



December 4, 2019

Mr. Jesse O'Brien  
Senior Policy Advisor  
Oregon Dept. of Consumer & Business Services  
Division of Financial Regulation  
350 Winter St. NE, 2<sup>nd</sup> Floor  
Salem OR 97301

*Via email: Jesse.E.Obrien@oregon.gov*

**Re: Comments on DCBS Discussion Draft – HB 2185 Rule Text**

Dear Mr. O'Brien:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) response on the Department of Consumer and Business Services' (DCBS) Discussion Draft – HB 2185 Rule Text. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which manage prescription drug benefits for large employers, health insurance carriers, labor trusts, government programs, and other payers. We appreciate the willingness of DCBS to solicit feedback from stakeholders before any formal rulemaking, appreciate the opportunity to serve on the Rulemaking Advisory Committee (RAC) to discuss HB 2185, and look forward to being involved in further discussions.

It's worth noting the law does not go into effect until 2021. Given the numerous questions raised by DCBS, we urge you take the full amount of time necessary to ensure any regulatory measures are both within the meaning and intent of the law, but are also the most practical for all concerned.

In response to the Discussion Draft, PCMA provides the following comments:

1. Section (1) establishes parameters for what may be considered an "ancillary service" for pharmacies mailing drugs to patients. PCMA supports the proposed language that allows a PBM and pharmacy or PSAO (Pharmacy Services Administrative Organization - PSAO, which contracts on behalf of the pharmacy) to agree through contract what "ancillary" means. However, the final clause of the section, "but these limits may not have the effect of preventing enrollees from accessing prescription drugs through a network pharmacy via mail, shipment, and delivery on the request of the enrollee," is an exception that swallows the rule.

PCMA believes that the simplest option for pharmacies, PBMs, and health plans would leave the term open to definition between contracting parties. If the term is defined in the contract between the PBM and the pharmacy or PSAO, evaluating compliance would be simple: if there is a complaint that a PBM is out of compliance, DCBS could request a



copy of the relevant provision of the contract from the pharmacy, PSAO, or PBM. Then DCBS could determine whether the PBM complied with the term as it is defined in contract. There is no need to adopt a standard definition in rule that would supersede or replace provisions agreed to between contracting parties.

PCMA suggests the following amendment:

(1) A pharmacy benefit manager shall allow a network pharmacy to mail, ship, or deliver prescription drugs to its patients as an ancillary service. A contract between a pharmacy benefit manager and a pharmacy may establish limits and parameters on a pharmacy's mail, shipment and deliver of prescription drugs to enrollees, ~~but these limits may not have the effect of preventing enrollees from accessing prescription drugs through a network pharmacy via mail, shipment, and delivery on the request of the enrollee.~~

2. Section (3) proposes an expanded definition of "specialty drug" and section (4) proposes an expanded definition of "specialty pharmacy" by laying out new criteria for these terms that are not included in the statute. PCMA does not believe defining these terms in regulation is necessary or appropriate. The legislature adopted definitions for both terms and thus there is no need for regulatory definitions. In fact, expanding upon or changing the definitions would be an unauthorized expansion of the statute itself. In addition, restrictions on health plan benefits requiring the use of mail service pharmacies have been in place in many states for a number of years and there is no evidence that there is a problem with the way that these rules and policies are being implemented.
3. Section (5) seeks to clarify that the provisions in the statute related to prescription fills or refills at specialty long-term care pharmacies apply only to the drugs dispensed to the *residents* of the long-term care facility. We agree with DCBS' intent, however, and suggest the language be further clarified and recommend the following:

(5) A pharmacy benefit manager shall reimburse the cost of a specialty drug that is filled or refilled at a network pharmacy that is a long-term care pharmacy, ~~provided that the specialty drug filled or refilled on behalf of an enrollee who is a resident of a long-term care facility served by the long-term care pharmacy for specialty drugs dispensed to patients residing in the long-term care facility.~~

4. Section (6) proposes to clarify the meaning and use of the term "generally available" for purposes of the maximum allowable cost law. PBMs do not have insight into individual pharmacy business needs. PBMs only have visibility into pharmacy transactions for their own plan sponsors, but into a pharmacy's transactions contracted with another PBM. Additionally, no PBM has visibility into pharmacy transactions for cash-paying patients. We are concerned compliance with this provision is conditioned on the PBM knowing *unknowable* information, or relying on information the PBM cannot independently verify. Under existing law, there are adequate reimbursement appeals processes in place if a PBM misses a mark on reimbursement—processes that have been acknowledged by representatives of the pharmacies in the RAC meeting. PCMA



remains concerned that compliance with the proposed provision is problematic and suggests striking the last sentence.

(6) A pharmacy benefit manager may not place a prescription drug on a maximum allowable cost list unless it is generally available for purchase in Oregon as defined by 2019 Or Laws chapter 526 Section 4. ~~A prescription drug is not generally available for purchase at a specified price if it is only available at that price if purchased in substantial quantities that are inconsistent with the business needs of a pharmacy. For the purposes of this subsection, "substantial quantities that are inconsistent with the business needs of a pharmacy" means quantities in excess of a typical 3-month supply of a drug for a pharmacy based on the pharmacy's dispensing history.~~

5. Section (7) provides for an exception to Section (6) but PCMA remains concerned, for the reasons stated above. PBMs do not have insight into the business needs of individual pharmacies, and only have access to information on their own books of business. While one PBM may conduct a lot of business with one pharmacy, another PBM may have very little. PBMs have no way of knowing the pharmacy's business transactions that are contracted via other PBMs nor do they have insight into any transactions conducted without the use of health insurance. PCMA is concerned the compliance will be conditioned upon PBM knowing unknowable information, or reliant on information that the PBM will not be able to independently verify, such as competitive business information of other PBMs and their network pharmacies. PCMA suggests striking this provision.

Thank you for the opportunity to provide feedback. Please contact me at 202-756-5745 if you have any questions. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Bill Head", with a long, sweeping flourish extending to the right.

Bill Head  
Senior Director, State Affairs