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 Oklahoma Health Care Authority (OHCA) Health Policy Unit http://www.okhca.org/proposed-rule-changes.aspx

OHCA COMMENT DUE DATE: February 17, 2017

The proposed policy was submitted to the Medical Advisory Committee on November 17, 2016 as an emergency policy change. The proposed policy was presented for Tribal Consultation on September 6, 2016. These rules are currently in effect as emergency rules but must be promulgated through the permanent rulemaking process. The proposed Permanent Rule change is scheduled to be presented to the OHCA Board of Directors on March 23, 2017.
Reference: APA WF 16-13

SUMMARY:
16-13 Pharmacy Reimbursement – The proposed policy amends the reimbursement structure for Indian Health Services, Tribal Programs, and Urban Indian Clinics (I/T/U) and non-I/T/U pharmacy providers. Revisions modify the current pharmacy pricing methodology and will allow I/T/U pharmacies to be reimbursed at the federal Office of Management and Budget (OMB) encounter rate. Rules are also revised to modify the current structure for the dispensing fee. Further, policy is revised to remove the limitations for smoking cessation benefits, and to update references to outdated policy.

LEGAL AUTHORITY
The Oklahoma Health Care Authority Board; The Oklahoma Health Care Authority Act, Section 5003 through 5016 of Title 63 of Oklahoma Statutes; 42 CFR 447

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 #16-13

A. Brief description of the purpose of the rule:

The proposed revisions to modify the reimbursement structure for Indian Health Services, Tribal Programs, Urban Indian Clinics (I/T/U), and non-I/T/U pharmacies are requested to comply with Federal regulation. Revisions align reimbursement for covered outpatient drugs with Actual Acquisition Cost and create new pricing terms for specialty pharmaceutical products. Revisions also modify the current dispensing fee to a professional dispensing fee. Additionally, revisions amend the reimbursement structure for I/T/U pharmacies; these pharmacies will be reimbursed at the Federal Office of Management and Budget encounter rate. I/T/U pharmacies will receive one rate per member per facility per day regardless of the number of prescriptions dispensed to the member on that day. Revisions also removed limitations for someone cessation benefits 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:

SoonerCare contracted I/T/U and non-I/T/U pharmacies that are reimbursed for covered outpatient drugs may be impacted by this rule change. The federal government will likely bear the cost associated with the changes as the rates are reimbursed at 100 percent.

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

Members who utilize prescription drug services will benefit due to increased access to pharmacies for medication. I/T/U pharmacies may benefit due to the change in reimbursement as the pharmacies are currently reimbursed fee for service for prescription drugs. For example, the change allows I/T/U pharmacies that may currently bill for one prescription drug with ingredient cost of $12.25, to now bill at the annually calculated OMB rate.

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:

OHCA does not expect a significant economic impact as the ingredient cost is adjusted slightly downward as the dispensing

fee is adjusted upward. This is to more accurately reflect each portion of the pharmacy reimbursement.

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 affect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

The OMB encounter rate is 100 percent federally funded, so there is no anticipated impact to the state budget for the proposed revisions for I/T/U pharmacies. The pharmacy claims for generic drugs will generally increase due to the increased dispensing fee and claims for brand drugs will generally decrease to the decreased ingredient cost. Therefore, the proposed revision for non-I/T/U pharmacies is expected to remain budget neutral.

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 agency has determined that there is no potential adverse effect on small business as a result of the proposed rule change.

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:

There should be no compliance costs associated with the proposed revisions. The SoonerCare claims processing system will automatically calculate the new reimbursement methodology and appropriately price the claim. There is no change for pharmacies in how claims must be submitted to OHCA.

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 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:

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:

The rule impact statement was prepared August 12, 2016.

Modified date: November 18, 2016

RULE TEXT

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

SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES

PART 5. PHARMACIES

317:30-5-72.1. 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 ~~(E)~~(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) 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) Agents used for smoking cessation. A limited smoking cessation benefit is available.~~

~~(D)~~(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 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)~~(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~~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.

317:30-5-78. 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 the 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%.~~

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

for brand and generic drugs dispensed by a retail community pharmacy or for a member residing in a long term care facility.

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

(1) **Maximum Allowable Cost.** 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 information from their wholesaler(s) to certify a net cost higher than the calculated SMAC price and that there is not another product available to them which is generically equivalent to the higher priced product.

