EXHIBIT O

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: 340B Modifiers on Physician Administered Drugs

DESCRIPTION:

Statement of Necessity

This change is a broad scope of work along with other State agencies, including the Medicaid Fraud Control Unit (MFCU), and is necessary to ensure that 340B providers are billing the actual invoice price but no greater than the ceiling price, and to ensure that DHS is reimbursing providers no more than the ceiling price on physician administered drugs. Additionally, the CMS modifiers of "JG" and "TB" need to be promulgated to identify 340B purchased drugs. The use of these modifiers will identify any 340B purchased drug and will ensure that all other physician administered drugs without the modifiers will then be eligible for rebate invoicing.

Rule Summary

CMS approved modifiers "JG" (drug or biological acquired with 340B drug pricing program discount) and "TB" (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes), will be required on provider claims by 340B providers for proper payment of the lesser of actual invoice price or the ceiling price per unit. The ceiling price for physician administered drugs will be supplied by the pharmacy vendor into MMIS.

PUBLIC COMMENT: A public hearing was held on this rule on October 19, 2022. The public comment period expired on November 6, 2022. The agency provided the following summary of the public comments it received and its responses to those comments:

Commenter's Name: Jack Geisser, Sr. Director, Healthcare Policy, Medicaid, and State Initiatives, Biotechnology Innovation Organization (BIO)

1. I am writing to submit comments on behalf of the Biotechnology Innovation Organization (BIO) regarding the Department of Medical Services' proposed rule to implement "340B Modifiers on Physician-Administered Drugs."

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

The 340B Program is now the second largest pharmaceutical program in the federal government behind Medicare, totaling $44 billion in 2021. By some conservative estimates, duplicate discounts amount to 3% to 5% of total 340B claims. *(1)* This means that these conservative estimates indicate that duplicate discounts could total more than $1.32 Billion to $2.2 Billion. Minimizing diversion and duplicate discounts is essential to program integrity to protect against waste and abuse. While BIO strongly supports the use of 340B modifiers to identify all 340B claims, we have some concerns that part of this rule, as drafted, is confusing and should be deleted.

Specifically, in 142.200 (H), the proposed rule states,
". . . A covered outpatient drug includes outpatient drugs and drugs used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), and (O)."
BIO believes the sentence above should be deleted from the proposed rule as it is unnecessary and confusing, and more importantly is inconsistent with federal law.

Section 1927(k) of the Social Security Act defines "covered outpatient drugs," and specifically excludes, among others, drugs used in inpatient settings. Therefore, the reference to "inpatient" in the proposed rule contradicts federal law and should be removed from the proposed rule.
Reference:
1 Mundra, Ashwin, "The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark," The Drug Channels Institute, Blog, March 18, 2022.
https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html

RESPONSE: The State of Arkansas included full definitions of entities from the Federal guidance to define various facilities. However, only covered outpatient physician administered drugs will be required to be billed with the modifiers. The modifiers would not apply to inpatient drugs or per diem billing. The Arkansas 340B facilities are aware of the intent for outpatient drugs only, as they have been working with the state regularly to prepare for this change.

2. Secondly, the reference to "subparagraph (L), (M), (N), and (O)" does not appear to attach to corresponding subparagraphs in the provider manual the proposed rule is amending. These subparagraphs appear to be in reference to 340B covered entity types in the federal statute, but the proposed rule does not indicate this, and such a reference would be inappropriate and unnecessary for the purposes of requiring modifiers on 340B-purchased physician-administered drugs. *(2)*

Notwithstanding these concerns, as noted, BIO strongly supports the use of 340B modifiers on all appropriate claims. Program integrity is of the utmost importance to BIO and its members. We believe claim modifiers are essential mechanism to reduce the

incidence of duplicate discounts and diversion, which are prohibited by federal statute. Thank you for the opportunity to comment on this proposed rule.
Reference:
2 42 U.S.C §256b(b)(2)

RESPONSE: Several Official Notices have been provided to all providers for best practices for use of the modifiers on the covered outpatient physician administered drugs. Also, the State of Arkansas has met and communicated with 340B providers regularly to make sure that covered entity billing departments are ready and understand the changes. The state also intends to hold billing clinics to help 340B providers be ready for the changes.

