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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 431
OREGON HEALTH AUTHORITY
OREGON PRESCRIPTION DRUG PROGRAM

FILED
03/29/2024 9:04 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Redefinition of Critical Access Pharmacies (CAPs), as they specifically relate to the ArrayRx program.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 04/22/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Pete Edlund
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HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 04/16/2024
TIME: 10:05 AM - 10:55 AM
OFFICER: Pete Edlund

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
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CONFERENCE ID: 1619173834
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NEED FOR THE RULE(S)

CAPs have existed within the ArrayRx program, since 2009. The definition currently is only based on geography. We are working to redefine CAPs through an equity lens, taking into account any pharmacies that serve Tribal populations, pharmacies located within high poverty census tracts, those pharmacies within frontier counties, as well as establishing criteria that pharmacies must meet to be a CAP, including offering vaccines and medication assisted therapy (MAT) or pharmacist protocol-based prescribing.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Guadamuz JS, Alexander GC, Zenk SN, et. al. (2020) "Assessment of Pharmacy Closures in the United States From 2009 Through 2015." JAMA Internal Medicine 180(1): 157-60.

Wisseh C, Hildreth K, and Marshall J et. al. Social Determinants of Pharmacy Deserts in Los Angeles County." J Racial and Ethnic Health Disparities 2021; 8: 1424-34.

The US Census Bureau and Economic Development Administration Poverty Status Viewer - It uses data from the American Community Survey, the Small Area Income Poverty Estimates, and the 2020 National Census.

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

1a. There are no specific racial/ethnic populations that will be disproportionately and potentially adversely impacted by the proposed rule changes. The rule change will be helpful to small business providers (pharmacies) because potentially more pharmacies will be included in this designation and none of the current pharmacies designated as a CAP will lose that status.

1b. There are no potential disproportionate impacts on the Tribes or any specific racial/ethnic populations. The Tribal Consultation process was adhered to throughout.

1c. Data on current pharmacies in business in Oregon was used from the Oregon Board of Pharmacy. The US Census Bureau and Economic Development Administration Poverty Status Viewer - It uses data from the American Community Survey, the Small Area Income Poverty Estimates, and the 2020 National Census, was also used.

1d. Per review and discussion with Tribal Affairs, this rule has not been identified as a critical event per the tribal consultation policy. Notification to Tribes was sent by Liz Stuart on 3/5/2024. It was determined that a Dear Tribal Leader Letter was not necessary. Messaging was sent out on 11/7/2023 for the 1/29/2024 preliminary RAC and again on 3/5/2024 for the 3/18/2024 RAC. It was deemed that a consultation meeting with Tribal partners was not needed. The email sent on 3/5/2024 was planned for 2/6/2024, but due to unforeseen Tribal Affairs staff issue, this was delayed until 3/5/2024.

2a. A variety of business entities' input has been sought. The Clinical Pharmacist within the DSI Pharmacy Team has reached to several small, independent pharmacies to make them aware of this RAC. DSI Pharmacy/ArrayRx staff have presented at multiple Community Pharmacy Partner meetings throughout 2023 and during 2024 to make pharmacy staff aware of the RAC which will be held on 3/18/2024. As mentioned in Section 1, there are no specific racial populations that will be disproportionately and potentially adversely impacted by the proposed rule changes. As mentioned in Section 1d, outreach occurred in conjunction with Tribal Affairs.

2c. There has been no decision to not engage with affected communities. There are no barriers.

3. Appropriate channels for communicating the permanent rule change will be utilized.

4. There are no potential negative impacts to racial equity or racially/ethically specific communities.

FISCAL AND ECONOMIC IMPACT:

Implementation of a new definition for CAPs will include more pharmacies throughout Oregon which will be designated as a CAP. This will have a positive fiscal impact on these pharmacies because they are paid a higher dispense fee through this program. There is no negative fiscal impact, because there will be no reduction in pharmacies that are already CAPs, it will only add more.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). The public will only be affected tangentially. The intent of designating more pharmacies with a CAP status is to provide an increased reimbursement rate, for those pharmacies within the ArrayRx program, which will potentially help them remain in business. There is a positive effect for the public, with potentially more pharmacies remaining open for business and less pharmacy deserts.
(2) Effect on Small Businesses: For the most part, pharmacies designated as a CAP, and receiving this greater reimbursement, will be small, independent businesses, with very few chain pharmacies.
(a) Estimate the number and type of small businesses subject to the rule(s); With the proposed new definition for CAPs, it is proposed that there will be 16 pharmacies designated as a CAP within frontier counties in Oregon. In frontier counties it will be a mixture of both small, independent pharmacies as well as 6 chain pharmacies. Within rural counties, there will be 30 pharmacies designated as a CAP. No chain pharmacies will be included in the rural designation. All are

small, independent pharmacies. Within the urban designation, 6 pharmacies will be included as a CAP. None of these pharmacies are chain pharmacies. All are small, independent pharmacies.
(b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); Frequency of analysis has not yet been determined. It is currently conducted on a yearly basis. Once the new analysis has been established, there may be additional time requirements than what currently already exist today, related to the analysis.
(c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).
Once the new analysis has been established, there may be additional time requirements or increased administration than what currently already exist today, related to the analysis.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

We conducted outreach to multiple small, independent pharmacies. There are at least two small business owners (pharmacies) serving on the RAC. We have provided multiple presentations on the upcoming RAC for CAPs at Community Pharmacy Partner meetings throughout 2023 and into 2024. Our most recent presentation was held on Tues., Mar. 12th.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
431-121-2000, 431-121-2020

AMEND: 431-121-2000

RULE SUMMARY: Expanding the CAP program aligns with the Oregon Health Authority's mission and goals and focus on improving both quality and access to healthcare in Oregon, as well as advancing health equity. In redefining the definition of a critical access pharmacy, we see an opportunity to work towards achieving OHAs mission and goals while supporting pharmacies within the state.

Given the pharmacy access environment in the state, we must act in order to preserve pharmacy access for all Oregonians. Adjusting the definition of a CAP to be more inclusive provides an opportunity to provide financial benefit to pharmacies serving communities at greatest risk of experiencing a pharmacy closure and experiencing health disparities. OHA has the authority to do this for prescriptions filled by the Oregon Prescription Drug Program, ArrayRx. In making these adjustments, Oregon can serve as a model for other states and private payors.

With an understanding of pharmacy access issues in the state and the mission and goals of OHA, setting goals for updating the CAP program started with a reflection on what services were essential for pharmacies to provide to all citizens in the state. Certainly, it is important to make sure that any changes maintain CAP status for current CAPs. Our goal was to be intentional about how we could build upon the current CAP program, to increase pharmacy services that we feel are essential and incorporate social determinants of health, like poverty level. Our goal in doing this is to improve health equity for all Oregonians, regardless of where they live, their income, or their race or ethnicity.

Because Oregon is a diverse state, we wanted the definition to respect the challenges in pharmacy access in different areas. In order to better characterize pharmacies that are more likely to close or serve community at risk of diminished pharmacy access, we collected and analyzed data about pharmacies around the state. We started with a list of 592 pharmacies. From this list, we excluded 398 pharmacies that maintained ownership outside of the state and 46 pharmacies that were not open to the public. This left us with 148 pharmacies to investigate. Each year, the Office of Rural Health publishes classifications of areas of the state: Frontier counties, rural zip codes, and urban zip codes.

Based on the classification scheme from 2023, 10 of these were in frontier counties, 66 were in rural zip codes, and 72 were in urban zip codes. Additionally, to better inform our recommendations, we also collected data on 333 urban pharmacies (independent of the type or location of ownership).

We analyzed a list of community pharmacies and their addresses that were licensed in the state. Additional data about prescription volume and dispensing fee tier were available from an annual state pharmacy survey. Using the US Census Bureau and Economic Development Administration Poverty Status Viewer – which uses information from the American Community Survey, Small Area Income Poverty Estimates, and 2020 national census - pharmacies were geolocated into their census tracts and their corresponding poverty level was recorded. High poverty census tracts, where greater than 20% of the population lives below the poverty level and possible high poverty census tracts, where the confidence interval of the percentage of the population that lives below the poverty level includes 20%, were both investigated. Using google maps, the distance of the pharmacy to the closest high and possibly high poverty areas as well as the distance to the nearest pharmacy was collected. Access to public transportation in the area surrounding the pharmacies was also collected.

