Oklahoma Health Care Authority

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

OHCA COMMENT DUE DATE: December 7, 2016

The proposed policy is an Emergency Rule. This proposal is scheduled to be presented to the Medical Advisory Committee (MAC) on November 17, 2016 and the (OHCA) Board of Directors on December 8, 2016.
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 Further, policy is revised to remove the limitations for smoking cessation benefits, and to update references to outdated policy.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 Pharmacy revisions amend the reimbursement structure for I/T/U and non I/T/U pharmacies. The I/T/U pharmacies will be reimbursed at the federal Office of

Management and Budget (OMB) encounter rate. The 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 revise ingredient cost methodology. The revision will align reimbursement for covered outpatient drugs with the Actual Acquisition Cost (AAC) and create a new pricing term for specialty pharmaceutical products. In addition, rules are amended to modify the current dispensing fee to a professional dispensing fee. Further, policy is revised to remove the limitations for smoking cessation benefits, and to update references to outdated policy.

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

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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:

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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 9, 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 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

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who supply these products to pharmacy providers in Oklahoma. Pharmacies may challenge a specific product's SMAC price by providing information from at least two wholesalers to certify a net cost higher than the calculated SMAC price and that there is not another product available to them which are 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 specialty drug is defined as having 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.

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(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.

PART 110. INDIAN HEALTH SERVICES, TRIBAL PROGRAMS, AND URBAN INDIAN CLINICS (I/T/Us)

317:30-5-1090. Provision of other health services outside of the I/T/U encounter

(a) Medically necessary SoonerCare covered services that are not included in the I/T/U outpatient encounter rate may be billed outside the encounter rate within the scope of the SoonerCare fee-for-service contract. The services will be reimbursed at the fee-for-service rate, and will be subject to any limitations, restrictions or prior authorization requirements. Examples of these services include but are not limited to:

~~(1) pharmaceuticals/drugs;~~
~~(2)~~(1) durable medical equipment;
~~(3)~~(2) glasses;
~~(4)~~(3) ambulance;
~~(5)~~(4) home health;
~~(6)~~(5) inpatient practitioner services;
~~(7)~~(6) non-emergency transportation [refer to OAC 317:35-3-2];
~~(8)~~(7) behavioral health case management ~~[refer to OAC 317:30-5-240 through 317:30-5-249];~~ [refer to OAC 317:30-5-241.6];
~~(9)~~(8) psychosocial rehabilitative services ~~[refer to OAC 317:30-5-240 through 317:30-5-249];~~ [refer to OAC 317:30-5-241.3]; and
~~(10)~~(9) psychiatric residential treatment facility services ~~[refer to OAC 317:30-5-96.3].~~[refer to OAC 317:30-5, Part 6, Inpatient Psychiatric Hospitals].

(b) If the I/T/U facility chooses to provide other SoonerCare State Plan covered health services which are not included in the I/T/U encounter definition, those service providers must be contracted with OHCA and bill for those services under their assigned provider number consistent with program coverage limitations and billing procedures described by the OHCA.

317:30-5-1098. I/T/U outpatient encounters

(a) I/T/U outpatient encounters that are billed to the OHCA must meet the definition in this Section and are limited to services covered by the OHCA. These services include health services included in the State Plan under Title XIX or Title XXI of the Social Security Act.

(b) The following words and terms have the following meaning unless the context clearly indicates otherwise:

(1) An I/T/U encounter means a face to face or telemedicine contact between a health care professional and an IHS eligible SoonerCare member for the provision of medically necessary Title XIX or Title XXI covered services through an IHS or Tribal 638 facility or an urban Indian clinic within a 24-hour period ending at midnight, as documented in the patient's record.

(2) An I/T/U outpatient encounter means outpatient services that may be covered when furnished to a patient by a contracted SoonerCare provider employed by the I/T/U facility and rendered at the I/T/U facility or other location, including the patient's place of residence.

(c) The following services may be considered reimbursable encounters subject to the limitations of the Oklahoma State Plan and include any related medical supplies provided during the course of the encounter:

(1) Medical;

(2) Diagnostic;

(3) Behavioral Health services [refer to OAC 317:30-5-1094];

(4) Dental, Medical and Mental Health Screenings;

(5) Vision;

(6) Physical Therapy;

(7) Occupational Therapy;

(8) Podiatry;

(9) Speech;

(10) Hearing;

(11) Visiting Nurse Service [refer to OAC 317:30-5-1093];

(12) Smoking and Tobacco Use Cessation Counseling

(13) Other Title XIX or XXI services as allowed under OHCA's SoonerCare State Plan and OHCA Administrative Rules;

(14) Drugs or medication treatments provided during a clinic visit are part of the encounter rate. For example, a member has come into the clinic with high blood pressure and is treated at the clinic with a hypertensive drug or drug sample. Drug samples are included in the encounter rate. ~~Prescriptions are not included in the encounter rate and must be billed through the pharmacy program by a qualified enrolled pharmacy;~~ Prescriptions are reimbursed pursuant to OAC 317:30-5-78(b)(4)(B).

(15) Encounters with a registered professional nurse or a licensed practical nurse and related medical supplies (other than drugs and biologicals) furnished on a part-time or intermittent basis to home-bound members; and

(16) I/T/U Multiple Outpatient Encounters.

(A) OHCA will cover one medically necessary outpatient medical encounter per member per day unless if due to an emergency, the same member returns on the same day for a second visit with a different diagnosis. Then, a second encounter is allowed.

(B) OHCA will cover one dental encounter per member per day regardless of how many procedures are done or how many providers are seen unless if due to an emergency, the same

member returns on the same day for a second visit and has a different diagnosis. Then, a second encounter is allowed.

(C) OHCA will cover one behavioral health professional outpatient encounter per member per day unless if due to an emergency, the same member returns on the same day for a second visit and has a different diagnosis. Then, a second encounter is allowed.

(D) Each service must have distinctly different diagnoses in order to meet the criteria for multiple I/T/U outpatient encounters.

(d) More than one outpatient visit with a medical professional within a 24-hour period for distinctly different diagnoses may be reported as two encounters. This does not imply that if a member is seen at a single office visit with multiple problems that multiple encounters can be billed. For example, a member comes to the clinic in the morning for an immunization, and in the afternoon, the member falls and breaks an arm. This would be considered multiple medical encounters and can be billed as two encounters. However, a member who comes to the I/T/U facility for a diabetic wellness screening and is then referred to a podiatrist within the clinic for diabetes-related follow-up on the same date of service would not be considered a distinctly different diagnosis and can only be billed as a single encounter.

(e) The following services may be considered as separate or multiple encounters when two or more services are provided on the same date of service with distinctly different diagnoses:

(1) Medical Services;

(2) Dental Services;

(3) Mental Health and addiction services with similar diagnoses can only be billed as one encounter. In addition, if the member is also seen for a medical office visit with a mental health or addiction diagnosis, then it is considered a single encounter;

(4) Physical or occupational therapy (PT/OT). If this service is also performed on the same date of service as the medical encounter that determined the need for PT/OT (initial referral), then it is considered a single encounter;

(5) Administration of immunizations. If no other medical office visit occurs on the same date of services; and

(6) Tobacco cessation limited to state plan services. If no other medical or addiction encounter occurs on the same date of service.

(f) I/T/U outpatient encounters for IHS eligible SoonerCare members whether medical, dental, or behavioral health, are not subject to prior authorization. Other State Plan covered services that the I/T/U facility chooses to provide but which are not part of the I/T/U encounter are subject to all applicable SoonerCare regulations which govern the provision and coverage for that service.

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