TO: Health and Human Services Commission Executive Council

DATE: December 6, 2018

FROM: Priscilla Parrilla, HHSC Pharmacy Operations

AGENDA ITEM: 2.m

SUBJECT: Pharmacy Dispensing Fee and Medication Synchronization

BACKGROUND: ☒ Federal ☒ Legislative ☐ Other: Program Initiative

The Texas Health and Human Services Commission (HHSC) proposes amendments to Texas Administrative Code (TAC) Title 1, Part 15, Chapters 354 and 355: §354.1831, concerning Covered Drugs; §354.1867, concerning Refills; §354.1921, concerning Addition of Drugs to the Texas Drug Code Index; §355.8541, concerning Legend and Nonlegend Medications; §355.8548, concerning 340B Covered Entities; and §355.8551, concerning Professional Dispensing Fee.

The amendments serve many purposes.

The amendment to §354.1867 implements, for purposes of the Texas Medicaid fee-for-service program, Texas Insurance Code provisions the Texas Legislature adopted in 2017 pertaining to medication synchronization plans for the filling or refilling of multiple prescriptions. *See* Act of May 23, 2017, 85th Leg., R.S., §1 (H.B. 1296) (enacting Tex. Ins. Code ch. 1369, subch. J). Texas Insurance Code §1369.456(b) requires a health benefit plan, such as coverage of medical or surgical expenses offered by a health maintenance organization or managed care organization, to "establish a process through which" a health benefit plan (the payor), the enrollee, the prescribing physician or health care provider, and a pharmacist "may jointly approve a medication synchronization plan for medication to treat an enrollee's chronic illness." *See* Tex. Ins. Code §1369.452(a)(3) (including coverage offered by a health maintenance organization within the scope of health benefit plans to which chapter 1369, subchapter J applies). An approved medication synchronization plan would coordinate the refill dates of multiple prescriptions for an enrollee with chronic illness so that the enrollee could pick up filled refills on a single day each month instead of having to make multiple pharmacy visits to obtain different prescription medications with different refill dates. Medications dispensed in accordance with a medication synchronization plan would be covered. The medication

synchronization process will ensure enrollees can obtain medically necessary drugs used to treat chronic conditions.

Other amendments reflect the use of a drug's acquisition cost in calculating reimbursement. Under the current Medicaid State Plan and consistent with 42 CFR §447.512, HHSC calculates pharmacy reimbursement for all medications using a drug's acquisition cost or the usual and customary price charged to the general public. The proposed amendments are consistent with the current Medicaid State Plan and federal law. The proposed rule amendments do not constitute a change to current pharmacy reimbursement under Medicaid fee-for-service (FFS); reimbursement is calculated consistently with the Medicaid State Plan and federal law.

In addition, the amendments to Title 1, §354.1921 of the Texas Administrative Code define the terms "NADAC," "retail Pharmacy Acquisition Cost," and "Specialty pharmacy acquisition cost." NADAC, retail Pharmacy Acquisition Cost and Specialty pharmacy acquisition cost are used in calculating reimbursement.

The purpose of the other proposed amendments is to clarify that a limited set of home health supplies is available through the pharmacy benefit, to revise the formula for calculating the professional dispensing fee, to revise the methodology for reimbursement of 340B covered outpatient drugs, and to align rule language with the Medicaid State Plan.

ISSUES AND ALTERNATIVES:

The changes made to the rules related to provider reimbursement are conforming changes required under federal law and do not constitute a reimbursement change. The provisions were mandatory and no alternative to their adoption is available to HHSC. The changes made to the rules related to medication synchronization are required under Texas Insurance Code Chapter 1369, Subchapter J and also are mandatory. No alternative to their adoption is available to HHSC.

STAKEHOLDER INVOLVEMENT:

HHSC requested feedback on the Pharmacy Dispensing Fee and Medication Synchronization draft rules and received an informal comment from pharmacy stakeholders regarding: frequency of acquisition cost (AC) updates; a request for clarification of both the definition for Retail Pharmacy Acquisition Cost (RetailPAC) and the formula for the Professional Dispensing Fee; and ascertainment of "reasonable" in terms of dispensing fees. HHSC clarified that RetailPAC is based on the National Average Drug Acquisition

Cost (NADAC), which the Centers for Medicare & Medicaid Services updates weekly. Stakeholders were assured that while the language was being updated the formulas were not being changed in FFS. HHSC explained that network adequacy is used as a proxy measure for reasonable dispensing fees in Texas' managed care Medicaid. Both the FFS dispensing fee and RetailPAC formulas are detailed in the state plan amendment. HHSC will continue to engage stakeholders during this rule amendment process.

