NOTICE OF PROPOSED RULEMAKING
STATEMENT OF NEED AND FISCAL IMPACT

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT EQUITY IN THIS STATE:

(*Who is this going to impact and how might it impact one group of people differently than others)?*

The proposed rules will impact pharmaceutical drug manufacturers subject to the Prescription Drug Price Transparency Act as well as consumers of prescription drugs. To the extent that the rule changes improve the effectiveness of the program in creating transparency in pharmaceutical pricing, greater transparency may impact the price of prescription drugs and thus have a downstream economic impact on consumers and the public. However, the extent of this impact and any differential impacts for different groups of affected people is impossible to predict from the information available to the department.

FISCAL AND ECONOMIC IMPACT:

(Based on information available to DCBS, briefly discuss the cost of compliance for businesses, generally).

The proposed rules will not have a new significant economic impact, however, the Prescription Drug Price Transparency Act and the underlying rules continue to have a significant economic impact on prescription drug manufacturers. There are likely a limited number of drug manufacturers that are also small businesses; those that are would have compliance costs. The proposed rules continue to not be likely to have a fiscal or economic impact on state agencies, local governments, or the public.

COST OF COMPLIANCE FOR SMALL BUSINESSES:

(1)Identify any state agencies, units of local government, and members of the public (including specific interest groups) likely to be economically affected by the rulemaking.

The proposed rules continue to not be likely to have a fiscal or economic impact on state agencies, local governments, or the public. While the underlying statutory provisions have a significant impact on DCBS, the proposed rules do not. The proposed rules provide finer details regarding the administration of the program and are expected to have a negligible impact on costs to the department and indeed will perhaps increase program efficiency.

The proposed rules do not add any new requirements on public entities, but instead clarify DCBS's supervisory expectations with regard to the administration of the Oregon Prescription Drug Price Transparency program. Other state agencies and local governments are not expected to incur any fiscal impact, because the requirements established by the Prescription Drug Price Transparency Act are not applicable to these entities.

The proposed rules will not have economic impact on the general public beyond the underlying, existing statutory requirements.

(2)(a) Estimate the number and type of small businesses subject to the rule(s).
The proposed rules are not expected to require significant additional costs beyond the costs of the existing compliance requirements of the underlying rules. DCBS does not have data on the specific number of pharmaceutical manufacturers that are small businesses doing business in Oregon.

DCBS convened a rulemaking advisory committee, which included representatives from drug manufacturers, trade associations, and consumer advocates. One committee member was a representative from a drug manufacturer that is a small business. The changes in the proposed rules would not significantly alter the existing requirements of reporting manufacturers subject to the rules, including any that are small businesses.

(2)(b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s).
The administrative costs for complying with the Prescription Drug Price Transparency Act are substantial. However, the proposed rules largely provide clarification of the existing rules and the new requirements are minimal. The overarching intent is to improve language consistency, align the annual price increase section with previous rulemaking revisions, which clarifies statutory intent, and resume mandatory data collection following a Ninth Circuit opinion.

For example, the proposed rules increase the price threshold for reporting new prescription drugs, which would result in fewer reports for manufacturers and, thus, a decreased administrative burden.

The proposed rules clarify the reporting requirements for the description of marketing to include types of marketing, target audience, and timeframes for the marketing spending. The proposed rules also enumerate potential factors that a reporting manufacturer may use in its methodology to increase prices. The potential factors include other prescription drugs, and estimated costs for manufacturing, marketing, distribution, and ongoing safety and effectiveness research for the

new prescription drug. These changes in the proposed rules, which have already been adopted for new prescription drug reports, are intended as clarifications of existing requirements and are unlikely to represent a significant increase in administrative costs.

Additionally, the proposed rules do add two reporting requirements for the annual price increase reports. First, it adds reporting the wholesale acquisition cost of the annual price increase drug at the beginning and end of the calendar year before the year preceding the report. It also adds reporting any wholesale acquisition cost changes, and the associated dates, during the calendar year preceding the report. This newly proposed information should be easily accessible by the manufacturer, is publicly available, and it is necessary for program staff to verify that a report is statutorily required.

(2)(c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

The administrative costs for complying with the Prescription Drug Price Transparency Act and the underlying rules are substantial, and may include additional equipment, supplies and labor costs, but the proposed rules largely provide clarification of the existing rules and do not impose additional requirements. The additional requirements and clarifications in the proposed rule outlined in subsection b. above may impose limited additional equipment, supplies and labor costs on prescription drug manufacturers.

How were small businesses involved in the development of the rule?
The RAC members represented consumer advocates and coalitions, large and small pharmaceutical manufacturers, trade associations, and third party compliance partners. One member of the RAC represented a small business.

Was an administrative rule advisory committee consulted? Yes.

DID MEMBERSHIP OF THE RAC REPRESENT THE INTERESTS OF PERSONS AND COMMUNITIES LIKELY TO BE AFFECTED BY THE RULE?

Specify the interested communities (BIPOC, professions, occupations, geographic location, recreational interests, aging/older adults, individuals w/disabilities, LGBTQ+, religion, veterans).

Yes, drug manufacturers, trade associations of drug manufacturers, and consumer advocates were all included in the RAC.

RULE NUMBER AND SUMMARY:

List each rule number and a short summary of what the rule does.

AMEND:
RULE SUMMARY:

ADOPT:
RULE SUMMARY:

STATUTORY REFERENCE:

STATUTORY/OTHER AUTHORITY:

STATUTES/OTHER IMPLEMENTED: