Oklahoma Health Care Authority

The Oklahoma Health Care Authority (OHCA) values your feedback and input. It is very important that you provide your comments regarding the proposed rule change by the comment due date. Comments can be submitted on the OHCA's Proposed Changes Blog.

OHCA COMMENT DUE DATE: November 17, 2019

The proposed policy is an Emergency Rule. The proposed policy was presented at the June 18, 2019 Tribal Consultation. Additionally, this proposal is scheduled to be presented to the Medical Advisory Committee on November 7, 2019 and the OHCA Board of Directors on November 20, 2019.

Reference: APA WF # 19-19B

SUMMARY:
Step therapy exception process - The proposed revisions will comply with Oklahoma Senate Bill (SB) 509, which was signed into law on April 16, 2019. SB 509 directed the OHCA to revise current step therapy protocols for medications approved by the Drug Utilization Review (DUR) Board and provide for exceptions to the drug step therapy protocol. Further, revisions will establish an appeals process for step therapy exception requests that have been denied. Other revisions are needed to correct outdated language.

LEGAL AUTHORITY
The Oklahoma Health Care Authority Act, Section 5007 of Title 63 of Oklahoma Statutes; and the Oklahoma Health Care Authority Board, SB 509.

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

TO: Maria Maule
Legal Services

FROM: Vanessa Andrade
Federal and State Authorities

SUBJECT: Rule Impact Statement
APA WF # 19-19B

A. Brief description of the purpose of the rule:

The proposed revisions will comply with Oklahoma Senate Bill (SB) 509, which was signed into law on April 16, 2019. SB 509 directed the OHCA to revise current step therapy protocols for medications approved by the Drug Utilization Review (DUR) Board and provide for exceptions to the drug step therapy protocol. The exception applies to cases when: the required prescribed drug will likely cause an adverse reaction or harm; the prescription drug will likely be ineffective; the patient has already tried the prescription drug and discontinued use; or the prescription drug is not in the best interest of the patient; or the patient is stable on another prescription drug. Further, revisions will establish an appeals process for step therapy exception requests that have been denied. Other revisions are needed to correct outdated language.

B. A description of the classes of persons who most likely will be affected by the proposed rule, including classes that will bear the cost of the proposed rule, and any information on cost impacts received by the agency from any private or public entities:

No classes of persons will be affected by the proposed rule changes.

C. A description of the classes of persons who will benefit from the proposed rule:

The proposed rule changes will benefit the OHCA because the rules will be brought into compliance with State law requirements. Additionally, the proposed rule changes will benefit members by ensuring their ability, in appropriate cases, to obtain the more expensive medication their doctor ordered for them.

D. A description of the probable economic impact of the proposed rule upon the affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee change:

There is no probable impact of the proposed rule changes upon any classes of persons or political subdivisions.

E. The probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated effect on state revenues, including a projected net loss or gain in

such revenues if it can be projected by the agency:

The proposed changes would potentially result in an estimated 6-month total cost for the remainder of SFY20 of $15,000,000 with a state share of $2,548,500 and an estimated annual total cost for SFY21 of $30,0000,000 with a state share of $4,875,000.

F. A determination of whether implementation of the proposed rule will have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule:

There is no economic impact on political subdivisions.

G. A determination of whether implementation of the proposed rule will have an adverse effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act:

The proposed rule changes will not have an adverse effect on small business.

H. An explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or non-regulatory methods or less intrusive methods for achieving the purpose of the proposed rule:

The agency has taken measures to determine that there is no less costly or non-regulatory method or less intrusive method for achieving the purpose of the proposed rule changes.

I. A determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk:

The proposed rule changes should have no adverse effect on the public health, safety, and environment.

J. A determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented:

OHCA does not believe there is a detrimental effect on the public health and safety if the rule changes are not passed.