FISCAL IMPACT:

☒ None

SERVICES IMPACT STATEMENT:

The rule amendments do not affect reimbursement to pharmacies and will therefore not affect client services.

RULE DEVELOPMENT SCHEDULE:

November 8, 2018	Present at Medical Care Advisory Committee
December 6, 2018	Present to HHSC Executive Council
December 2018	Publish proposed rules in *Texas Register*
March 2019	Publish adopted rules in *Texas Register*
March 2019	Effective date

PROPOSED PREAMBLE

The Texas Health and Human Services Commission (HHSC) proposes an amendment to §354.1831, concerning Covered Drugs; §354.1867, concerning Refills; and §354.1921, concerning Addition of Drugs to the Texas Drug Code Index.

BACKGROUND AND PURPOSE

The amendments serve various purposes.

The amendment to §354.1867 implements, for purposes of the Texas Medicaid fee-for-service program, Texas Insurance Code provisions the Texas Legislature adopted in 2017 pertaining to medication synchronization plans for the filling or refilling of multiple prescriptions. *See* Act of May 23, 2017, 85th Leg., R.S., §1 (H.B. 1296) (enacting Tex. Ins. Code ch. 1369, subch. J). Texas Insurance Code §1369.456(b) requires a health benefit plan, such as coverage of medical or surgical expenses offered by a health maintenance organization or managed care organization, to “establish a process through which” a health benefit plan (the payor), the enrollee, the prescribing physician or health care provider, and a pharmacist "may jointly approve a medication synchronization plan for medication to treat an enrollee’s chronic illness.” *See* Tex. Ins. Code §1369.452(a)(3) (including coverage offered by a health maintenance organization within the scope of health benefit plans to which chapter 1369, subchapter J applies). An approved medication synchronization plan would coordinate the refill dates of multiple prescriptions for an enrollee with chronic illness so that the enrollee could pick up filled refills on a single day each month instead of having to make multiple pharmacy visits to obtain different prescription medications with different refill dates. Medications dispensed in accordance with a medication synchronization plan would be covered. The medication synchronization process will ensure enrollees can obtain medically necessary drugs used to treat chronic conditions.

Other amendments reflect the use of a drug's acquisition cost in calculating reimbursement. Under the current Medicaid State Plan and consistent with 42 CFR §447.512, HHSC calculates pharmacy reimbursement for all medications using a drug's acquisition cost or the usual and customary price charged to the general public. The proposed amendments are consistent with the current Medicaid State Plan and federal law. The proposed rule amendments do not constitute a change to current pharmacy reimbursement under Medicaid fee-for-service (FFS); reimbursement is calculated consistently with the Medicaid State Plan and federal law.

In addition, the amendments to Title 1, Chapter 354 of the Texas Administrative Code define the terms "NADAC," "retail Pharmacy Acquisition Cost," and "Specialty pharmacy acquisition cost." NADAC, retail Pharmacy Acquisition Cost and Specialty pharmacy acquisition cost are used in calculating reimbursement.

The purpose of the other proposed amendments is to clarify that a limited set of home health supplies is available through the pharmacy benefit and to align rule language with the Medicaid State Plan.

SECTION-BY-SECTION SUMMARY

The proposed amendment of §354.1831, concerning Covered Drugs, clarifies that HHSC allows for certain home health supply products that are a covered Texas Medicaid benefit to be provided by pharmacies enrolled in the Vendor Drug Program (VDP). These products are classified as a Title XIX (Medicaid) home health benefit and as durable medical equipment or medical supplies, and are available to people enrolled in Medicaid, the Children's Health Insurance Program (CHIP), the Children with Special Health Care Needs (CSHCN) Services Program, and the Kidney Health Care (KHC) Program.

The proposed amendment of §354.1867, concerning Refills, allows, in the fee-for-service program, for early refills of drugs used to treat and manage chronic illness in accordance with a medication synchronization plan.