CHANGES TO RULE:

431-121-2000
Definitions ¶

(1) "340B" means Section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities," and any and all related rules, guidance, interpretations, and operational directives adopted by the federal Health Resources and Services Administration (HRSA) or any other governmental agency with jurisdiction over the enforcement of Section 340B.¶
(2) "Administrator" means the Administrator of the Oregon Prescription Drug Program (OPDP).¶
(3) "Authority" means the Oregon Health Authority.¶
(4) A "Critical Access Pharmacy (CAP)" ~~means a pharmacy in Oregon~~is defined as a pharmacy in Oregon that provides pharmacy services in communities at greatest risk of experiencing a pharmacy closure. To qualify as a CAP, except for (a) and (d) below, the pharmacy must have Oregon-based ownership, be public facing, and provide access to immunizations and either medication therapy management or pharmacist protocol-based prescribing. All pharmacies located on tribal lands or serving tribal communities will be designated as a CAP. In alignment with urban, rural, and frontier designations determined by the Office of Rural Health (ORH), a critical access pharmacy will meet the following criteria:¶
(a) In a frontier county, a critical access pharmacy is one that is further than a ten-mile radius from any other pharmacy. (If one CAP's ten-mile radius intersects with that of another CAP, both shall be considered a CAP if either CAP's closure could result in impaired access for rural areas.) Additionally, if a county has three or fewer pharmacies, all pharmacies, regardless of ownership, will be considered a CAP.¶
(b) In a rural zip code, a critical access pharmacy is one that is further than a ten-mile radius from any other pharmacy. (If one CAP's ten-mile radius intersects with that of another CAP, both shall be considered a CAP if either CAP's closure could result in impaired access for rural areas.) Additionally, if the pharmacy has Oregon based ownership and is located in a high poverty census tract (as defined by the US census bureau), it will be considered a CAP. ¶
(c) In an urban zip code, a pharmacy may be considered a CAP if the pharmacy has Oregon based ownership and is the sole pharmacy located in a high poverty census tract (as defined by the US census bureau).¶
(d) A pharmacy may be designated as a CAP at the discretion of the Director of the OPDP accounting for factors related to pharmacy access.¶
(e) Assessment of CAP designation will be conducted quarterly. Pharmacies that previously qualified as a CAP, but no longer meet the aforementioned criteria, will have 12 months before losing this designation.¶
(5) "Designated Entity" means an entity contracted by the Authority to perform administrative duties of the OPDP including but not limited to determining program prices, processing and paying claims, issuing identification cards, maintaining eligibility files, network development maintenance, and performing replenishment administration. Designated entities may include but are not limited to pharmacy benefits managers, third party administrators, insurance carriers, health maintenance organizations (HMOs), mail order and specialty drug suppliers, replenishment administrators, group purchasing organizations, and wholesalers.¶
(6) "Discount Card Program" or "DCP" means a state pharmacy benefit program for eligible uninsured individuals pursuant to ORS 414.312(4)(e) administered by the OPDP.¶

