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: February 16, 2018

The proposed policy was submitted to the Medical Advisory Committee on July 20, 2017 as an Emergency Rule. The Emergency Rule was presented for Tribal Consultation on May 23, 2017. The proposed *Permanent Rule* is scheduled to be presented for Tribal Consultation on January 2, 2018, to the Medical Advisory Committee on March 15, 2018 and to the OHCA Board of Directors on March 22, 2018.
Reference: APA WF #17-06

SUMMARY:
Pharmacy revisions – The proposed pharmacy revisions will amend coverage and prior authorization of non-prescription drugs and compounded prescriptions, discontinue coverage of over the counter antihistamines for adults, and exempt naloxone for use in opioid overdose from the prescription limit. The proposed changes will also clarify claim submission and reversals when not picked up by the member within 15 days of the date of service, and update pharmacy policy to align with current practice.

LEGAL AUTHORITY

The Oklahoma Health Care Authority Act, Section 5007 (F)(1) and (3) of Title 63 of Oklahoma Statutes; Section 5003 through 5016 of Title 63 of Oklahoma Statutes; The Oklahoma Health Care Authority Board; Article 10, Section 23 of the Oklahoma Constitution; Oklahoma Administrative Code 535:15-3-9; The Oklahoma Pharmacy Act

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

TO: Tywanda Cox
Federal and State Policy

FROM: Vanessa Andrade
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 removed 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 required a prior authorization for allowable cost exceeding a pre-determined limit. Rules amended the number of prescriptions allowed for adults receiving services under the 1915 (c) Home and Community-Based Services Waivers from two to three, which aligned policy with current practices. **The aforementioned changes were approved during promulgation of the emergency rule. The following are proposed changes not previously reviewed:**

The proposed pharmacy revisions will clarify eligible provider qualifications for pharmacies. Revisions will outline that pharmacies may be selected for audits; therefore, pharmacy records must be available for seven years. Language regarding Phenylketonuria (PKU) formula and amino acid bars is stricken as coverage criteria is outlined in another section of policy. Additionally, naloxone for use in opioid overdose will be exempted from the prescription limit. Revisions will also remove coverage for over the counter cough and cold medicine. New rules will require providers to substitute generic medications for brand name medication when the net cost of the brand name is lower than the net cost of the generic medication. Furthermore, language will clarify and outline claim submission and reversals when not picked up by the member within 15 days of the date of service. Finally, revisions will update policy terminology to align with current practice.

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:

Pharmacy providers that do not currently retain records for seven years for audit purposes may be burdened with the new recordkeeping requirement.

Pharmacy providers who have received payment for prescriptions not picked up by the member within 15 days of the date of service will most likely be affected due to the required reversal of the claim and submission of a new claim for the quantity actually dispensed.

Members who currently receive over the counter cough and cold medicine may be impacted; however, the impact should be minimal, if any.

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 economic 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:

Savings regarding the removal of coverage of optional non-prescription drugs for adults were approved during promulgation of the emergency rule; the rule change will not result in any additional costs and/or savings to the agency.

The proposed rule that exempts the drug naloxone for use in opioid overdose from the prescription limit will result in a minimal budget impact, if any. Due to the minimal budget impact, the agency is unable to provide a measurable budget impact.

The proposed rule that removes coverage for over the counter cough and cold medicine will result in a minimal budget impact, if any. Due to the minimal budget impact, the agency is unable to provide a measurable budget impact.

The proposed rule that requires pharmacy providers who have received payment for prescriptions not picked up by the member within 15 days of the date of service to reverse the claim and submit a new claim for the quantity actually dispensed will result in savings; however until changes are implemented, the agency is unable to project the savings amount.

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: December 20, 2017
Modified: January 11, 2018

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~~twenty-one (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~~the Oklahoma Health Care Authority (OHCA).

(6) Outpatient ~~Mental Health Services~~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~~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~~twenty-one (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 (1) visual screening and glasses each ~~12~~twelve (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 (2) 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~~psychological services as outlined in OAC 317:30-5-275 through ~~OAC~~ 317:30-5-278.
(J) Inpatient ~~Psychotherapy~~psychiatric 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~~twenty-one (21) years of age and older who are legally competent, not institutionalized and have signed the "Consent Form" at least ~~30~~thirty (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~~ Intermediate Care Facilities for Individuals with Intellectual Disabilities (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 (4) 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~~state law, furnished by licensed practitioners within the scope of their practice as defined by ~~State~~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 (6) prescriptions with a limit of two (2) brand name prescriptions per month. Exceptions to the six (6) prescription limit are:

(A) unlimited medically necessary monthly prescriptions for:
(i) members under the age of ~~21~~twenty-one (21) years; and
(ii) residents of ~~Nursing Facilities~~nursing facilities or ~~Intermediate Care Facilities for Individuals with Intellectual Disabilities~~ICF/IID.