The proposed amendment of §354.1921, concerning Addition of Drugs to the Texas Drug Code Index, adds definitions for Acquisition Cost, National Average Drug Acquisition Cost, and Retail Pharmacy Acquisition Cost. The proposed amendment also revises the definition for specialty pharmacy acquisition cost. The definitional changes are necessary to define terms used in amendments proposed to Title 1, Chapter 355 of the Texas Administrative Code in this issue of the *Texas Register*.

FISCAL NOTE

Greta Rymal, Deputy Executive Commissioner for Financial Services, has determined that for each year of the first five years that the rules will be in effect, there is no anticipated impact to costs and revenues of state or local governments as a result of enforcing and administering the rules as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;
(2) implementation of the proposed rules will not affect the number of employee positions;
(3) implementation of the proposed rules will not require an increase or decrease in future legislative appropriations;
(4) the proposed rules will not affect fees paid to the agency;
(5) the proposed rules will not create a new rule;
(6) the proposed rules will expand an existing rule;
(7) the proposed rules will increase the number of individuals subject to the rule; and
(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Ms. Rymal has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities to comply with the rules as proposed. The proposed amendments are consistent with the current Medicaid State Plan and implement a process in Texas fee-for-service Medicaid to allow for medication synchronization consistent with state law. Medication synchronization is a common pharmacy industry practice used today. Pharmacies submitting claims to synchronize medications are reimbursed using the same payment methodology as all other prescription. Dispensing fees will not be prorated. Managed care organizations and the fee-for-service claims processor have existing system capabilities to allow for medication synchronization.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There is no anticipated cost to persons required to comply with the rules as proposed because they will not be required to alter their business practices.

There is no anticipated negative impact on local employment.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the

residents of Texas and are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rule.

PUBLIC BENEFIT

Stephanie Muth, State Medicaid Director, has determined that for each year of the first five years the rules are in effect, the public benefit anticipated as a result of enforcing or administering the rules is that Medicaid enrollees will find it easier to maintain and continue prescription drug treatment and management of chronic illnesses. Transportation needs and other barriers to obtaining medically necessary medications and refills will be reduced. In addition, the rules define terms used in proposed amendments to Title 1, Chapter 355 of the Texas Administrative Code. The rule also clarifies that a limited set of home health supplies is available through the pharmacy benefit, therefore increasing access to these products.

TAKINGS IMPACT ASSESSMENT

HHSC has determined the proposal does not restrict or limit an owner's right to her or his property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 149030, Mail Code 4102, Austin, Texas 78714-9030 or 4900 North Lamar Boulevard, Mail Code 4102, Austin, Texas 78751; or e-mailed to *HHSRulesCoordinationOffice@hhsc.state.tx.us* within 30 days of publication of this proposal in the *Texas Register*.

To be considered, comments must be submitted no later than 30 days after the date of this issue of the *Texas Register*. The last day to submit comments falls on a Sunday; therefore, comments must be: (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) e-mailed by midnight on the last day of the comment period. When e-mailing comments, please indicate "Comments on Proposed Rule 18R026” in the subject line.

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.033, which requires HHSC’s Executive Commissioner to adopt rules to carry out

HHSC's duties; Texas Government Code §531.302(a), which requires HHSC's Executive Commissioner to adopt rules for the state prescription drug program; and Texas Human Resources Code §32.021(c), which requires HHSC's Executive Commissioner to adopt rules as necessary to properly and efficiently operate the Medicaid program.

The amendments implement Texas Government Code §531.021(a) and Texas Human Resources Code §32.021(a), which authorize HHSC to operate the Medicaid program; and Texas Insurance Code ch. 1369, subch. J, which requires a process for adopting medical synchronization plans.

This agency hereby certifies that this proposal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

TITLE 1 ADMINISTRATION
PART 15 TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHAPTER 354 MEDICAID HEALTH SERVICES
SUBCHAPTER F PHARMACY SERVICES
DIVISION 2 ADMINISTRATION

§354.1831. Covered Drugs.

(a) Only those drugs and Limited Home Health Supplies listed in the latest edition of the Texas Drug Code Index (TDCI) are covered by the program and are payable. Venosets, catheters, and other medical accessories are not covered and are not included when claiming for intravenous and irrigating solutions.