The proposed effective date is January 1, 2023.

FINANCIAL IMPACT: The agency indicated that this rule has a financial impact.

Per the agency, the proposed rule will result in savings of $1,604,351 for the current fiscal year ($455,315 in general revenue and $1,149,036 in federal funds) and savings of $2,139,135 for the next fiscal year ($607,086 in general revenue and $1,532,048 in federal funds). The total estimated cost reduction by fiscal year to state, county, and municipal government as a result of this rule is $455,315 for the current fiscal year and $607,086 for the next fiscal year.

LEGAL AUTHORIZATION: The Department of Human Services has the responsibility to administer assigned forms of public assistance and is specifically authorized to maintain an indigent medical care program (Arkansas Medicaid). *See* Ark. Code Ann. §§ 20-76-201(1), 20-77-107(a)(1). The Department has the authority to make rules that are necessary or desirable to carry out its public assistance duties. Ark. Code Ann. § 20-76-201(12). The Department and its divisions also have the authority to promulgate rules as necessary to conform their programs to federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

Division of Medical Services
P.O. Box 1437, Slot S295, Little Rock, AR 72203-1437
P: 501.682.8292 F: 501.682.1197

MEMORANDUM

TO: Interested Persons and Providers

FROM: Elizabeth Pitman, Director, Division of Medical Services

DATE: October 7, 2022

SUBJ: 340B Modifiers on Physician Administered Drugs

As a part of the Arkansas Administrative Procedure Act process, attached for your review and comment are proposed rule revisions.

Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

If you have any comments, please submit those comments in writing, no later than November 6, 2022.

All DHS proposed rules, public notices, and recently finalized rules may also be viewed at: Proposed Rules & Public Notices.

NOTICE OF RULE MAKING

The Director of the Division of Medical Services of the Department of Human Services announces for a public comment period of thirty (30) calendar days a notice of rulemaking for the following proposed rule under one or more of the following chapters, subchapters, or sections of the Arkansas Code: §§20-76-201, 20-77-107, and 25-10-129.

Effective January 1, 2023**:**

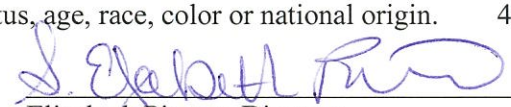
The Director of the Division of Medical Services amends the Pharmacy Provider Manual and Medicaid State Plan to ensure that 340B providers are billing the actual invoice price but no greater than the ceiling price and that DHS is reimbursing providers no more than the ceiling price on physician administered drugs. Additionally, the CMS modifiers of "JG" and "TB" are promulgated to identify 340B purchased drugs. The use of these modifiers identifies any 340B purchased drug and ensures that all other physician administered drugs without the modifiers will then be eligible for rebate invoicing. The projected annual cost of the renewals for the state fiscal year (SFY) for 2023 is ($1,604,351) (Federal share: ($1,149,036) and State share: ($455,315)) and for SFY 2024 is ($2,139,135) (Federal share: $($1,532,048) and State share: ($607,086).

The proposed rule is available for review at the Department of Human Services (DHS) Office of Rules Promulgation, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. You may also access and download the proposed rule at https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/. Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than November 6, 2022. Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

A public hearing by remote access only through a Zoom webinar will be held on October 19, 2022, at 11:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at https://us02web.zoom.us/j/81544048824. The webinar ID is 815 4404 8824. If you would like the electronic link, "one-tap" mobile information, listening only dial-in phone numbers, or international phone numbers, please contact ORP at ORP@dhs.arkansas.gov.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-534-4138.

The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color or national origin. 4502100209



Elizabeth Pitman, Director
Division of Medical Services

142.200 Conditions Related to Billing for Medicaid Services 1~~10~~-1-22~~23~~

A. Any covered service performed by a provider must be billed only after the service has been provided. ~~-~~No service or procedure may be pre-billed.

B. Endorsement of the provider check issued by the Medicaid fiscal agent certifies that the services were rendered by or under the direct supervision of the provider as billed.

C. It is the responsibility of each provider to be alert to the possibility of ~~third party~~third-party sources of payment and to report receipt of funds from these sources to DMS.

