doi.healthcareanalytics@ins.nh.gov.

Within 30 days of notifying the Department, the drug manufacturer must submit to the Department the following:

a) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

b) The estimated volume of patients who may be prescribed the drug;

c) Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and

d) The date and price of acquisition if the drug was not developed by the manufacturer.

This information must be submitted using the "High-Cost Prescription Drug File Template" available on the Department's website at https://www.nh.gov/insurance/legal/high-cost-prescription-drugs.htm. Drug manufacturers may include multiple drugs in a filing, but each drug and its corresponding information

must be listed on a separate line. The drug manufacturer is only required to provide information that is already publically available.

The "High-Cost Prescription Drug File Template" requires the drug manufacturer provide the following information: manufacturer name, 11-digit NDC, Name of prescription drug, strength, pack size or volume, wholesale acquisition cost (WAC), date of commercial availability, estimated volume of patients who may be prescribed drug, date of acquisition if not developed by the manufacturer, and a description of the marketing and pricing plans. Additionally, the drug manufacturer must indicate whether the drug has breakthrough therapy designation or priority review.

Definitions Relevant to this Bulletin:

"Breakthrough Therapy Designation" means a prescription drug that has been designated as a "breakthrough therapy" as provided in 21 U.S.C. §356.

"Date of Commercial Availability" means the commercial launch date or the day the manufacturer begins selling and shipping the drug.

"Priority Review" means review and action as provided in 21 U.S.C. §360bbb-4a (a)(2).

"New prescription drug" means a prescription drug that has received initial approval under an original new drug application under 21 U.S.C. 355(b), under an abbreviated new drug application under 21 U.S.C. 355(j), or under a biologics license application under 42 U.S.C. 262.

"NDC" means National Drug Code as defined in 21 CFR §207.33.

"Wholesale acquisition cost" or "WAC" means "wholesale acquisition cost" as defined in 42 CFR 403.1201.

The Department will publish all reports on its website at https://www.nh.gov/insurance/legal/high-cost-prescription-drugs.htm. This new requirement has an effective date of January 1, 2020, even though the bill was not enacted until February 10, 2020. The Department expects that any drug manufacturer that would have been required to provide notice as of January 1, 2020, submit the High-Cost Prescription Drug File Template for any affected drugs within 30 days of this bulletin.

Questions should be directed to Maureen Mustard at Maureen.A.Mustard@ins.nh.gov.