(b) The Commission may limit coverage of drugs listed in the TDCI. Procedures used to limit utilization may include prior approval, cost containment caps, or adherence to specific dosage limitations recommended by manufacturers. Limitations placed on the specific drugs are indicated in the TDCI.

TITLE 1 ADMINISTRATION
PART 15 TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHAPTER 354 MEDICAID HEALTH SERVICES
SUBCHAPTER F PHARMACY SERVICES
DIVISION 4 LIMITATIONS

§354.1867. Refills.

(a) As many as eleven refills may be authorized by the prescriber, but the total amount authorized must be dispensed within one year of the original prescription. Refills for controlled substances must conform to Drug Enforcement Administration and Texas State Board of Pharmacy rules. All refills are counted when determining compliance with the authorized refill limitation. In the absence of specific refill instructions, the prescription must be interpreted as not refillable. If a prescription notes specific refill instructions, any future dispensings must be considered refills of the original prescription, unless the prescriber has been contacted for authorization to dispense a new supply of medication. If authorization is granted, a new and separate prescription is prepared.

(b) In accordance with Texas Insurance Code 1369, Subchapter J, early refills of drugs used to treat chronic conditions included in a Medication Synchronization Plan may be jointly approved by HHSC, the applicable pharmacist, enrollee, and the prescribing physician or health care provider. A pharmacist requesting an early refill for the purpose of medication synchronization must adhere to the process described in the Vendor Drug Program pharmacy provider procedure manual. Dispensing fees will not be prorated.

TITLE 1	ADMINISTRATION
PART 15	TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHAPTER 354	MEDICAID HEALTH SERVICES
SUBCHAPTER F	PHARMACY SERVICES
DIVISION 7	TEXAS DRUG CODE INDEX--ADDITIONS, RETENTIONS, AND DELETIONS

§354.1921. Addition of Drugs to the Texas Drug Code Index.

(a) A drug company that has a valid rebate agreement under 42 U.S.C. §1396r-8 may apply to the Health and Human Services Commission (Commission) to add a drug to the Texas Drug Code Index (TDCI). The term "drug company" includes any manufacturer, repackager, or private labeler.

(b) To apply for the addition of a drug to the TDCI, a drug company must complete each section of the Certification of Information for the Addition of a Drug Product to the TDCI provided by the Commission.

(c) A drug company must also:

(1) update the Commission with changes to formulation, product status, or availability; and

(2) submit changes to the prices requested in the Price Certification section of the Certification of Information, if requested by the Commission, within 10 calendar days of receiving the request.

(d) Sources other than drug companies may request the addition of a drug not currently listed in the TDCI. If the request is not from a drug company, the Commission may request that the manufacturer submit a Certification of Information as described in subsection (b) of this section.

(e) The drug company and other sources, if applicable, are entitled to receive notification of approved or denied Certifications of Information. If a Certification of Information is denied, the Commission will state the reasons for the denial.

(f) Notwithstanding any other state law, pricing information reported by a drug company under this subchapter is confidential and must not be disclosed by the Commission, its agents, contractors, or any other State agency in a format that discloses the identity of a specific manufacturer or labeler, or the prices charged by a specific manufacturer or labeler for a specific drug, except as necessary to permit the Attorney General to enforce state and federal law.

(g) Definitions. The following words and terms, when used in this chapter and in Chapter 355 of this title (relating to Reimbursement Rates), have the following meanings unless the context clearly indicates otherwise.

(1) Acquisition Cost (AC)--HHSC's determination of the price pharmacy providers pay to acquire drug products marketed or sold by specific manufacturers. AC is based on NADAC, wholesale acquisition cost (WAC), or pharmacy invoice, in accordance with the Medicaid state plan.

(2) [~~(1)~~] Average Manufacturer Price (AMP)--The average manufacturer price as defined in 42 USC §1396r-8(k)(1).

(3) [~~(2)~~] Average Wholesale Price (AWP)--The average wholesale price for a drug as published in a price reporting compendium such as First DataBank or Medispan.

(4) [~~(3)~~] Customary Prompt Pay Discount--Any discount off the purchase price of a drug routinely offered by the drug company to a wholesaler or distributor for prompt payment of purchased drugs within a specified time frame and consistent with customary business practices for payment.