D. Each provider must accept Medicare assignment under Title XVIII (Medicare) in order to receive payment under Title XIX (Medicaid) for any Medicare deductible or coinsurance due and payable under Title XIX (Medicaid). ~~-~~See Section 142.700 for more information and detail~~sed information~~.

E. Each provider must accept payment from Medicaid as payment in full for covered services, make no additional charges, and accept no additional payment from the beneficiary for these services.

F. Medicaid providers may not charge beneficiaries for the completion and submission of a Medicaid claim form. ~~-~~If the provider agrees to accept the patient as a Medicaid beneficiary and agrees to bill Medicaid for the services rendered, the beneficiary may not be charged for this billing procedure.

G. Claims for services provided to eligible Medicaid beneficiaries must be submitted to the Medicaid fiscal agent within twelve (12) months from the date of service.

H. Federal Public Health Service's 340B Drug Pricing Program: All covered entities that participate in the Federal Public Health Service's 340B Drug Pricing Program ~~(340B)~~ that carve Arkansas Medicaid into the 340B program are required to bill Arkansas Medicaid using their 340B actual invoice price for covered outpatient drugs. Reimbursement shall be no more than the 340B ceiling price. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. ~~-~~A covered outpatient drug includes outpatient drugs and drugs used in connection with an inpatient or outpatient service provided by a hospital ~~described in subparagraph (L), (M), (N), and (O)~~. Covered entities must also identify all 340B drug claims using the medical modifiers JG or TB. Medical drug claims from covered 340B entities without the modifiers JG or TB will be considered non-340B drug claims and will be subject to rebate invoicing.~~———~~

I. ~~———~~340B drug claims will be subject to post payment review. Providers are responsible for maintaining documentation to support billed amounts.~~———~~

217.000 Federal Public Health Service's 340B Drug Pricing Program

~~4-1-17~~~~10~~-1-2~~22~~

All covered entities that participate in the Federal Public Health Service's 340B Drug Pricing Program ~~(340B)~~ that carve Arkansas Medicaid into the 340B program are required to bill Arkansas Medicaid using their 340B Actual Invoice Price for drugs.

A. Covered entities that bill Arkansas Medicaid for physician administered drugs, including specialty drugs, are required to bill Arkansas Medicaid using their 340B Actual Invoice Price.

B. Pharmacies are required to bill Arkansas Medicaid using their 340B Actual Invoice Price for Covered Legend and non-legend drugs, including specialty drugs, purchased through the Federal Public Health Service's 340B Drug Pricing Program ~~(340B)~~. The 340B covered entity pharmacies that carve Medicaid into the 340B Drug Pricing Program will be reimbursed ~~at~~ the lesser of the 340B Actual Invoice Price~~,~~ or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee, minus the beneficiary's copayment. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. The 340B pharmacies will identify on claim submission using the National Council for Prescription Drug Programs (NCPDP) indicator for drugs purchased through the 340B program. Drugs purchased outside the 340B program shall be submitted without the NCPDP 340B claim indicator and will be reimbursed using the lesser of methodology plus the established professional dispensing fee minus the beneficiary's copayment. All applicable federal and state supplemental rebates will be applied to claims submitted without the NCPDP 340B claim indicator. The State will not recognize 340B contract pharmacies. The 340B contract pharmacies are required to carve Medicaid claims out of the 340B Drug Pricing Program. Claims exceeding the 340B ceiling price as published or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA) will be subject to audit and may reject at point of sale.

Pharmacy providers who submit NCPDP claims to the Arkansas Medicaid Program on or after January 1, ~~2012~~2012, will be required to send value 07, 08, or 13 in the Basis of Cost Determination field (423-DN). The 340B providers have contractual agreements with federally qualified 340B entities, enabling special purchase of medication at federal bid pricing. These medications are reserved for only beneficiaries meeting the federal definition of 340B patients. Claims for prescriptions filled with medications purchased through the 340B program will carry the 08 value (340B Pricing) in the Basis of Cost Determination Field. Claims submitted with usual and customary pricing will carry the 07 value (Usual and Customary Pricing) in this field. Claims for prescriptions filled with non-340B purchased medication AND given a special price will carry the 13 value (Special Pricing) in this field.

251.000 Method of Reimbursement

~~4-1-17~~~~10~~-1-2~~22~~

A. Payment for ingredient cost for covered outpatient legend and non-legend drugs for all pharmacy and medication types that are not otherwise identified within this section shall be based upon the lesser of methodology.

