

Oklahoma Health Care Authority

It is very important that you provide your comments regarding the proposed rule change by the comment due date. Comments are directed to the [Oklahoma Health Care Authority \(OHCA\) Proposed Changes Blog](#).

OHCA COMMENT DUE DATE: July 14, 2017

The proposed policy is an Emergency Rule. The proposed policy was presented at the May 23, 2017 Tribal Consultation and is scheduled to be presented to the Medical Advisory Committee on July 20, 2017 and the OHCA Board of Directors on August 10, 2017.

Reference: APA WF #17-06

SUMMARY:

Pharmacy Revisions – The proposed pharmacy revisions reduce brand name prescriptions and remove coverage of optional non-prescription drugs for adults.

LEGAL AUTHORITY

The Oklahoma Health Care Authority Board; The Oklahoma Health Care Authority Act, Section 5003 through 5016 of Title 63 of Oklahoma Statutes; Article 10, Section 23 of the Oklahoma Constitution

RULE IMPACT STATEMENT:

**STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY**

TO: Tywanda Cox
Federal and State Policy

FROM: Tatiana Reed
Federal and State Authorities

SUBJECT: Rule Impact Statement
APA WF # 17-06

A. Brief description of the purpose of the rule:

The proposed pharmacy revisions reduce brand name prescriptions from two (2) to one (1) per month per eligible non-institutionalized and non-wavier adult member. In addition, revisions add that some drugs will be excluded from the brand limit when the branded drug is preferred over the generic due to net cost, however, these drugs will still count toward the six (6) prescription monthly limit. Revisions also remove coverage

of optional non-prescription drugs for adults. (Insulin, nicotine replacement products for smoking cessation, and family planning products are not optional.) Additionally, compounded prescriptions for topical use will require a prior authorization for allowable cost exceeding a pre-determined limit. The purpose of the rule is to limit or reduce spending for brand name drugs and non-prescription products, and to ensure the compounded medications are medically necessary. Further, revisions clarify policy that was inadvertently missed. Rules clean up language by correcting the number of prescriptions allowed for adults receiving services under the 1915 (c) Home and Community-Based Services Waivers from two to three which will align with current practices.

- 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:

Adult SoonerCare members who receive more than one brand name prescription per month and optional non-prescription drugs will most likely be affected by the proposed rule. Also, adult SoonerCare members who receive coverage for optional non-prescription drugs will most likely be affected.

Pharmacy providers who are reimbursed for compound prescription for topical use will most likely be affected due to the required prior authorization.

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

The proposed rule will benefit the taxpayers of Oklahoma by assuring medical necessity is met.

- 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 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 rule that reduces the monthly brand limit from two to one will result in a total budget savings of \$13.5 million for SFY 2018; State Share \$5.5 million; Federal Share \$8.0 million.

The proposed rule that removes coverage of optional non-prescription drugs for adults will result in a total budget savings of \$825,000 for SFY 2018; State Share \$338,992.5; Federal Share \$486,007.50.

- 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 will not have an adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.

- 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.

- 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 should have no 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:

The Agency has determined that the proposed rules will have no detrimental effect on the public health, safety and environment

if they are not implemented.

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

Prepared: May 31, 2017

RULE TEXT

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

SUBCHAPTER 3. GENERAL PROVIDER POLICIES

PART 3. GENERAL MEDICAL PROGRAM INFORMATION

317:30-3-57. General SoonerCare coverage - categorically needy

The following are general SoonerCare coverage guidelines for the categorically needy:

- (1) Inpatient hospital services other than those provided in an institution for mental diseases.
 - (A) Adult coverage for inpatient hospital stays as described at OAC 317:30-5-41.
 - (B) Coverage for members under 21 years of age is not limited. All admissions must be medically necessary. All psychiatric admissions require prior authorization for an approved length of stay.
- (2) Emergency department services.
- (3) Dialysis in an outpatient hospital or free standing dialysis facility.
- (4) Outpatient therapeutic radiology or chemotherapy for proven malignancies or opportunistic infections.
- (5) Outpatient surgical services - facility payment for selected outpatient surgical procedures to hospitals which have a contract with OHCA.
- (6) Outpatient Mental Health Services for medical and remedial care including services provided on an outpatient basis by certified hospital based facilities that are also qualified mental health clinics.
- (7) Rural health clinic services and other ambulatory services furnished by rural health clinic.
- (8) Optometrists' services - only as listed in Subchapter 5, Part 45, Optometrist specific rules of this Chapter.
- (9) Maternity Clinic Services.
- (10) Outpatient diagnostic x-rays and lab services. Other outpatient services provided to adults, not specifically addressed, are covered only when prior authorized by the agency's Medical Authorization Unit.

(11) Medically necessary screening mammography. Additional follow-up mammograms are covered when medically necessary.

(12) Nursing facility services (other than services in an institution for tuberculosis or mental diseases).

(13) Early and Periodic Screening, Diagnosis and Treatment Services (EPSDT) are available for members under 21 years of age to provide access to regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. Federal regulations also require that diagnosis and treatment be provided for conditions identified during a screening whether or not they are covered under the State Plan, as long as federal funds are available for these services. These services must be necessary to ameliorate or correct defects and physical or mental illnesses or conditions and require prior authorization. EPSDT/OHCA Child Health services are outlined in OAC 317:30-3-65.2 through 317:30-3-65.4.

(A) Child health screening examinations for eligible children by a medical or osteopathic physician, physician assistant, or advanced practice nurse practitioner.

(B) Diagnostic x-rays, lab, and/or injections when prescribed by a provider.

(C) Immunizations.

(D) Outpatient care.

(E) Dental services as outlined in OAC 317:30-3-65.8.

(F) Optometrists' services. The EPSDT periodicity schedule provides for at least one visual screening and glasses each 12 months. In addition, payment is made for glasses for children with congenital aphakia or following cataract removal. Interperiodic screenings and glasses at intervals outside the periodicity schedule for optometrists are allowed when a visual condition is suspected. Payment is limited to two glasses per year. Any glasses beyond this limit must be prior authorized and determined to be medically necessary.

(G) Hearing services as outlined in OAC 317:30-3-65.9.

(H) Prescribed drugs.

(I) Outpatient Psychological services as outlined in OAC 317:30-5-275 through OAC 317:30-5-278.

(J) Inpatient Psychotherapy services and psychological testing as outlined in OAC 317:30-5-95 through OAC 317:30-5-97.

(K) Transportation. Provided when necessary in connection with examination or treatment when not otherwise available.

(L) Inpatient hospital services.

(M) Medical supplies, equipment, appliances and prosthetic devices beyond the normal scope of SoonerCare.

(N) EPSDT services furnished in a qualified child health center.

(14) Family planning services and supplies for members of child-bearing age, including counseling, insertion of intrauterine device, implantation of subdermal contraceptive device, and sterilization for members 21 years of age and older who are legally competent, not institutionalized and have signed the "Consent Form" at least 30 days prior to procedure. Reversal of sterilization procedures for the purposes of conception is not covered. Reversal of sterilization procedures are covered when medically indicated and substantiating documentation is attached to the claim.

(15) Physicians' services whether furnished in the office, the member's home, a hospital, a nursing facility, ICF/IID, or elsewhere. For adults, payment is made for compensable hospital days described at OAC 317:30-5-41. Office visits for adults are limited to four per month except when in connection with conditions as specified in OAC 317:30-5-9(b).

(16) Medical care and any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law. See applicable provider section for limitations to covered services for:

- (A) Podiatrists' services
- (B) Optometrists' services
- (C) Psychologists' services
- (D) Certified Registered Nurse Anesthetists
- (E) Certified Nurse Midwives
- (F) Advanced Practice Nurses
- (G) Anesthesiologist Assistants

(17) Free-standing ambulatory surgery centers.

(18) Prescribed drugs not to exceed a total of six prescriptions with a limit of ~~two~~ one brand name ~~prescriptions~~ prescription per month. Exceptions to the six prescription limit are:

- (A) unlimited medically necessary monthly prescriptions for:
 - (i) members under the age of 21 years; and
 - (ii) residents of Nursing Facilities or Intermediate Care Facilities for Individuals with Intellectual Disabilities.
- (B) seven medically necessary generic prescriptions per month in addition to the six covered under the State Plan (including three brand name prescriptions) are allowed for adults receiving services under the 1915(c) Home and Community Based Services Waivers. These additional medically necessary prescriptions beyond the ~~two~~ three brand name or thirteen total prescriptions are covered with prior authorization.

(19) Rental and/or purchase of durable medical equipment.

(20) Adaptive equipment, when prior authorized, for members residing in private ICF/IID's.

(21) Dental services for members residing in private ICF/IID's in accordance with the scope of dental services for members under age 21.

(22) Prosthetic devices limited to catheters and catheter accessories, colostomy and urostomy bags and accessories, tracheostomy accessories, nerve stimulators, hyperalimentation and accessories, home dialysis equipment and supplies, external breast prostheses and support accessories, oxygen/oxygen concentrator equipment and supplies, respirator or ventilator equipment and supplies, and those devices inserted during the course of a surgical procedure.

(23) Standard medical supplies.

(24) Eyeglasses under EPSDT for members under age 21. Payment is also made for glasses for children with congenital aphakia or following cataract removal. Payment is limited to two glasses per year. Any glasses beyond this limit must be prior authorized and determined to be medically necessary.

(25) Blood and blood fractions for members when administered on an outpatient basis.

(26) Inpatient services for members age 65 or older in institutions for mental diseases, limited to those members whose Medicare, Part A benefits are exhausted for this particular service and/or those members who are not eligible for Medicare services.

(27) Nursing facility services, limited to members preauthorized and approved by OHCA for such care.

(28) Inpatient psychiatric facility admissions for members under 21 are limited to an approved length of stay effective July 1, 1992, with provision for requests for extensions.

(29) Transportation and subsistence (room and board) to and from providers of medical services to meet member's needs (ambulance or bus, etc.), to obtain medical treatment.

(30) Extended services for pregnant women including all pregnancy-related and postpartum services to continue to be provided, as though the women were pregnant, for 60 days after the pregnancy ends, beginning on the last date of pregnancy.

(31) Nursing facility services for members under 21 years of age.

(32) Personal care in a member's home, prescribed in accordance with a plan of treatment and rendered by a qualified person under supervision of a R.N.

(33) Part A deductible and Part B Medicare Coinsurance and/or deductible.

(34) Home and Community Based Waiver Services for the intellectually disabled.

(35) Home health services limited to 36 visits per year and standard supplies for ~~one~~ (1) month in a 12-month period. The visits are limited to any combination of Registered Nurse and nurse aide visits, not to exceed 36 per year.

(36) Medically necessary solid organ and bone marrow/stem cell transplantation services for children and adults are covered services based upon the conditions listed in (A)-(D) of this

paragraph:

(A) Transplant procedures, except kidney and cornea, must be prior authorized to be compensable.

(B) To be prior authorized all procedures are reviewed based on appropriate medical criteria.

(C) To be compensable under the SoonerCare program, all transplants must be performed at a facility which meets the requirements contained in Section 1138 of the Social Security Act.

(D) Finally, procedures considered experimental or investigational are not covered.

(37) Home and community-based waiver services for intellectually disabled members who were determined to be inappropriately placed in a ~~NF~~Nursing Facility (Alternative Disposition Plan - ADP).

(38) Case Management services for the chronically and/or severely mentally ill.

(39) Emergency medical services including emergency labor and delivery for illegal or ineligible aliens.