(5) [~~(4)~~] Direct Price to Long Term Care Pharmacy--The amount paid by a pharmacy servicing a long term care facility, including a nursing facility, assisted living facility, and skilled nursing facility. The price should be net of price concessions. In reporting this price point to the Commission, if the price is reported as a range, the weighted average of these prices, based on unit sales, must be included. The following prices should be excluded from this price point:

(A) prices excluded from the determination of Medicaid Best Price at 42 C.F.R. §447.505; and

(B) prices to entities participating in the Health Resources and Services Administration (HRSA) 340b discount program.

(7) [~~(6)~~] Gross Amount Due--Has the meaning as defined by the National Council for Prescription Drug Programs.

(8) [~~(7)~~] Long term care facility--Facility that provides long term care services, such as a nursing home, skilled nursing facility, assisted living facility, group home, hospice facility, or intermediate care facility for individuals with an intellectual disability or related condition (ICF/IID).

(9) [~~(8)~~] Long term care pharmacy--A pharmacy for which the total Medicaid claims for prescription drugs to residents of long term care facilities exceeds 50 percent of the pharmacy's total Medicaid claims per year. Long term care pharmacies are [~~typically~~] not open to the public for walk-in business.

(10) [~~(9)~~] Long term care pharmacy acquisition cost (LTCPAC)--The acquisition cost determined by the Commission for a drug product purchased by a long term care pharmacy.]

(11) [~~(10)~~] "May [~~may~~] apply to the Commission"--The act of applying to have a drug included on the TDCI. This includes completing the Certification of Information for the Addition of a New Drug Product to the Texas Drug Code Index, submitting National Drug Code (NDC) changes, submitting price updates, and submitting additional package sizes for a drug that is already included on the TDCI.

(12) NADAC--National Average Drug Acquisition Cost.

(13) [~~(11)~~] National Drug Code (NDC)--The 11-digit numerical code established by the U.S. Food and Drug Administration that indicates the labeler, product, and package size.

(14) [~~(12)~~] Pharmacy--An entity with an approved community pharmacy license or an institutional pharmacy license.

(15) [~~(13)~~] Price concession--An action by a manufacturer (other than a customary prompt-pay discount as defined in this section) that has the effect of reducing the net cost of a product to a purchaser. The term includes discounts, rebates, billbacks, chargebacks, or other adjustments to pricing or payment terms. Lagged price concessions must be accounted for in the Reported Manufacturer Pricing by operation of a 12-month average estimation methodology as described in 42 C.F.R. §414.804. For new, at launch products, if a manufacturer has forecasted price concessions, the initial Reported Manufacturer Pricing should reflect this internal business information.

(16) [~~(14)~~] Price to Wholesaler/Distributor--The amount paid by a wholesaler or a distributor. The price should be net of price concessions. In reporting this price point to the Commission, if the price is reported as a range, the weighted average of these prices, based on unit sales, must be included. The following prices should be excluded from this price point:

(A) prices excluded from the determination of Medicaid Best Price at 42 C.F.R. §447.505; and

(B) prices to entities participating in the Health Resources and Services Administration (HRSA) 340b discount program.

(17) [~~(15)~~] Reliable Sources--Sources including other state or federal agencies and pricing services, as well as verifiable reports by contracted providers and Vendor Drug Program formulary and field staff.

(18) [~~(16)~~] Reported Manufacturer Pricing--Pricing information submitted to the Commission by a drug company on a Certification of Information, or in subsequent price updates as described in subsections (b) and (c) of this section. This includes: Average Wholesale Price, Average Manufacturer Price, Price to Wholesaler/Distributor, Direct Price to Pharmacy, and Direct Price to Long Term Care Pharmacy. If a drug company does not have a single price for a price point, it must report a range of prices. If a drug company reports a range of prices, it must also provide the weighted average of these prices based on unit sales.

(19) Retail Pharmacy Acquisition Cost (RetailPAC)--HHSC's determination of the price a retail pharmacy pays to acquire drug products marketed or sold by specific manufacturers.