Lesser of Methodology:

1. Brand Drugs

   a. The usual and customary charge to the public or submitted ingredient cost;

   ~~OR~~

b. The National Average Drug Acquisition Cost (NADAC), as defined in B, plus the established professional dispensing fee;

~~**OR**~~

c. The ACA Federal Upper Limit (FUL) plus the established professional dispensing fee;

OR

d. The calculated State Actual Acquisition Cost (SAAC), as defined in C, plus the established professional dispensing fee.

2. Generic Drugs

a. The usual and customary charge to the public or submitted ingredient cost;

~~**OR**~~

b. The National Average Drug Acquisition Cost (NADAC), as defined in B, plus the established professional dispensing fee;

~~**OR**~~

c. The ACA Federal Upper Limit (FUL) plus the established professional dispensing fee;

OR

d. The calculated State Actual Acquisition Cost (SAAC), as defined in C, plus the established professional dispensing fee.

3. Backup Ingredient Cost Benchmark

If NADAC is not available, the allowed ingredient cost, unless otherwise defined, shall be the lesser of Wholesale Acquisition Cost (WAC) ~~+~~ plus zero percent (+0%), State Actual Acquisition Cost (SAAC) or ACA Federal Upper Limit.

4. Limited Access and Specialty Drugs

Limited Access Drugs, defined as drugs not available for dispensing in all retail pharmacies based on price or separate agreements between manufacturer and pharmacy, and Specialty Drugs, will be reimbursed at the Lesser of Methodology plus the established professional dispensing fee. ~~-~~If NADAC is not available, then the Backup Ingredient Cost Benchmark will apply, which will use the lesser of Wholesale Acquisition Cost (WAC) plus~~+~~ zero percent (+0%) or State Actual Acquisition Cost (SAAC).

5. 340B Drug Pricing Program

a. Covered Legend and non-legend drugs, including specialty drugs~~,~~ purchased through the Federal Public Health Service's 340B Drug Pricing Program ~~(340B)~~ by pharmacies that carve Medicaid into the 340B Drug Pricing Program, shall be reimbursed ~~at~~ the lesser of the 340B Actual Invoice Price ~~but no more than~~or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. Drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies are not covered.

b. Physician administered drugs, including specialty drugs, purchased through the 340B Program, will be reimbursed ~~at~~ the lesser of the 340B Actual Invoice Price ~~but no more than~~or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)]. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being

processed. Physician administered drugs include outpatient drugs and drugs used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), and (O). Covered entities must also identify all 340B drug claims using the medical modifiers JG or TB. Medical drug claims from covered 340B entities, without the modifiers JG or TB, will be considered non-340B drug claims and will be subject to rebate invoicing.

6. Federal Supply Schedule (FSS) and FQHC

   Facilities purchasing drugs, specialty drugs, and physician administered drugs through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340B Drug Pricing Program, shall be reimbursed no more than the Federal Supply Schedule price. The addition of the established professional dispensing fee for pharmacies will apply, except in the cases of physician administered drugs. Federally Qualified Health Centers (FQHC) that purchase drugs through the 340B program, and carve in Medicaid, will be reimbursed by the encounter rate except in the case of implantable contraceptive capsules, intrauterine devices, and contraceptive injections in which case reimbursement will be no more than the 340B ceiling price. Federally Qualified Health Centers (FQHC) that do not participate in the 340B program, or carve out Medicaid, will be reimbursed by the encounter rate except in the case of implantable contraceptive capsules, intrauterine devices, and contraceptive injections in which case reimbursement will be at the actual acquisition cost.

7. Clotting Factor

   a. Pharmacies dispensing Antihemophilic Factor products will be reimbursed at the lesser of methodology plus the established professional dispensing fee. The lesser of methodology for the allowed ingredient cost shall be the Wholesale Acquisition Cost (WAC) plus~~+~~ zero percent (+0%) or State Actual Acquisition Cost (SAAC).

   b. Pharmacies dispensing Antihemophilic Factor products purchased through the Federal Public Health Service's 340B Drug Pricing Program ~~(340B)~~ by pharmacies that carve Medicaid into the 340B Drug Pricing Program shall be reimbursed at the lesser of ~~methodology~~ the 340B actual invoice price or the 340B ceiling price {provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee. ~~The lesser of methodology for the allowed ingredient cost shall be the Wholesale Acquisition Cost (WAC) plus+ zero percent (+0%) or State Actual Acquisition Cost (SAAC).~~ The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed.

