From: Kevin Russell <krussell@samhealth.org>
Sent: Wednesday, October 30, 2019 6:18 PM
To: OBRIEN Jesse E * DCBS <Jesse.E.Obrien@oregon.gov>
Cc: Niki Terzieff <niki@leadingedgepublicaffairs.com>; Bill Cross <Bill@wvcross.com>; 'Michele@grantspasspharmacy.com' <Michele@grantspasspharmacy.com>
Subject: RE: RAC comments from Oregon Pharmacy Coalition

Jesse,

You have a great memory and are correct. We do not want the REMS language in there. That was my mistake copying it from an earlier version. Do you need me to resubmit anything?

Kevin

From: OBRIEN Jesse E * DCBS <Jesse.E.Obrien@oregon.gov>
Sent: Wednesday, October 30, 2019 1:42 PM
To: Kevin Russell <krussell@samhealth.org>
Cc: Niki Terzieff <niki@leadingedgepublicaffairs.com>; Bill Cross <Bill@wvcross.com>; 'Michele@grantspasspharmacy.com' <Michele@grantspasspharmacy.com>
Subject: RE: RAC comments from Oregon Pharmacy Coalition

Hi Kevin,

Thanks for your comments. I have one follow-up question that I thought I'd ask prior to the RAC so that I can better understand your suggestions. Of course, we can discuss this further in person next week if that works better for you.

You suggest that the definition of "specialty drug" include drugs subject to a REMS requirement. This is an objective reference point, which would be very helpful, since there are a lot of tricky judgment calls with more subjective terms here like "difficult" and "unusual." However, I seem to recall some concern expressed at the last RAC meeting that there are drugs with a REMS requirement that no-one considers to be specialty drugs, such as certain anti-depressants. If we included reference to REMS in this definition, would that raise any concerns about how those drugs would be handled for the purpose of this law?

Best,
Jesse

From: Kevin Russell <krussell@samhealth.org>
Sent: Tuesday, October 29, 2019 8:28 AM
To: OBRIEN Jesse E * DCBS <Jesse.E.Obrien@oregon.gov>
Cc: Niki Terzieff <niki@leadingedgepublicaffairs.com>; Bill Cross <Bill@wvcross.com>; 'Michele@grantspasspharmacy.com' <Michele@grantspasspharmacy.com>
Subject: RAC comments from Oregon Pharmacy Coalition
Importance: High

Jesse, please see comments below I am submitting on behalf of the Oregon Pharmacy Coalition.

Kevin Russell RPH, MBA, BCACP
Legislative Chair
Oregon State Pharmacy Association
541-609-0306 cell

• Section 2 (2)(b) of the law permits PBMs to limit reimbursement of specialty drugs to drug dispensed by a specialty pharmacy (with the exception of long term care pharmacies—see below).

(12) "Specialty drug" means a drug that:
(a) Is subject to restricted distribution by the United States Food and Drug Administration; or
(b) Requires special handling, provider coordination or patient education that cannot be provided by a retail pharmacy.
(13) "Specialty pharmacy" means a pharmacy capable of meeting the requirements applicable to specialty drugs.
[*(6)*] **(14)** "Third party administrator"

The definition of "specialty drug" provided by Section 3 (12) includes a drug that "requires special handling, provider coordination or patient education that cannot be provided by a retail pharmacy," but the bill does not define the phrase "retail pharmacy," and "specialty pharmacy" is defined by Section 3 (13) with reference to the "specialty drug" definition. Without clarification, this circularity could cause confusion about which pharmacies a PBM may consider to be specialty pharmacies, and what drugs a PBM may limit to specialty pharmacies.
At the October 14 meeting, DCBS suggested that, in lieu of a comprehensive definition of "specialty drug" accepted across the industry, one possible approach for the administrative rules would be to provide a non-exclusive list of criteria that qualify a drug for specialty status. Such a list would not necessarily disallow PBMs from adopting additional reasonable criteria as the specialty drug market evolves, but it would provide more clarity to industry and regulators. DCBS requests feedback on the merits of this approach, specific suggestions about potential criteria that could be used for this purpose, and any suggestions for alternative approaches.