(20) [~~(17)~~] Specialty pharmacy--A pharmacy that meets all of the following criteria:

(A) total Medicaid claims for specialty drugs, as described in §354.1853 of this subchapter (relating to Specialty Drugs), exceeds 10 percent of the pharmacy's total Medicaid claims per year;

(B) obtains volume-based discounts or rebates on specialty drugs from manufacturers or wholesalers; and

(C) delivers at least 80 percent of dispensed prescriptions by shipment through the U.S. Postal Service or other common carrier to customers or healthcare professionals (including physicians and home health providers).

(21) [~~(18)~~] Specialty pharmacy acquisition cost (SPAC)--HHSC's determination of the price a retail pharmacy pays to acquire drug products marketed or sold by specific manufacturers. [~~The acquisition cost determined by the Commission for a drug product purchased by a specialty pharmacy.~~]

PROPOSED PREAMBLE

The Texas Health and Human Services Commission (HHSC) proposes amendments to §355.8541, concerning Legend and Nonlegend Medications; §355.8548, concerning 340B Covered Entities; and §355.8551, concerning Professional Dispensing Fee.

BACKGROUND AND PURPOSE

Under the current Medicaid State Plan and consistent with 42 CFR §447.512, HHSC calculates pharmacy reimbursement for all medications using a drug's acquisition cost or the usual and customary price charged to the general public. The proposed amendments are consistent with the current Medicaid State Plan and federal law. The proposed rule amendments do not constitute a change to current pharmacy reimbursement under Medicaid fee-for-service (FFS); reimbursement is calculated consistently with the Medicaid State Plan and federal law.

The terms "Acquisition Cost," "NADAC," "retail Pharmacy Acquisition Cost," and "Specialty pharmacy acquisition cost" are defined in proposed amendments to Title 1, Chapter 354 of the Texas Administrative Code, published in this issue of the *Texas Register*.

SECTION-BY-SECTION SUMMARY

The proposed amendment of §355.8541, concerning Legend and Nonlegend Medications, updates the definition of "acquisition cost (AC)" to align rule language with Texas Medicaid State Plan language and is a conforming change only. The amendment does not constitute a change to provider reimbursement for covered outpatient drugs.

The proposed amendment of §355.8548, concerning 340B Covered Entities, aligns rule language with Texas Medicaid State Plan language and is a conforming change only. The amendment does not constitute a change to provider reimbursement for covered outpatient drugs.

The proposed amendment of §355.8551, concerning Professional Dispensing Fee, updates the CFR references in the definition for "Professional Dispensing Fee." This amendment aligns rule language with Texas Medicaid State Plan language and is a conforming change only. The amendment does not constitute a change to provider reimbursement for covered outpatient drugs.

FISCAL NOTE

Greta Rymal, Deputy Executive Commissioner for Financial Services, has determined that for each year of the first five years that the rules will be in effect, there is no anticipated impact to costs and revenues of state or local governments as a result of enforcing and administering the rules as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years the rules will be in effect:

(1) the proposed rules will not create or eliminate a government program;
(2) implementation of the proposed rules will not affect the number of employee positions;
(3) implementation of the proposed rules will not require an increase or decrease in future legislative appropriations;
(4) the proposed rules will not affect fees paid to the agency;
(5) the proposed rules will not create a new rule;
(6) the proposed rules will expand an existing rule;
(7) the proposed rules will increase the number of individuals subject to the rule; and
(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Ms. Rymal has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. The proposed amendments bring Medicaid/CHIP Pharmacy rules into alignment with the current Medicaid State Plan and are conforming changes only.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the rules as proposed.

There is no anticipated negative impact on local employment.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the

residents of Texas and are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rule.

PUBLIC BENEFIT

Stephanie Muth, State Medicaid Director, has determined that for each year of the first five years the section is in effect, the public benefit anticipated as a result of enforcing or administering the rules will be increasing clarity by aligning TAC language with Texas Medicaid State Plan language.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 149030, Mail Code 4102, Austin, Texas 78714-9030 or 4900 North Lamar Boulevard, Mail Code 4102, Austin, Texas 78751; or e-mailed to *HHSRulesCoordinationOffice@hhsc.state.tx.us* within 30 days of publication of this proposal in the *Texas Register*.

