October 28, 2019

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

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

Re: DCBS Request for Information (RFI) – HB 2185 Implementation

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) Request for Information on a potential rulemaking to implement HB 2185 (2019). 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 the 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.

At the outset, we note that the law does not go into effect until 2021 and there is a legislative session between now and that time. The legislature has committed to continue work on this statute during the 2020 legislative session. We encourage the DCBS to wait until after the end of the 2020 legislative session to finalize discussions on any rulemaking.

In response to the RFI, PCMA provides the following comments:

1. DCBS requested feedback on the adoption of a more refined definition of "specialty drug" or "specialty pharmacy," due to the perceived circularity of the use of these terms in the statute. PCMA does not believe defining these terms is needed. The legislature adopted definitions for both terms and thus there is no need for regulatory definitions. In fact, expanding upon or changing the definitions will be an unauthorized expansion of the statute itself. In addition, restrictions on health plan benefits requiring the use of mail service pharmacies and those restrictions' impact on the use of specialty pharmacies has been in place in Oregon and in many places over the country, and there is no evidence that there is a problem with the way that these rules and policies are working. PBMs are "on notice" as to the requirements, as they are set forth in the statute.

2. DCBS requested feedback on the statutory language relating to long term care pharmacy. We agree with the intent that DCBS and stakeholders discussed at the RAC meeting, which is that this provision applies only to the drugs dispensed to the *residents* of the LTC facility.

3. DCBS requested feedback on how to define "ancillary service." 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 Pharmacy Services Administrative Organization - PSAO, which contracts on behalf of the pharmacy), 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.

4. DCBS requested feedback on the definition of "generally available" and how to assess the business needs of a pharmacy. PCMA is very concerned about this provision because it causes significant compliance problems for PBMs. PBMs do not have insight into individual pharmacy business needs. We are concerned compliance with this provision of the statute is conditioned on the PBM knowing *unknowable* information. There are adequate reimbursement appeals processes in place if a PBM misses a mark on reimbursement, which was acknowledged in the RAC meeting by representatives of the pharmacies. PCMA remains concerned that compliance with this provision is problematic.

5. Finally, DCBS requested information regarding the prohibition on different payments to pharmacies participating in the 340B program. The question was presented why PBMs ask pharmacies for information about their participation in the 340B program upon contracting. PBMs that participate in the Medicare Part D and Medicaid programs need to know this information because whether a pharmacy participates in the 340B federal program impacts how PBMs report certain manufacturer rebate information to stay in compliance with the Medicare and Medicaid programs. The pharmacy's participation in the 340B program dictates what happens with certain revenues that flow through the health plan and PBM, based on federal laws in this area.

Thank you for the opportunity to provide feedback. Please contact me at 202-756-5743 if you have any questions. Thank you.

Sincerely,

April C. Alexander
Vice President, State Legislative and Regulatory Affairs