(7) "Group Purchasing Organization (GPO)" means any organization purchasing on a group basis established to meet the criteria of the Nonprofit Institutions Act, 15 USC 13c, or that is exempt under the Robinson Patman Antidiscrimination Act, 15 USC 13, or is a governmental entity performing traditional government functions.¶
(8) "Mail Order Pharmacy" means a pharmacy that fulfills prescriptions by mail or other delivery service.¶
(9) "Member" means individuals enrolled in a participating program to receive services under the OPDP.¶
(10) "Participating Program" means:¶
(a) A group, facility, or entity that is eligible to participate in the OPDP pursuant to ORS 414.312(4) and has a participation agreement with the OPDP; or¶
(b) A DCP for individual Oregon residents who lack or are underinsured for prescription drug coverage pursuant to ORS 414.312(4)(e).¶
(11) "Pharmacy Benefit Manager (PBM)" means an entity that negotiates and executes contracts with pharmacies, manages Preferred Drug Lists (PDL), negotiates rebates with prescription drug manufacturers, and serves as an intermediary between the Administrator, prescription drug manufacturers, and pharmacies.¶
(12) "Pharmacy Provider" means retail, mail order, and specialty drug outlets that participate in the OPDP and that contract with the Authority or a designated entity as a pharmacy provider.¶
(13) "Preferred Drug List (PDL)" means a list of preferred prescription drugs in selected classes that the Authority, in consultation with the Office for Oregon Health Policy and Research (OHPR), has determined represent the most effective drugs available at the best possible price.¶
(14) "Prescription Drug" means:¶
(a) A drug prescribed by a prescribing practitioner;¶
(b) Supplies necessary to administer a prescription drug in a safe and effective manner, including but not limited to inhaler, spacers, diabetic test strips, syringes, and meters.¶
(15) "Prescribing Practitioner" means a physician or other practitioner authorized by law to prescribe prescription drugs.¶
(16) "Prescription Drug Claims Processor" (PDCP) means an entity that processes and pays prescription drug claims, adjudicates pharmacy claims, transmits prescription drug prices and claims data between pharmacies and the OPDP, and processes payments to pharmacies.¶
(17) "Program Price" means the reimbursement rates and prescription drug prices established by the OPDP Administrator directly or indirectly through a contract with a designated entity, including program cost, dispensing or administration fees, and all applicable manufacturers discounts and rebates.¶
(18) "Rebate" means all payments or discounts whether retrospective or not, including promotional or volume-related refunds, incentives or other credits however characterized, pre-arranged with pharmaceutical companies on certain prescription drugs, which are paid to or on behalf of OPDP or a designated entity, and are directly attributable to the utilization of certain drugs by members including administrative fees and software or data fees paid by pharmaceutical companies to OPDP or a designated entity. Rebate includes all rebates, discounts, payments or benefits (however characterized) generated by participating program's claims, or derived from any other payment or benefit for the dispensing of prescription drugs or classes or brands of drugs within participating program or arising out of any relationships OPDP or designated entity has with pharmaceutical companies, including but not limited to rebate sharing, market share allowances, educational allowances, gifts, promotions, or other form of revenue.¶
(19) "Replenishment Administration" means tracking GPO or 340B program usage by pharmacy providers and ordering replacement inventory including associated reporting; GPO and 340B retail and mail order pharmacy contracting; GPO and 340B contracting; or as otherwise defined by contract.¶
(20) "Retail Pharmacy" means a pharmacy in a retail store and excludes any mail order pharmacy or specialty pharmacy.¶
(21) "Specialty Pharmacy" means a pharmacy provider where specialty drugs are dispensed and delivered to members or to prescribing practitioners for members.¶
(22) "Third Party Administrator (TPA)" means an entity that, in addition to being a PDCP, facilitates program management including processing and paying prescription drug claims; transmitting prescription drug prices and claims and enrollment data between pharmacies and the OPDP and its participating programs; maintaining enrollment and issuing identification cards; and processing payments to pharmacies. The TPA may be contracted through the Authority or PBMs, or other designated entities.
Statutory/Other Authority: ORS 414.320
Statutes/Other Implemented: ORS 414.312 - 414.320

AMEND: 431-121-2020

RULE SUMMARY: Removal of the text “in rural areas” within rule, allows for expanding the CAP program to areas other than those that have a rural designation. While we have already sought the opinion of our DOJ and current language in rule already allows for this, we are seeking this change simply to clarify the language.

CHANGES TO RULE:

431-121-2020
Program Price ¶

(1) The price for a prescription drug a pharmacy provider may charge a member under the OPDP is the lesser of the following on the date of the transaction:¶
(a) The program price, or¶
(b) The pharmacy provider's usual and customary price, including program cost and dispensing fee.¶
(2) The designated entity shall transmit the price of the prescription drugs to the pharmacy providers electronically.¶
(3) The OPDP is limited to prescription drugs prescribed in the name of and for the use by the member, except as otherwise provided in section (7) of this rule.¶
(4) Prescription drug benefit access shall be available on member identification cards.¶
(5) The OPDP does not include prescriptions for over-the-counter drugs.¶
(6) The Administrator, or designated entity, may establish different program prices for CAP providers ~~in rural areas~~ to maintain statewide access to the OPDP.¶
(7) Unique pricing arrangements may be agreed upon between pharmacy providers and designated entity to accommodate group purchasing or 340B pricing for qualified entities.
Statutory/Other Authority: ORS 414.320
Statutes/Other Implemented: ORS 414.312 - 414.320