To be considered, comments must be submitted no later than 30 days after the date of this issue of the *Texas Register*. The last day to submit comments falls on a Sunday; therefore, comments must be: (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) e-mailed by midnight on the last day of the comment period. When e-mailing comments, please indicate "Comments on Proposed Rule 18R026” in the subject line.

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.033, which provides HHSC’s Executive Commissioner with broad authority to adopt rules to carry out HHSC’s duties; Texas Government Code §531.302(a), which requires HHSC’s Executive Commissioner to adopt rules for the state prescription drug program; Texas Government Code §531.021(b-1), which requires HHSC’s Executive Commissioner to adopt rules governing the determination of rates for Medicaid payments; and Texas Human Resources Code §32.021(c), which requires HHSC’s Executive

Commissioner to adopt rules as necessary to properly and efficiently operate the Medicaid program.

The amendments implement Texas Government Code §531.021(a) and Texas Human Resources Code §32.021(a), which authorize HHSC to operate the Medicaid program; and Texas Government Code §531.021(d), which authorizes HHSC's Executive Commissioner to provide for payment of Medicaid rates in accordance with applicable federal law.

This agency hereby certifies that this proposal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

TITLE 1 ADMINISTRATION
PART 15 TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHAPTER 355 REIMBURSEMENT RATES
SUBCHAPTER J PURCHASED HEALTH SERVICES
DIVISION 28 PHARMACY SERVICES: REIMBURSEMENT

§355.8541. Legend and Nonlegend Medications.

(a) Legend and nonlegend drug reimbursement. A pharmaceutical provider is reimbursed for legend and nonlegend drugs based on the lesser of the:

(1) acquisition cost (AC) plus the Health and Human Services Commission's (HHSC's) currently established professional dispensing fee per prescription;

(2) usual and customary price charged the general public; or

(3) Gross Amount Due, if provided.

(b) AC. [~~Acquisition cost (AC). The AC is an estimate of prices generally and currently paid in the market.~~]

[~~(1) The AC is defined as the:~~]

[~~(A) wholesale estimated acquisition cost (WEAC);~~]

[~~(B) direct estimated acquisition cost (DEAC), according to the pharmacist's usual purchasing source and the pharmacist's usual purchasing quantity;~~]

[~~(C) long term care pharmacy acquisition cost (LTCPAC); or~~]

[~~(D) specialty pharmacy acquisition cost (SPAC).~~]

[~~(2)~~] The AC is verifiable by invoice audit conducted by HHSC to include necessary supporting documentation that will verify the final cost to the provider.

[~~(3) The WEAC, LTCPAC, and SPAC are established using market or government sources, which include, but are not limited to:~~]

[~~(A) Reported Manufacturer Pricing;~~]

[~~(B) First Databank;~~]

[~~(C) Redbook;~~]

[~~(D) Weighted AMP, as published by the Centers for Medicare & Medicaid Services (CMS);~~]

[~~(E) National Average Drug Acquisition Cost (NADAC), as published by the CMS; or~~]

[~~(F) Gold Standard.~~]

[~~(4) The DEAC is established by HHSC using direct price information supplied by a drug company. Providers are reimbursed only at the DEAC on all drug products that are available from select manufacturers/distributors who actively seek and encourage direct purchasing.~~]

(c) Public hearing. Notice of a public hearing to receive comments on proposed changes to general pricing determinations derived under this section will be published in the *Texas Register*.

(d) Definitions. The terms used in this section have the meanings as defined for the same terms in §354.1921(g) of this title (relating to Addition of Drugs to the Texas Drug Code Index).

TITLE 1 ADMINISTRATION
PART 15 TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHAPTER 355 REIMBURSEMENT RATES
SUBCHAPTER J PURCHASED HEALTH SERVICES
DIVISION 28 PHARMACY SERVICES: REIMBURSEMENT

§355.8548. 340B Covered Entities.

(a) Scope. This section applies to each manufacturer of outpatient drugs that has executed an agreement with the Secretary of the United States Department of Health and Human Services under Section 340B of the Public Health Service Act (42 U.S.C. §256b).

(b) Definitions. For purposes of this section, the following terms are defined as follows:

(1) 340B covered entity--A health-care organization enrolled in the 340B Program.

(2) 340B covered outpatient drug--A drug eligible for purchase through the 340B Program, as defined in 42 C.F.R. §10.20 and §10.21.