K. The date the rule impact statement was prepared and if modified, the date modified:

Prepared: September 25, 2019
Modified: October 16, 2019

RULE TEXT:

TITLE 317. OKLAHOMA HEALTH CARE AUTHORITY
CHAPTER 30. MEDICAL PROVIDERS-FEE FOR SERVICE

SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES

PART 5. PHARMACIES

317:30-5-77.2. Prior authorization

(a) **Definition.** The term prior authorization in pharmacy means an approval for payment by ~~OHCA~~the Oklahoma Health Care Authority (OHCA) to the pharmacy before a prescription is dispensed by the pharmacy. An updated list of all products requiring prior authorization is available at the agency's website.

(b) **Process.** Because of the required interaction between a prescribing provider (such as a physician) and a pharmacist to receive a prior authorization, OHCA allows a pharmacist up to thirty (30) calendar days from the point of sale notification to provide the data necessary for OHCA to make a decision regarding prior authorization. Should a pharmacist fill a prescription prior to the actual authorization he/she takes a business risk that payment for filling the prescription will be denied. In the case that information regarding the prior authorization is not provided within the thirty (30) days, claims will be denied.

(c) **Documentation.** Prior authorization petitions with clinical exceptions must be mailed or faxed to the Medication Authorization Unit of OHCA's contracted prior authorization processor. Other authorization petitions, claims processing questions and questions pertaining to ~~DUR~~Drug Utilization Review (DUR) alerts must be addressed by contacting the pharmacy help desk. Authorization petitions with complete information are reviewed and a response returned to the dispensing pharmacy within twenty-four (24) hours. Petitions and other claim forms are available on the OHCA public website.

(d) **Emergencies.** In an emergency situation, the OHCA will authorize a seventy-two (72) hour supply of medications to a member. The authorization for a seventy-two (72) hour emergency supply of medications does not count against the SoonerCare limit described in OAC 317:30-5-72(a)(1).

(e) **Utilization and scope.** There are three (3) reasons for the use of prior authorization: utilization controls, scope controls and product based controls. ~~Product based prior authorizations is~~ Product-based prior authorizations, including step therapy protocols as defined by Title 63 of the Oklahoma Statutes (O.S.) § 7310(A)(4), are covered in OAC 317:30-5-77.3. The ~~Drug~~

~~Utilization Review~~DUR Board recommends the approved clinical criteria and any restrictions or limitations.

(1) **Utilization controls.** Prior authorizations that fall under this category generally apply to the quantity of medication or duration of therapy approved.

(2) **Scope controls.** Scope controls are used to ensure a drug is used for an approved indication and is clinically appropriate, medically necessary and cost effective.

(A) Medications which have been approved by the FDA for multiple indications may be subject to a scope-based prior authorization when at least one (1) of the approved indications places that drug into a therapeutic category or treatment class for which a prior authorization is required. Prior authorizations for these drugs may be structured as step therapy or a tiered approach as recommended by the ~~Drug Utilization Review~~DUR Board and approved by the OHCA ~~Board of Directors~~.

(B) Prior authorization may be required to assure compliance with FDA approved and/or medically accepted indications, dosage, duration of therapy, quantity, or other appropriate use criteria including pharmacoeconomic consideration.

(C) Prior authorization may be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.

(D) Prior authorization may be required for certain compounded prescriptions if the allowable cost exceeds a predetermined limit as published on the agency's website.