Whereas we cannot change the definitions of specialty drug or specialty pharmacy as written in the bill, we would like to submit alternate definitions which can be used to help clarify what would qualify as a specialty drug or specialty pharmacy. This is in collaboration with two Oregon based specialty pharmacies.

"**Specialty drug**" means a drug: (a) That requires difficult or unusual: (A) Preparation; (B) Handling; (C) Storage; (D) Inventory; or (E) Distribution; (b) That has difficult or unusual data collection or administrative requirements associated with it; (c) For which the United States Food and Drug Administration requires a Risk Evaluation and Mitigation Strategy; or (d) That requires a pharmacist to manage the patient's use of the drug by: (A) Monitoring; or (B) Providing disease or therapeutic support systems.

"**Specialty Pharmacy**" means a pharmacy that solely or largely provides specialty drugs and specialized, disease-specific clinical care and services for people with serious or chronic health conditions requiring complex medication therapies, and has been validated for meeting quality, safety and accountability standards for specialty pharmacy practice through accreditation in specialty pharmacy by a nationally recognized, independent organization such as URAC® or Accreditation Commission for Health Care (ACHC).

• Section 2 (2)(c) requires PBMs to reimburse the cost of a specialty drug prescription filled or refilled at a long term care pharmacy. At the October 14 meeting, stakeholders appeared to agree that it is worth clarifying that this requirement only applies to specialty drugs provided to residents of the facility served by the long term care

pharmacy. DCBS requests feedback on the merits of such a clarification, as well as specific suggestions for rule language to address this issue.

We agree that the intent of this provision was to allow for dispensing/payment for patients in long term care facilities. Long term care pharmacies need to care for often urgent needs of patients in facilities which includes some drugs which may be defined as specialty drugs.

• Section 2 (2)(d) of the law requires PBMs to permit network pharmacies to deliver drugs by mail as an "ancillary service," but it does not define this term. Without further clarity, this may cause confusion and conflict about how much mail delivery is allowed, and how DCBS will determine compliance in this area.
At the October 14 meeting, RAC members discussed potential approaches to this issue, including establishing a specific threshold percentage or requirements related to the provisions of a PBM contract. DCBS requests feedback about the merits of these approaches, as well as specific suggestions regarding potential rule language.

We recommend defining the term "ancillary" as <50% of the quantity of dispensed prescriptions are delivered to patients through the mail. Patients should be able to choose how they get their prescriptions delivered from their local pharmacy. This definition will allow patients to do so. PBMs can learn of this percentage by asking on an application or recredentialing form.

• Section 4 (1)(a) provides that a drug will not be considered "generally available to purchase" at a specific price for the purposes of a Maximum Allowable Cost (MAC) list if it is "available to a pharmacy at a price that is at or below the maximum allowable cost only if purchased in substantial quantities that are inconsistent with the business needs of a pharmacy." This appears to be intended to protect small pharmacies from MAC pricing based on volume discounts only available to large pharmacy chains. However, it is unclear how to define a pharmacy's "business needs," or what standards PBMs should use in this area.
At the October 14 meeting, RAC members suggested that there may be a common-sense rule of thumb in this area, perhaps based on the monthly prescribing volume of a pharmacy. DCBS requests feedback and specific suggestions regarding an approach to ensuring compliance with this requirement.

We recommend defining "business needs" as requiring to purchase a quantity of no more than a 3 month supply for that pharmacy. A PBM will learn of this when a pharmacy files a MAC appeal if applicable. It would be a rare appeal when this would apply.

• Section 4 (1)(h) prohibits PBMs from reimbursing pharmacies that participate in the federal 340B drug discount program "differently" than other pharmacies based on their 340B status. This will likely require clarification, since PBMs reimburse different pharmacies differently for a wide variety of reasons. There will likely need to be a more specific standard for when a different reimbursement arrangement would be disallowed due to this provision.

We do not think further clarification is needed. Each situation may be unique and evidence will need to be presented in a complaint situation. We do recommend a rule be written to prevent PBMs from asking for a pharmacy's 340B status or to require submitting 340B claim eligibility. The 340B program is independent of the payor side of the healthcare industry. PBMs have no reasons for collecting this data unless they plan on paying pharmacies differently or using it outside of the payor/pharmacy relationship.