(3) 340B price--The maximum price that the United States Health Resources and Services Administration will allow a drug manufacturer to charge a 340B covered entity for a 340B covered outpatient drug purchased through the 340B program. The 340B price is also known as the "ceiling price."

(4) 340B program--A drug-pricing program established under Section 340B of the Public Health Service Act (42 U.S.C. §256b) under which a manufacturer of covered outpatient drugs agrees that it will not charge a 340B covered entity more than the 340B price for a 340B covered outpatient drug.

(5) HHSC--The Texas Health and Human Services Commission or its designee.

(c) Reimbursement methodology. HHSC reimburses a 340B covered entity for a 340B covered outpatient drug purchased through the 340B program and dispensed to a patient of a 340B covered entity based on HHSC's estimate of the 340B price plus a professional dispensing fee assigned by HHSC in accordance with §355.8551 of this division (relating to Dispensing Fee). [~~HHSC establishes the estimate of the 340B price using market or government sources, which include, but are not limited to:~~]

[~~(1) Reported manufacturer pricing;~~]

[~~(2) Weekly data from national drug pricing publishers; and~~]

[~~(3) Quarterly data from the Centers for Medicare and Medicaid Services.~~]

TITLE 1 ADMINISTRATION
PART 15 TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHAPTER 355 REIMBURSEMENT RATES
SUBCHAPTER J PURCHASED HEALTH SERVICES
DIVISION 28 PHARMACY SERVICES: REIMBURSEMENT

§355.8551. Professional Dispensing Fee.

(a) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise.

(1) Acquisition Cost--As defined in §355.8541 of this division (relating to Legend and Nonlegend Medications).

(2) Delivery Incentive--An incentive for offering no-charge prescription delivery to all Medicaid recipients, in accordance with subsection (d) of this section.

(3) Professional Dispensing Fee--The portion of the reimbursement paid to a pharmacy under §355.8541 of this division, in accordance with 42 C.F.R., Subpart I and the Medicaid State Plan [~~42 C.F.R. §50.504 and 42 C.F.R. §447.502~~], to provide a reasonable payment for the cost of dispensing a prescription drug, including the pharmacist's professional services, and which may include incentive amounts for providers that qualify under this section.

(4) Fixed Component--A component that provides the base reimbursement to a pharmacy for the cost of dispensing a prescription; it includes reimbursement for professional services costs and overhead costs.

(5) Preferred Generic Incentive--An incentive to fill a Medicaid prescription with a premium preferred generic drug for which a drug manufacturer has agreed to pay a supplemental rebate.

(6) Variable Component--A component that is expressed as a percentage of the acquisition cost, and provides an incentive to a pharmacy to stock and dispense higher-cost drugs by covering additional expenses incurred when providing those drugs.

(b) The Texas Health and Human Services Commission (HHSC) reimburses contracted Medicaid pharmacy providers according to the following formula: Professional Dispensing Fee = (((AC + Fixed Component) divided by (1 – the percentage used to calculate the Variable Component)) - AC) + Delivery Incentive + Preferred Generic Incentive. [~~Professional Dispensing Fee =~~

~~(((Acquisition Cost + Fixed Component) divided by (1 - the percentage used to calculate the Variable Component)) - Acquisition Cost) + Delivery Incentive + Preferred Generic Incentive.~~]

(c) A delivery incentive is paid to approved providers who certify in a form prescribed by HHSC that the delivery services meet minimum conditions for payment of the incentive. These conditions include: making deliveries to individuals rather than just to institutions, such as nursing homes; offering no-charge prescription delivery to all Medicaid recipients requesting delivery in the same manner as to the general public; and publicly displaying the availability of prescription delivery services at no charge. The delivery incentive is to be paid on all Medicaid prescriptions filled for legend drugs. This delivery incentive is not to be paid for over-the-counter drugs that are prescribed as a benefit of this program.

(d) Preferred generic drugs are subject to the Preferred Drug List requirements.

(e) The total professional dispensing fee will not exceed $200 per prescription.

(f) Notwithstanding other provisions of this section, HHSC may adjust the dispensing fee to address budgetary constraints in accordance with the provisions of §355.201 of this division (relating to Establishment and Adjustment of Reimbursement Rates by the Health and Human Services Commission).