8. Drugs Purchased at Nominal Price

   Facilities purchasing drugs at Nominal Price (outside of 340B or FSS) shall be reimbursed by their actual acquisition cost.

B. The National Average Drug Acquisition Cost (NADAC) is a pricing benchmark published by CMS that calculates ingredient average acquisition costs experienced by retail community providers across the country. When Brand and Generic NADACs are available for the same ingredient, reimbursement will be based on the Generic NADAC except in the case of Preferred Brand Drugs. The allowed ingredient cost for Preferred Brand Medications shall be reimbursed on the lesser of the Brand NADAC, WAC, or SAAC.

C. State Actual Acquisition Cost shall apply to certain drugs identified administratively, judicially, or by a federal agency as having a published price exceeding the ingredient cost. The calculated SAAC shall be obtained from actual acquisition costs from multiple resources, if available. Depending on the variance, either the highest acquisition cost, an

average of the acquisition costs, or invoice price shall be used in determining a SAAC. When Brand and Generic drugs are available for the same ingredient, reimbursement will be based on the Generic State Actual Acquisition Cost (SAAC). The SAAC was previously referred to as State Upper Limit (SUL), Generic Upper Limit (GUL), Maximum Allowed Cost (MAC), and Cap Upper Limit (CAP).

D. Investigational drugs are excluded from coverage.

E. The Professional Dispensing Fee for covered outpatient legend and non-legend drugs shall take into consideration the State's Preferred Drug List status, for the drug being dispensed, and equals the average professional dispensing fee in the aggregate:

1. Brand and Non-preferred Brand = Nine Dollars ($9.00); or
2. Brand Preferred and Generic Medication drug = Ten Dollars and Fifty Cents ($10.50).

Drug pricing files are updated weekly.

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye, or by an optometrist

a. Prescribed Drugs (Continued)

iv. Limited Access and Specialty Drugs

Limited Access Drugs are , defined as drugs not available for dispensing in all retail pharmacies based on price or separate agreements between manufacturer and pharmacy., Limited Access Drugs and Specialty Drugs will be reimbursed at the Lesser of Methodology plus the established professional dispensing fee. If NADAC is not availableavailable, then the Backup Ingredient Cost Benchmark will apply which will use the lesser of Wholesale Acquisition Cost (WAC) plus+ zero percent (+0%) or State Actual Acquisition Cost (SAAC).

v. 340B Drug Pricing Program

a. Covered Legend and non-legend drugs, including specialty drugs,, purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B) by pharmacies that carve Medicaid into the 340B Drug Pricing Program, shall be reimbursed at the lesser of the 340B actual Invoice invoice Price price but no more thanor the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.

b. Physician administered drugs, including specialty drugs,, purchased through the 340B Program, will be reimbursed at the lesser of the 340B actual invoice price but no more thanor the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)]. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed.

vi. Federal Supply Schedule (FSS) and FQHC

Facilities purchasing drugs, specialty drugs, and physician administered drugs through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340B Drug Pricing Program, shall be reimbursed no more than the Federal Supply Schedule price. The addition of the established professional dispensing fee for pharmacies will apply, except in the cases of physician administered drugs. Federally Qualified Health Centers (FQHC) that purchase drugs through the 340B program and carve in Medicaid will be reimbursed by the encounter rate, except in the case of Implantable Contraceptive Capsules, Intrauterine Devices, and Contraceptive Injections, in which case reimbursement will be no more than the 340B ceiling price. Federally Qualified Health Centers (FQHC) that do not participate in the 340B program, or carve out Medicaid, will be reimbursed by the encounter rate, except in the case of Implantable Contraceptive Capsules, Intrauterine Devices, and Contraceptive Injections, in which case reimbursement will be at the actual acquisition cost.

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye, or by an optometrist

a. Prescribed Drugs (Continued)

vii. Clotting Factor

a. Pharmacies dispensing Antihemophilic Factor products will be reimbursed at the lesser of methodology plus the established professional dispensing fee. The lesser of methodology for the allowed ingredient cost shall be the Wholesale Acquisition Cost (WAC) plus zero percent (0%) or State Actual Acquisition Cost (SAAC).

b. Pharmacies dispensing Antihemophilic Factor products purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B) by pharmacies that carve Medicaid into the 340B Drug Pricing Program shall be reimbursed at the lesser of the 340B actual invoice price methodology plus the established professional dispensing fee. The lesser of methodology for the allowed ingredient cost shall be the Wholesale Acquisition Cost (WAC) plus zero percent (0%) or State Actual Acquisition Cost (SAAC). The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed.

viii. Drugs Purchased at Nominal Price

Facilities purchasing drugs at Nominal Price (outside of 340B or FSS) shall be reimbursed by their actual acquisition cost.

ix. Physician Administered Drugs

Reimbursement rates for Physician Administered Drugs are a "fee schedule" as determined by the Medicare rate (ASP plus six percent (6%)). If the Medicare rate is not available, then other published pricing or manual pricing shall be used to determine reimbursement. Under the fee schedule methodology, reimbursement is based on the lesser of the billed charge for each procedure or the maximum allowable for each procedure.

B. State Upper Limit (SUL) shall apply to certain drugs identified administratively, judicially, or by a federal agency as having a published price exceeding the ingredient cost. The calculated SAAC shall be obtained from actual acquisition costs from multiple resources, if available. Depending on the variance, either the highest acquisition cost, an average of the acquisition costs, or invoice price shall be used in determining a SAAC. When Brand and Generic drugs are available for the same ingredient, reimbursement will be based on the Generic State Actual Acquisition Cost (SAAC).

DHS Responses to Public Comments Regarding 340B Modifiers on Physician Administered Drugs

Jack Geisser, Sr. Director, Healthcare Policy, Medicaid, and State Initiatives

Biotechnology Innovation Organization (BIO)

Comment: I am writing to submit comments on behalf of the Biotechnology Innovation Organization (BIO) regarding the Department of Medical Services' proposed rule to implement "340B Modifiers on Physician-Administered Drugs."

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

The 340B Program is now the second largest pharmaceutical program in the federal government behind Medicare, totaling $44 billion in 2021. By some conservative estimates, duplicate discounts amount to 3% to 5% of total 340B claims. *(1)* This means that these conservative estimates indicate that duplicate discounts could total more than $1.32 Billion to $2.2 Billion. Minimizing diversion and duplicate discounts is essential to program integrity to protect against waste and abuse. While BIO strongly supports the use of 340B modifiers to identify all 340B claims, we have some concerns that part of this rule, as drafted, is confusing and should be deleted.

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Reference:
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Response: The State of Arkansas included full definitions of entities from the Federal guidance to define various facilities. However, only covered outpatient physician administered drugs will be required to be billed with the modifiers. The modifiers would not apply to inpatient drugs or per diem billing. The

Arkansas 340B facilities are aware of the intent for outpatient drugs only, as they have been working with the state regularly to prepare for this change.

Comment: Secondly, the reference to "subparagraph (L), (M), (N), and (O)" does not appear to attach to corresponding subparagraphs in the provider manual the proposed rule is amending. These subparagraphs appear to be in reference to 340B covered entity types in the federal statute, but the proposed rule does not indicate this, and such a reference would be inappropriate and unnecessary for the purposes of requiring modifiers on 340B-purchased physician-administered drugs. *(2)*

Notwithstanding these concerns, as noted, BIO strongly supports the use of 340B modifiers on all appropriate claims. Program integrity is of the utmost importance to BIO and its members. We believe claim modifiers are essential mechanism to reduce the incidence of duplicate discounts and diversion, which are prohibited by federal statute. Thank you for the opportunity to comment on this proposed rule.

Reference:
2 42 U.S.C §256b(b)(2)

Response: Several Official Notices have been provided to all providers for best practices for use of the modifiers on the covered outpatient physician administered drugs. Also, the State of Arkansas has met and communicated with 340B providers regularly to make sure that covered entity billing departments are ready and understand the changes. The state also intends to hold billing clinics to help 340B providers be ready for the changes.