317:30-5-77.3. ~~Product-Based Prior Authorization~~Product-based prior authorization (PBPA)

~~The Oklahoma Health Care Authority utilizes a prior authorization system subject to their authority under 42 U.S.C. 1396r-8 and 63 O.S. 5030.3(B). The prior authorization program is not a drug formulary which is separately authorized in 42 U.S.C 1396r-8. Drugs are placed into two or more tiers based on similarities in clinical efficacy, side-effect profile and cost-effectiveness after recommendation by the Drug Utilization Review Board and approved by the OHCA Board of Directors. Drugs placed in tier number one generally require no prior authorization. Drugs placed in any tier other than tier number one may require prior authorization.~~

~~(1) Three general exceptions exist to the requirement of prior authorization:~~

~~(A) inadequate response to one or more tier one products,~~

~~(B) a clinical exception for a certain product in the particular therapeutic category, or~~

~~(C) the manufacturer or labeler of a product may opt to participate in the state supplemental drug rebate program to~~

~~move a product from a higher tier to a lower tier which will remove or reduce the prior authorization requirement for that product.~~

~~(i) After a drug or drug category has been added to the Prior Authorization program, OHCA or its contractor may establish a cost-effective benchmark value for each therapeutic category or individual drug. The benchmark value may be calculated based on an average cost, an average cost per day, a weighted average cost per day or any other generally accepted economic formula. A single formula for all drugs or drug categories is not required. Supplemental rebate offers from manufacturers which are greater than the minimum required supplemental rebate will be accepted and may establish a new benchmark rebate value for the category.~~

~~(ii) Manufacturers of products assigned to tiers number two and higher may choose to pay a supplemental rebate to the state in order to remove or reduce a prior authorization requirement on their product or products assigned to the higher tier.~~

~~(iii) Supplemental rebate agreements shall be in effect for one year and may be terminated at the option of either party with a 60 day notice. Supplemental rebate agreements are subject to the approval of CMS. Termination of a Supplemental Rebate agreement will result in the specific product reverting to the previously assigned higher tier in the PBPA program.~~

~~(iv) The supplemental unit rebate amount for a tier two or higher product will be calculated by subtracting the federal rebate amount per unit from the benchmark rebate amount per unit.~~

~~(v) Supplemental rebates will be invoiced concurrent with the federal rebates and are subject to the same terms with respect to payment due dates, interest, and penalties for non-payment as specified at 42 U.S.C. Section 1396r-8. All terms and conditions not specifically listed in federal or state law shall be included in the supplemental rebate agreement as approved by CMS.~~

~~(vi) Drugs or drug categories which are not part of the Product Based Prior Authorization program as outlined in 63 O.S. Section 5030.5 may be eligible for supplemental rebate participation. The OHCA Drug Utilization Review Board shall recommend supplemental rebate eligibility for drugs or drug categories after considering clinical efficacy, side effect profile, cost-effectiveness and other applicable criteria.~~

~~(2) All clinical exceptions are recommended by the Drug~~

~~Utilization Review Board and demonstrated by documentation sent by the prescribing physician and/or pharmacist.~~

The Oklahoma Health Care Authority (OHCA) utilizes a PBPA system pursuant to its authority under 42 United States Code (U.S.C.) Section 1396r-8 and Title 63 of the Oklahoma Statutes (O.S.) § 5030.3(A). The PBPA program, which includes step therapy protocols as defined in 63 O.S. § 7310(A)(4), is not a drug formulary, which is separately authorized in 42 U.S.C. § 1396r-8. In the PBPA system, drugs are placed into two (2) or more tiers based on similarities in clinical efficacy, side-effect profile, and cost-effectiveness, after recommendation by the Drug Utilization Review (DUR) Board and approval by the OHCA Board. Drugs placed in tier one (1) generally require no prior authorization; however, drugs placed in any tier may be subject to prior authorization.

(1) Exceptions to the requirement of prior authorization shall be granted based upon a properly-supported justification submitted by the prescribing provider demonstrating one (1) or more of the bases for exception identified in Oklahoma Administrative Code (OAC) 317:30-5-77.4(b)(3).

(2) The manufacturer or labeler of a product may opt to participate in the state supplemental drug rebate program to move a product from a higher tier to a lower tier which will remove or reduce the prior authorization requirement for that product. Supplemental rebate negotiations are done through Sovereign States Drug Consortium (SSDC); a multi-state purchasing pool.

