Oregon Department of Consumer and Business Services
Division of Financial Regulation, Bulletin No. DFR 2020-??

TO: All manufacturers of prescription drugs sold in Oregon

DATE:

RE: The definition of "new prescription drug" for reporting under the Oregon Drug Price Transparency Act.

Purpose:

This bulletin clarifies the definition of "new prescription drug" in OAR 836-200-0505, regarding whether a report is required under OAR 836-200-0520 and ORS 646A.689. The term "original new drug application," for "specialty drug" reports required under ORS 646A.689, includes both novel drugs and acquired drugs previously approved.

Authority:

- ORS 646A.689

Background:

The Oregon Prescription Drug Price Transparency Act (the "Act")[1] requires all manufacturers of prescription drugs sold in the state of Oregon to report certain information to the Department of Consumer and Business Services (the Department) within 30 days of introducing a new prescription drug for sale at a price that exceeds the threshold established for specialty drugs in the Medicare Part D program.[2]

For the purposes of the Act, "new prescription drug" is defined at OAR 836-200-0505(6), as follows:

> "'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. In cases where multiple products are included on an application, each product will be considered a new prescription drug. A new prescription drug's introduction date is the date of its market entry."

[1] ORS 646A.689 – 646A.692
[2] ORS 646A.689, OAR 836-200-0520

An analysis of the reports submitted to the Department during the first three quarters of 2020 and an external drug pricing data source suggests that drug manufacturers are interpreting the term "original new drug application" in different ways. The Department is issuing this guidance to clarify the circumstances under which a report is required from a manufacturer who brings a new specialty drug to market.

Guidance for manufacturers

Under OAR 836-200-0505(6), the term "new prescription drug" is defined as applying to original new drug applications, abbreviated new drug applications, and biologics license applications[3]. The word "original" only appears referring to 21 U.S.C. 355(b), and does not modify the meaning of either "abbreviated new drug applications" or "biologics license applications."

The word "original" functions solely to distinguish new drug applications for compounds that still have market exclusivity from abbreviated new drug applications submitted for generic compounds. It **does not** restrict the reporting requirement for "new specialty drugs" to the first labeler to market a particular drug.

If the word "original" is interpreted as requiring reports only from manufacturers who developed a particular drug, it would lead to a situation where biologics manufacturers and generic manufacturers must submit new drug reports for acquired products, but brand-name manufacturers of small-molecule drugs would not be required to file for acquired products. Since biologic products and generic drugs can be sold from one manufacturer to another just as easily as brand name drugs, such an interpretation would cause unfair application of the Act by putting a higher compliance and fee burden on biologic and generic manufacturers. The Act does not distinguish between the different types of drug manufacturers, therefore, the reporting requirements for specialty drug reporting should be consistent for all types. The Department expects drug manufacturers to file a new drug report for both novel drugs and acquired drugs that meet the reporting requirements as specified in ORS 646A.689.

Exemptions

The Department has exercised its discretion to not require reports for a "new prescription drug" that matches the above definition where requiring reports would create an unusually difficult reporting burden due to the specific characteristics of a particular drug product or class of product. The department will consider an exemption where a report would be redundant (e.g. solely a change in labeler without a change in product or ownership), and / or would not result in losing data (e.g. where a price increase report would not have been required if the NDC remained the same). Circumstances where the department may consider an exemption include, but are not limited, to:

1. The **same corporate entity** retains the authority to set the Wholesale Acquisition Cost ("WAC") price for the drug. (Example: a wholly owned subsidiary begins manufacturing the drug under a new labeler code, but the parent company continues to set the WAC price for the drug); AND/OR

[3] Types of drug applications and the definitions are found in the following federal codes: 21 U.S.C. 355(b), 21 U.S.C. 355(j), and 42 U.S.C. 262.

2. The WAC price for the new NDC(s) of a subsequent original new drug application for a previously approved compound, formulation, and dosage is **not 10% or more above the WAC price for the preceding application.** This difference must be verifiable based on the listed WAC price in an external drug pricing data source.[4]

Director's expectations for drug manufacturers

The word "original" in the phrase "original new drug application" functions solely to distinguish new prescription drug applications for compounds that still have market exclusivity from abbreviated new drug applications for generic prescription drug products. It does not restrict the reporting requirement for "new specialty drugs" to the first manufacturer to market a particular drug. The Department expects drug manufacturers to file a new drug report for both novel drugs and acquired drugs.

The Department recognizes that, under specific circumstances, this interpretation of the rule may cause a disproportionate burden on certain manufacturers without providing useful information to the Program. The conditions described in this bulletin identify circumstances where a report would be redundant (e.g. solely a change in labeler without a change in product or ownership), and would not result in losing data (e.g. where an annual price increase report would not be required if the NDC had not changed).

The bulletin clarifies the Department's interpretation of OAR 836-200-0505. The Department will allow 30 days from the effective date of this bulletin for manufacturers to file required new drug reports late to comply without penalty.

Dated this ____ day of month, 2021 at Salem, Oregon.

_____ _____

Andrew R. Stolfi
Insurance Commissioner and Director
Department of Consumer and Business Services

Date

[4] As of the date of this Bulletin, the Department uses the Medi-span pricing database maintained by Wolters Kluwer to verify pricing data, but other 3rd party data sources, not maintained by the relevant manufacturer, may also be used to verify this information.