(B) seven (7) medically necessary generic prescriptions per month in addition to the six (6) covered under the State Plan (including three (3) brand name prescriptions) are allowed for adults receiving services under the 1915(c) Home and Community Based Services Waivers (HCBS). These additional medically necessary prescriptions beyond the ~~two~~three (3) brand name or thirteen (13) 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~~twenty-one (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~~twenty-one (21). Payment is also made for glasses for children with congenital aphakia or following cataract removal. Payment is limited to two (2) 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~~sixty-five (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~~twenty-one (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~~sixty (60) days after the pregnancy ends, beginning on the last date of pregnancy.
(31) Nursing facility services for members under ~~21~~twenty-one (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.~~Registered Nurse (RN).
(33) Part A deductible and Part B Medicare Coinsurance and/or deductible.
(34) ~~Home and Community Based Waiver Services~~HCBS for the intellectually disabled.
(35) Home health services limited to ~~36~~thirty-six (36) visits per year and standard supplies for ~~1~~one (1) month in a ~~12-~~twelve (12) month period. The visits are limited to any combination of ~~Registered Nurse~~RN and nurse aide visits, not to exceed ~~36~~thirty-six (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~~HCBS for intellectually disabled members who were determined to be inappropriately placed in a ~~NF~~nursing facility (Alternative Disposition Plan - ADP).
(38) Case ~~Management~~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~~intervention services for children ages ~~0-3~~zero (0) to three (3).
(42) Residential ~~Behavior Management~~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~~HCBS for aged or physically disabled members.
(46) Outpatient ambulatory services for members infected with tuberculosis.
(47) Smoking and ~~Tobacco Use Cessation Counseling~~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 SPECIALTIES

PART 5. PHARMACIES

317:30-5-70. Eligible providers

~~Eligible providers are:~~
~~(1) entities licensed under Title 59 O.S. 353.9 as pharmacies, or~~
~~(2) entities licensed under another state's law as a pharmacy.~~
Eligible providers are entities licensed under applicable provisions of Oklahoma law as pharmacies, including non-resident pharmacies not located in Oklahoma that are transacting or doing business in Oklahoma by soliciting, receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

317:30-5-70.1. Pharmacist responsibility

Eligible providers in the SoonerCare program are expected to act in accordance with the rules of professional conduct as promulgated

by the Oklahoma Board of Pharmacy~~(or the state's rules of professional conduct where the pharmacy is licensed) under Title 59 O.S. 353.7(12).~~, 59 Oklahoma Statutes, Sec. 353.7(12). A pharmacist may refuse to dispense any prescription which appears to be improperly executed or which, in their professional judgment, is unsafe as presented.

317:30-5-70.2. Record retention/ Post ~~Payment Review~~payment review

Post-payment audits of the SoonerCare program are performed routinely by state and federal agencies. This Section applies to any post-payment audit regardless of the agency performing the audit. Pharmacies ~~are~~may be selected at random, as a result of a peer comparison, or data analysis for audits. The ~~Pharmacy~~pharmacy is required to provide original written prescriptions and signature logs as well as purchase invoices and other records necessary to document their compliance with program guidelines at the time of the audit. Written prescriptions must conform with the standards set forth in ~~42 USC 1396b(i)~~42 United States Code, Sec. 1396b(i) and related federal regulations requiring the use of a tamper-resistant prescription pad. These standards do not apply to prescriptions transmitted via telephone, facsimile or electronic prescription systems. Original written prescriptions are defined as any order for drug or medical supplies written or signed, or transmitted by word of mouth, telephone or other means of communication by a practitioner licensed by law to prescribe such drugs and medical supplies intended to be filled, compounded, or dispensed by a pharmacist. Signature logs are defined as any document which verifies that the prescription was delivered to the member or their representative. This may include electronic forms of tracking including but not limited to scanning a bar code of the filled prescription. The electronic tracking system must be able to produce a copy of the scan for audit purposes. Records must be available for seven (7) years. Failure to provide the requested information to the Reviewer may result in a recommendation ranging from a potential recoupment of SoonerCare payments for the service to contract termination.