(2) **Actual Acquisition Cost.** The Actual Acquisition Cost (AAC) means the cost of a particular drug product to the pharmacy based on a review of invoices or the Wholesale Acquisition Cost (WAC), whichever is lower. The National Average Drug Acquisition Cost (NADAC) is based on a review of invoices and published by Centers for Medicare and Medicaid Services (CMS) and will be used in the determination of AAC.

(3) **Specialty Pharmaceutical Allowable Cost.** Reimbursement for specialty drugs not typically dispensed by a retail community pharmacy and dispensed primarily by delivery, including clotting factor for hemophilia, shall be set as a Specialty Pharmaceutical Allowable Cost (SPAC). The Medicare Part B allowed charge, defined as Average Sales Price (ASP) plus 6%, WAC, and NADAC when available, will be considered in setting the SPAC rate. For the purpose of this section, a drug may be classified as a specialty drug when it has one or more of the following characteristics:

(A) Covered by Medicare Part B;

(B) "5i drug" – Injected, infused, instilled, inhaled, or implanted;

(C) Cost greater than $1,000.00 per claim;

(D) Licensed by the FDA under a Biological License Application;

(E) Special storage, shipping, or handling requirements;

(F) Available only through a limited distribution network; and/or

(G) Does not have a NADAC price from CMS.

(4) **Exceptions.**

(A) Physician administered drugs shall be priced based on a formula equivalent to the Medicare Part B allowed charge, defined as ASP plus 6%. If a price equivalent to the Medicare Part B allowed charge cannot be determined, a purchase invoice may be supplied by the provider and will be considered in setting the reimbursement.

(B) I/T/U pharmacies shall be reimbursed at the OMB encounter rate as a per member per facility per day fee regardless of

the number of prescriptions filled on that day. I/T/U pharmacies should not split prescriptions into quantities less than a one month supply for maintenance medications. For this purpose a maintenance medication is one that the member uses consistently month to month.

(C) Pharmacies other than I/T/U facilities that acquire drugs via the Federal Supply Schedule (FSS) or at nominal price outside the 340B program or FSS shall notify OHCA and submit claims at their actual invoice price plus a professional dispensing fee.

(c) ~~**Maximum allowable**~~ **Professional dispensing fee.** The ~~maximum allowable~~ professional 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~~

(1) the lower of Actual Acquisition Cost (AAC), State Maximum Allowable Cost (SMAC), or Specialty Pharmaceutical Allowable Cost (SPAC) plus a professional 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 and submit it to OHCA on each pharmacy claim. 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~~ actual acquisition cost and professional 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.

317:30-5-87. 340B Drug Discount Program

(a) The purpose of this Section is to provide special provisions for providers participating in the 340B Drug Discount program. The 340B Drug Discount program special provisions apply to a provider that has asserted it is a "covered entity" or a contract pharmacy for a covered entity under the provisions of 42 U.S.C. § 256b of the United States Code (otherwise known as the 340B Drug Discount Program).

(b) Covered Entities.

(1) The covered entity must notify OHCA in writing within 30 days of any changes in 340B participation, as well as any changes in name, address, NPI number, etc.

(2) The covered entity must maintain their status on the HRSA Medicaid exclusion file and report any changes to OHCA within 30 days.

(3) The covered entity must execute a contract addendum with OHCA in addition to their provider contract.

(4) To prevent a duplicate discount, quarterly adjustments will be made to all pharmacy or medical claims for drugs submitted by the covered entity. OHCA will adjust each claim by subtracting the ~~Unit Rebate Amount~~340B Ceiling Price from the amount reimbursed and ~~multiplied~~ multiplying the difference by the

quantity submitted. All drugs shall be adjusted by the ~~URA~~ 340B Ceiling Price whether purchased through the 340B program or otherwise when billed using the registered SoonerCare NPI number on the HRSA Medicaid Exclusion File. OHCA will use the ~~Unit Rebate Amount~~ 340B Ceiling Price applicable to the quarter in which the claim is ~~submitted to OHCA for payment~~ paid.

(c) Contract pharmacies for covered entities may be permitted to bill drug products purchased under the 340B Drug Discount Program to the Oklahoma Medicaid Program when certain conditions are met and an agreement is in place between OHCA, the contract pharmacy and the covered entity. These pharmacies will be subject to the recovery process stated above.