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: June 10, 2023

The proposed policy is an Emergency Rule. The proposed policy will be presented at the June 6, 2023 Tribal Consultation. Additionally, this proposal is scheduled to be presented to the Medical Advisory Committee on September 7, 2023 and the OHCA Board of Directors on September 20, 2023.

Reference: APA WF # 23-15

SUMMARY: Biosimilar Reimbursement — The proposed rule changes align reimbursement for certain biosimilar products with the Medicare Part B fee schedule pursuant to a change in the Inflation Reduction Act of 2022.

LEGAL AUTHORITY
The Oklahoma Health Care Authority Act, Section 5007 (C)(2) of Title 63 of Oklahoma Statutes; the Oklahoma Health Care Authority Board; and 63 O.S. Sections 5003 – 5016

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

SUBJECT: Rule Impact Statement
APA WF # 23-15

A. Brief description of the purpose of the rule:

The proposed policy revisions to align reimbursement for certain biosimilar products with the Medicare Part B fee schedule. The Inflation Reduction Act (2022) included a provision directing Medicare Part B to increase reimbursement for certain biosimilar products from Average Sales Price (ASP) + 6% to ASP + 8%. Based on CMS guidance, OHCA is amending the State Plan and rules to replace specific references to ASP + 6% with language indicating payment will match Medicare Part B's fee schedule.

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:

The proposed rule changes will affect SoonerCare members who rely on a new class of treatments, which Congress seeks to promote through a boosted Medicare Part B

reimbursement rate. This rule change should not place any cost burden on private or public entities. No information on any cost impacts were received from any entity.

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

The proposed rule changes will benefit SoonerCare members who rely on biosimilar treatments by aligning reimbursement rates with Medicare Part B rates. The proposed rule changes have the potential to improve access to care and health equity.

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 and there are no fee changes associated with the rule change for the above classes of persons or any 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 affect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

The estimated total cost for SFY 2023 is $200,320 ($154,967 in federal share and $45,353 in state share). The estimated total cost for SFY 2024 is $600,961 ($411,583 in federal share and $189,378 in state share).

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:

The proposed rule changes will not have an economic impact on any political subdivision or require their cooperation in implementing or enforcing the rule changes.

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 does not anticipate that the proposed rule changes will have an adverse effect on small businesses.

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 are no other legal methods to achieve the purpose of the proposed rule. Measures included a formal public comment period and tribal consultation.

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 or environment.

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

The agency does not anticipate any detrimental effect on the public health and safety if the proposed rule is not passed.

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

Prepared date: May 26, 2023

TITLE 317. OKLAHOMA HEALTH CARE AUTHORITY

CHAPTER 30. MEDICAL PROVIDERS-FEE FOR SERVICE

SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES

PART 5. PHARMACIES

317:30-5-78. Reimbursement

(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" B 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) **Professional dispensing fee.** The 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 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 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.

PART 17. MEDICAL SUPPLIERS

317:30-5-218. Reimbursement

(a) **Medical supplies, equipment and appliances.**

(1) Reimbursement for medical supplies, equipment, and appliances will be made using an amount derived from the lesser of the Oklahoma Health Care Authority (OHCA) maximum allowable fee or the provider's usual and customary charge. The maximum allowable fee is the maximum amount that the OHCA will pay a provider for an allowable procedure. When a code is not assigned a maximum allowable fee for a unit of service, a fee will be established.

(2) The fee schedule will be reviewed annually. Adjustments to the fee schedule may be possible at any time based on efficiency, budget considerations, federal regulations, and quality of care as determined by the OHCA.

(3) Payment for medical supplies, equipment, and appliances will be calculated using the rate methodologies found in the Oklahoma Medicaid State Plan.

(4) Payment is not made for medical supplies, equipment, and appliances that are not deemed as medically necessary or considered over-the-counter.

(5) OHCA does not reimburse medical supplies, equipment, and appliances providers separately for services that are included as part of the payment for another treatment program. For example, all items required during inpatient stays are paid through the inpatient payment structure.

(6) Medical supplies, equipment, and appliance products purchased at a pharmacy are paid the equivalent to the Medicare Part B allowed charge~~, average sales price (ASP) + six percent (6%)~~. When ~~ASP~~ the Medicare Part B allowed charge is not available, an equivalent price is calculated using wholesale acquisition cost (WAC). If no Medicare~~, ASP,~~ or WAC pricing is available, then the price will be calculated based on invoice cost.

(b) **Manually-priced medical equipment and supplies.** There may be instances when manual pricing is required. When it is, the following pricing methods will be used:

(1) **Invoice pricing.** Reimbursement is at the provider's documented manufacturer's suggested retail price (MSRP) minus thirty percent (30%) or at the provider's invoice cost plus thirty percent (30%), whichever is the lesser of the two.

(2) **Fair market pricing.** OHCA may establish a fair market price through claims review and analysis. For a list of medical equipment and supplies that are fair market-priced, refer to the OHCA website at www.okhca.org for the fair market value list (Selected medical supplies, equipment, and appliance items priced at fair market price).

(c) **Oxygen equipment and supplies.**

(1) Payment for stationary oxygen systems (liquid oxygen systems, gaseous oxygen systems, and oxygen concentrators) is based on continuous rental, i.e., a continuous monthly payment that is made as long as it is medically necessary. The rental payment includes all contents and supplies, e.g., regulators, tubing, masks, etc. Portable oxygen systems are considered continuous rental. Ownership of the equipment remains with the supplier.

(2) Separate payment will not be made for maintenance, servicing, delivery, or for the supplier to pick up the equipment when it is no longer medically necessary. In addition, the provider/supplier will not be reimbursed for mileage.

(3) Payment for oxygen and oxygen equipment and supplies will not exceed the Medicare fee for the same procedure code.

(4) For residents in a long-term care facility, durable medical equipment products, including oxygen, are included in the facility's per diem rate.