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 (6) covered prescriptions per month with a limit of two (2) brand name prescriptions. A prior authorization may be granted for a third brand name if determined to be medically necessary by OHCA and if the member has not already utilized their six (6) 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 (6) medically necessary prescriptions per month limit are:

(A) unlimited monthly medically necessary prescriptions for categorically related individuals who are residents of ~~Nursing Facilities~~nursing facilities or ~~Intermediate Care Facilities for the Mentally Retarded~~ICF/IID; and

(B) seven (7) additional medically necessary prescriptions which are generic products per month to the six (6) covered under the State Plan (including three (3) brand name prescriptions) are allowed for adults receiving services under the 1915(c) ~~Home and Community Based Services~~HCBS Waivers. Medically necessary prescriptions beyond the ~~two~~three (3) brand name or thirteen (13) 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,~~naloxone for use in opioid overdose, 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~~twenty-one (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~~42 U.S.C. § 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~~.~~ including agents that have been approved by the FDA but are being investigated for additional indications.

(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~~FDA.

(H) Agents used for the symptomatic relief of cough and colds.

(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 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)~~(A) 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 fifty (50)~~;

(ii) fluoride preparations are covered for persons under ~~16~~sixteen (16) years of age or pregnant;

(iii) vitamin D, metabolites, and analogs when used to treat chronic kidney disease or 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~~twenty-one (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)~~(B) 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)~~(C) 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.

317:30-5-76. Generic drugs

All eligible providers are required to substitute generic medications for prescription name brand medications with the exception of prescriptions in which a brand necessary certification

as provided in OAC 317:30-5-77 is made by a prescribing provider~~.~~ or when the agency has notified pharmacy providers that the net cost of the brand name medication is lower than the net cost of the generic medication.

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~~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 ~~30~~thirty (30) days, claims will be denied.

(c) **Documentation.** Prior ~~Authorization~~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~~pharmacy help desk. Authorization petitions with complete information are reviewed and a response returned to the dispensing pharmacy within ~~24~~twenty-four (24) hours. Petitions and other claim forms are available on the OHCA public website.

(d) **Emergencies.** In an emergency situation the ~~Health Care Authority~~OHCA will authorize a ~~72~~seventy-two (72) hour supply of medications to a member. The authorization for a ~~72~~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 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.

317:30-5-78.1. Special billing procedures

(a) **Antihemophiliac Factor (AHF) Products.** AHF products are sold by the amount of drug (International Units of AHF) in the container. For their products, regardless of the container size, the package size is always "1". Therefore, pricing assumes that the "package size" actually dispensed is the actual number of units dispensed. Examples: If 250 AHF units are dispensed and multiplied by a unit cost of $.25, the allowable cost would be $62.50. Metric Quantity is shown as 250; if 500 AHF units are dispensed and multiplied by a unit cost of $.25, the allowable would be $125.00. Metric Quantity is shown as 500.

(b) **Compound and intravenous drugs.** Prescriptions claims for compound and Intravenous (IV) drugs are billed and reimbursed using the NDC number and quantity for each compensable ingredient in the compound or IV, up to 25 ingredients. Ingredients without an NDC number are not compensable. A dispensing fee as described in OAC 317:30-5-78(c) is added to the total ingredient cost.

(c) ~~**Co-Payment**~~ **Coordination of benefits.** Pharmacies must pursue all third party resources before filing a claim with the OHCA as set out in ~~42 CFR 433.139~~State Fiscal Administration, 42 Code of Federal Regulation, Sec. 433.139.

(d) **Over-the-counter drugs.** Payment for covered over-the-counter medication is made according to the reimbursement methodology in OAC 317:30-5-78(d).

(e) **Individuals eligible for Part B of Medicare.** Payment is made utilizing the SoonerCare allowable for comparable services. The appropriate Durable Medical Equipment Regional Carrier ~~(DMERC)~~must be billed prior to billing OHCA for all Medicare compensable drugs. Part B crossover claims cannot be submitted through the pharmacy point of sale system and must be submitted using the CMS 1500 form or electronic equivalent.

(f) **Claims for prescriptions which are not picked up.** A prescription for a member which has been submitted to and approved for payment by OHCA which has not been received by the member within ~~15~~fifteen (15) days of the date of service must be reversed no later than the 15th day after claim submission. An electronic reversal will cause a refund to be generated to the agency. Claims may also be reversed using a manual process if electronic reversal is not possible. For the purpose of this Section, the date of service means the date the prescription was filled.

~~(g) **Non-prescription products.** The coverage of non-prescription products that are determined to be medically necessary must be billed through the pharmacy point of sale system.~~

(g) **Partially–filled prescriptions**. If a member has not picked up the remainder of any partially-filled prescription within fifteen (15) days of the date of service, the claim must be reversed on the 15th day and a new claim submitted for the quantity actually dispensed.