(40) Services delivered in Federally Qualified Health Centers. Payment is made on an encounter basis.

(41) Early Intervention services for children ages 0-3.

(42) Residential Behavior Management in therapeutic foster care setting.

(43) Birthing center services.

(44) Case management services through the Oklahoma Department of Mental Health and Substance Abuse Services.

(45) Home and Community-Based Waiver services for aged or physically disabled members.

(46) Outpatient ambulatory services for members infected with tuberculosis.

(47) Smoking and Tobacco Use Cessation Counseling for children and adults.

(48) Services delivered to American Indians/Alaskan Natives in I/T/Us. Payment is made on an encounter basis.

(49) OHCA contracts with designated agents to provide disease state management for individuals diagnosed with certain chronic conditions. Disease state management treatments are based on protocols developed using evidence-based guidelines.

SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALITIES

PART 5. PHARMACIES

317:30-5-72. Categories of service eligibility

(a) **Coverage for adults.** Prescription drugs for categorically needy adults are covered as set forth in this subsection.

(1) With the exception of (2) and (3) of this subsection,

categorically needy adults are eligible for a maximum of six covered prescriptions per month with a limit of ~~two~~one brand name ~~prescriptions~~prescription. A prior authorization may be granted for a ~~third~~second brand name if determined to be medically necessary by OHCA and if the member has not already utilized their six covered prescriptions for the month.

(2) Subject to the limitations set forth in OAC 317:30-5-72.1, OAC 317:30-5-77.2, and OAC 317:30-5-77.3, exceptions to the six medically necessary prescriptions per month limit are:

(A) unlimited monthly medically necessary prescriptions for categorically related individuals who are residents of Nursing Facilities or Intermediate Care Facilities for ~~the Mentally Retarded~~Individuals with Intellectual Disabilities; and

(B) seven additional medically necessary prescriptions which are generic products per month to the six covered under the State Plan (including three brand name prescriptions) are allowed for adults receiving services under the 1915(c) Home and Community Based Services Waivers. Medically necessary prescriptions beyond the ~~two~~three brand name or thirteen total prescriptions will be covered with prior authorization.

(3) Drugs exempt from the prescription limit include: Antineoplastics, anti-retroviral agents for persons diagnosed with Acquired Immune Deficiency Syndrome (AIDS) or who have tested positive for the Human Immunodeficiency Virus (HIV), certain prescriptions that require frequent laboratory monitoring, birth control prescriptions, over the counter contraceptives, hemophilia drugs, compensable smoking cessation products, low-phenylalanine formula and amino acid bars for persons with a diagnosis of PKU, certain carrier or diluent solutions used in compounds (i.e. sodium chloride, sterile water, etc.), and drugs used for the treatment of tuberculosis. For purposes of this Section, exclusion from the prescription limit means claims filed for any of these prescriptions will not count toward the prescriptions allowed per month.

(4) When a brand drug is preferred over its generic equivalent due to lower net cost, that drug shall not count toward the brand limit; however, it will count toward the monthly prescription limit.

(b) **Coverage for children.** Prescription drugs for SoonerCare eligible individuals under 21 years of age are not limited in number per month, but may be subject to prior authorization, quantity limits or other restrictions.

(c) **Individuals eligible for Part B of Medicare.** Individuals eligible for Part B of Medicare are also eligible for the Medicare Part D prescription drug benefit. Coordination of benefits between Medicare Part B and Medicare Part D is the responsibility of the pharmacy provider. The SoonerCare pharmacy benefit does not include any products which are available through either Part B or Part D of

Medicare.

(d) **Individuals eligible for a prescription drug benefit through a Prescription Drug Plan (PDP) or Medicare Advantage - Prescription Drug (MA-PD) plan as described in the Medicare Modernization Act (MMA) of 2003.** Individuals who qualify for enrollment in a PDP or MA-PD are specifically excluded from coverage under the SoonerCare pharmacy benefit. This exclusion applies to these individuals in any situation which results in a loss of Federal Financial Participation for the SoonerCare program. This exclusion shall not apply to items covered at OAC 317:30-5-72.1(2) unless those items are required to be covered by the prescription drug provider in the MMA or subsequent federal action.

