TITLE 317. OKLAHOMA HEALTH CARE AUTHORITY
CHAPTER 30. MEDICAL PROVIDERS-FEE FOR SERVICE
SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES
PART 5. PHARMACIES

317:30-5-72. 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 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 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; and

(B) seven additional medically necessary prescriptions which are generic products per month to the six covered under the State Plan are allowed for adults receiving services under the ~~915(c)~~ 1915(c) Home and Community Based Services Waivers. Medically necessary prescriptions beyond the two 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.

(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. The exclusion will become effective January 1, 2006, or the date Medicare Part D is implemented for dual eligible individuals, whichever is later. 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 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.

(2) The drug categories listed in (A) through (E) 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) 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; ~~and~~

(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) Agents used for smoking cessation. A limited smoking cessation benefit is available.

(D) 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 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.

(E) 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.

317:30-5-77.3. Product

(a) The Oklahoma Health Care Authority utilizes a prior authorization system subject to their authority under ~~42 U.S.C. 396r-8~~ 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. 396r-8~~ 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 OHCA Board approval. Drugs placed in tier number one require no prior authorization. Drugs placed in any tier other than tier number one require prior authorization.

(1) Three 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 avoid a prior authorization 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 determine 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 pharmacist.

(b) Additional therapeutic categories of drugs will be subject to subsection (a) of this Section if recommended by the Drug Utilization Review Board, considered by the Medical Advisory Committee and approved by the OHCA Board.

317:30-5-78. Reimbursement

(a) **Reimbursement**. Reimbursement for pharmacy claims is based on the sum of an estimate of the ingredient cost plus a dispensing fee.

(b) **Ingredient Cost.** Ingredient cost is estimated by one of the following methods:

(1) **Maximum Allowable Cost.**

(A) The State Maximum Allowable Cost (SMAC) is established for certain products which have a Food and Drug Administration (FDA) approved generic equivalent. The SMAC will be calculated using prices from pharmaceutical wholesalers who supply these products to pharmacy providers in Oklahoma. Pharmacies may challenge a specific product's SMAC price by providing invoices that reflect a net cost higher than the calculated SMAC price and by certifying that there is not another product available to them which is generically equivalent to the higher priced product.

(B) The Federal Upper Limit (FUL) is established by CMS in accordance with applicable federal laws and regulations.

(C) Injectable drugs which are dispensed by a retail pharmacy through the Vendor Drug Program shall be priced based on a formula equivalent to the Medicare allowed charge whether they are furnished through the pharmacy program or through the medical program.

(2) **The Estimated Acquisition Cost.** The Estimated Acquisition Cost (EAC) means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler. EAC is typically based on a benchmark published price plus or minus a percentage. The current benchmark price is the Average Wholesale Price (AWP) as provided by the OHCA's pricing resource. EAC is calculated as AWP minus 12%. The Wholesale Acquisition Cost (WAC) means the price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. Should the AWP no longer be published by the agency's pricing vendor then the agency will use WAC as the benchmark price whereas the EAC will be calculated as WAC + 5.6%.

Comment [KS1]: Not sure if we needed to remove EAC language.

(c) **Maximum allowable dispensing fee.** The maximum allowable dispensing fee for prescribed medication is established by review of surveys. A recommendation is made by the State Plan Amendment Rate Committee and presented to the Oklahoma Health Care Authority Board for their approval. There may be more than one level or type of dispensing fee if approved by the OHCA Board and CMS. A contracted pharmacy agrees to participate in any survey conducted by the OHCA with regard to dispensing fees. The pharmacy shall furnish all necessary information to determine the cost of dispensing drug products. Failure to participate may result in administrative sanctions by the OHCA which may include but are not limited to a reduction in the dispensing fee.

(d) **Reimbursement for prescription claims.** Prescription claims will be reimbursed using the lower of the following calculation methods:

(1) the lower of estimated acquisition cost, Federal Upper Limit (FUL), or State Maximum Allowable Cost (SMAC) plus a dispensing fee, or

(2) usual and customary charge to the general public. The pharmacy is responsible to determine its usual and customary charge to the general public. The OHCA may conduct periodic reviews within its audit guidelines to verify the pharmacy's usual and customary charge to the general public and the pharmacy agrees to make available to the OHCA's reviewers prescription and pricing records deemed necessary by the reviewers. The OHCA defines general public as the patient group accounting for the largest number of non-SoonerCare prescriptions from the individual pharmacy, but does not include patients who purchase or receive their prescriptions through other third-party payers. If a pharmacy offers discount prices to a portion of its customers (i.e. -10% discount to senior citizens), these lower prices would be excluded from the usual and customary calculations unless the patients receiving the favorable prices represent more than 50% of the pharmacy's prescription volume. The usual and customary charge will be a single price which includes both the product price and the dispensing fee. For routine usual and customary reviews, the pharmacy may provide prescription records for non-SoonerCare customers in a manner which does not identify the customer by name so long as the customer's identity may be determined later if a subsequent audit is initiated. The OHCA will provide the pharmacy notice of its intent to conduct a review of usual and customary charges at least ten days in advance of its planned date of review.

(e) **Payment of Claims.** In order for an eligible provider to be paid for filling a prescription drug, the pharmacy must complete all of the following:

(1) have an existing provider agreement with OHCA,

(2) submit the claim in a format acceptable to OHCA,

(3) have a prior authorization before filling the prescription, if a prior authorization is necessary,

(4) have a proper brand name certification for the drug, if necessary, and

(5) include the usual and customary charges to the general public as well as the estimated acquisition cost and dispensing fee.

(f) **Claims.** Prescription reimbursement may be made only for individuals who are eligible for coverage at the time a prescription is filled. Member eligibility information may be accessed by swiping a SoonerCare identification card through a commercial card swipe machine which is connected to the eligibility database or via the Point of Sale (POS) system when

a prescription claim is submitted for payment. Persons who do not contract with commercial vendors can use the Member Eligibility Verification System (EVS) at no additional cost.