(A) Supplemental rebate agreements shall be in effect for one (1) year and may be terminated at the option of either party with a sixty (60) day notice. Supplemental rebate agreements are subject to the approval of the Centers for Medicare and Medicaid Services (CMS). Termination of a supplemental rebate agreement will result in the specific product reverting to the previously assigned higher tier in the PBPA program.

(B) Drugs or drug categories which are not part of the PBPA program as outlined in 63 O.S. § 5030.5 may be eligible for supplemental rebate participation. The OHCA DUR Board may recommend supplemental rebate eligibility for drugs or drug categories after considering clinical efficacy, side effect profile, cost-effectiveness, and other applicable criteria.

317:30-5-77.4. Step therapy exception process

(a) **Definitions.**

(1) **"Exigent circumstances"** means circumstances in which a delay in receiving a prescription drug will jeopardize the member's life or health or ability to attain, maintain, or regain maximum function.

(2) **"Step therapy"** or **"step therapy protocol"** means a protocol

or program that establishes a specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient are covered by Medicaid. Step therapy protocols are based upon the recommendation of the Drug Utilization Review (DUR) Board, as approved by the Oklahoma Health Care Authority (OHCA) Board.

(3) A **"step therapy exception"** means the process by which a step therapy protocol is overridden in favor of immediate coverage of a SoonerCare provider's selected prescription drug.

(b) **Process.** The step therapy exception process shall be initiated by a SoonerCare provider on behalf of a SoonerCare member. An exception can be requested following a denial of a prior authorization request for the specified prescription drug(s), or can be requested at the outset. In either case, the provider shall:

(1) Submit the exception request using the step therapy exception request form, which is available on the OHCA website and/or provider portal; and

(2) Submit with the step therapy exception request form, documentation or other information adequate to support the medical necessity for overriding the otherwise-applicable step therapy protocol for the particular prescription drug.

(3) A properly-supported step therapy exception request will be granted if it demonstrates that any of the following circumstances exists:

(A) The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient;

(B) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug;

(C) The patient has tried the required prescription drug while under the patient's current or a previous health insurance plan and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(D) The required prescription drug is not in the best interest of the patient, based on medical necessity; or

(E) The patient is stable on a prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on the patient's current or a previous health insurance plan.

(4) The OHCA or its contractor or designee may request additional information that is reasonably necessary to determine whether a step therapy exception request should be granted, as provided by Oklahoma law.

(c) **Notification.**

(1) The OHCA or its contractor or designee shall respond to any

step therapy exception request within seventy-two (72) hours of the submission of a completed and properly-supported request. For exigent circumstances, the OHCA shall respond to the exception request within twenty-four (24) hours of receipt. Provided, however, that if the timeframe for response ends on a weekend, or on any other day the OHCA is closed or closes early, including, but not limited to, legal holidays as defined by 25 O.S. § 82.1, the timeframe for response shall run until the close of the next full business day. Any exception request not responded to within this timeframe shall be deemed granted.

(2) The OHCA shall respond to a request for a step therapy exception by:

(A) Notifying the provider that the request is approved;

(B) Notifying the provider that the request is not approved based on medical necessity;

(C) Notifying the provider that the medical necessity of the requested exception cannot be approved or denied as a result of missing or incomplete documentation or information necessary to approve or disapprove the request;

(D) Notifying the provider that the member is no longer eligible for coverage; or

(E) Notifying the provider that the step therapy exemption request cannot be processed because it was not properly submitted using the required form.

(3) The rejection of a step therapy exception request based upon missing or incomplete documentation or other information, or because it was not properly submitted using the required form is not a denial, and shall not be subject to further appeal. It must, instead, be resubmitted as a new request for exception pursuant to this rule before it will be considered for approval.

(d) **Appeal.** If a step therapy exception request is denied, an appeal may be initiated by the member within thirty (30) days of the denial pursuant to Oklahoma Administrative Code (OAC) 317:2-1-18.