317:30-5-72.1. Drug benefit

OHCA administers and maintains an Open Formulary subject to the provisions of Title 42, United States Code (U.S.C.), Section 1396r-8. The OHCA covers a drug that has been approved by the Food and Drug Administration (FDA) and whose manufacturers have entered into a drug rebate agreement with the Centers for Medicare and Medicaid Services (CMS), subject to the following exclusions and limitations.

(1) The following drugs, classes of drugs, or their medical uses are excluded from coverage:

- (A) Agents used to promote fertility.
- (B) Agents primarily used to promote hair growth.
- (C) Agents used for cosmetic purposes.
- (D) Agents used primarily for the treatment of anorexia or weight gain. Drugs used primarily for the treatment of obesity, such as appetite suppressants are not covered. Drugs used primarily to increase weight are not covered unless otherwise specified.
- (E) Agents that are investigational, experimental or whose side effects make usage controversial.
- (F) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or designee.
- (G) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(2) The drug categories listed in (A) through (D) of this paragraph are covered at the option of the state and are subject to restrictions and limitations. An updated list of products in each of these drug categories is included on the OHCA's public website.

- (A) Agents used for the ~~systematic~~symptomatic relief of cough

and colds. ~~Antihistamines for allergies or antihistamine use associated with asthmatic conditions may be covered when medically necessary and prior authorized.~~

(B) Vitamins and Minerals. Vitamins and minerals are not covered except under the following conditions:

- (i) prenatal vitamins are covered for pregnant women up to age 50;
- (ii) fluoride preparations are covered for persons under 16 years of age or pregnant;
- (iii) vitamin D, metabolites, and analogs when used to treat end stage renal disease are covered;
- (iv) iron supplements may be covered for pregnant women if determined to be medically necessary;
- (v) vitamin preparations may be covered for children less than 21 years of age when medically necessary and furnished pursuant to EPSDT protocol; and
- (vi) some vitamins are covered for a specific diagnosis when the FDA has approved the use of that vitamin for a specific indication.

(C) Coverage of non-prescription or over the counter drugs is limited to:

- ~~(i) Insulin, PKU formula and amino acid bars, other certain nutritional formulas and bars for children diagnosed with certain rare metabolic conditions;~~
- (ii) certain smoking cessation products;
- (iii) family planning products;
- (iv) OTC products may be covered for children if the particular product is both cost-effective and clinically appropriate; and
- (v) prescription and non-prescription products which do not meet the definition of outpatient covered drugs, but are determined to be medically necessary.

(D) Coverage of food supplements is limited to PKU formula and amino acid bars for members diagnosed with PKU, other certain nutritional formulas and bars for children diagnosed with certain rare metabolic conditions when medically necessary and prior authorized.

(3) All covered outpatient drugs are subject to prior authorization as provided in OAC 317:30-5-77.2 and 317:30-5-77.3.

(4) All covered drugs may be excluded or coverage limited if:

- (A) the prescribed use is not for a medically accepted indication as provided under 42 U.S.C. § 1396r-8; or
- (B) the drug is subject to such restriction pursuant to the rebate agreement between the manufacturer and CMS.

317:30-5-77.2. Prior authorization

(a) **Definition.** The term prior authorization in pharmacy means an

approval for payment by 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 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 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 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 24 hours. Petitions and other claim forms are available on the OHCA public website.

(d) **Emergencies.** In an emergency situation the Health Care Authority will authorize a 72 hour supply of medications to a member. The authorization for a 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 reasons for the use of prior authorization: utilization controls, scope controls and product based controls. Product based prior authorization is covered in OAC 317:30-5-77.3. The Drug Utilization Review 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 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 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.

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