Written comments on the proposal may be submitted to Rhonda Hites, Senior Policy Analyst, Medicaid/CHIP Division, Health and Human Services Commission at 4900 N. Lamar Boulevard, P.O. Box 13247, Austin, Texas 78711, Mail Code 91X; by fax to (512) 249-3707; or by e-mail to rhonda.hites@hhsc.state.tx.us within 30 days of publication of this proposal in the *Texas Register.*

Statutory Authority

The amendment is proposed under the Texas Government Code §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; Texas Human Resources Code §32.021 and the Texas Government Code §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas.

The amendment affects Texas Human Resources Code, Chapter 32, and the Texas Government Code, Chapter 531. No other statutes, articles, or codes are affected by this proposal.

*§354.1077. Provider Participation Requirements.*

(a) A hospital must comply with each of the following requirements to qualify for participation as a hospital in the Texas Medical Assistance (Medicaid) Program. A hospital must:

(1) be licensed by the Department of State Health Services (department) as a general or special hospital, unless exempt from licensure by the appropriate licensing authority. This requirement does not apply to military hospitals providing inpatient emergency hospital services;

(2) be enrolled and participating in the Medicare Program as a hospital;

(3) sign a written provider agreement with the department or its designee to participate in the Medicaid program. The provider agreement requires the hospital to comply with the terms of the agreement and all requirements of the Medicaid program, including regulations, rules, handbooks, standards, and guidelines published by the department or its designee; and

(4) comply with the utilization review plan approved by the department or its designee.

(b) Effective December 1, 1991, the hospital must maintain policies and procedures regarding the following policies with respect to all adult individuals receiving inpatient services provided by the hospital:

(1) provide all adult individuals the following information regarding advance directives at the time of the individual's admission as an inpatient:

(A) the individual's rights under Texas law, whether statutory or as recognized by the courts of the state, to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives (directive to physicians/living will or durable power of attorney for health care); and

(B) the hospital's policies respecting the implementation of such rights;

(2) document in the individual's medical record whether or not the individual has executed an advance directive;

(3) not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) ensure compliance with the requirements of Texas law, whether statutory or as recognized by the courts of Texas, respecting advance directives at facilities of the provider or organization; and

(5) provide for education for staff and the community on issues concerning advance directives.

~~[(c) Notwithstanding subsections (a) and (b) of this section, effective September 1, 2006, a hospital in the Bexar, Dallas, El Paso, Harris, Lubbock, Nueces, Tarrant or Travis Service Areas will not be permitted to participate in the Texas Medical Assistance (Medicaid) Program unless the hospital agrees in writing to comply with the provisions of §355.8064 of this title (relating to Reimbursement Adjustment for Hospitals Providing Inpatient Services to SSI and SSI-Related Clients).]~~

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 2, 2012.

TRD-201201685
Steve Aragon
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: May 13, 2012
For further information, please call: (512) 424-6900

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## SUBCHAPTER F. PHARMACY SERVICES
## DIVISION 2. ADMINISTRATION

### 1 TAC §354.1831

The Texas Health and Human Services Commission (HHSC) proposes to amend §354.1831, concerning Covered Drugs.

Background and Justification

This proposed amendment removes the language in §354.1831(b) which states that with a few exceptions, the Vendor Drug Program (VDP) does not reimburse for vitamins and minerals. Currently, medically necessary vitamins and minerals are available for Medicaid clients under age 21 only through pharmacies that are specifically enrolled in the Medicaid Comprehensive Care Program (CCP). The 2012-13 General Appropriations Act, H.B. 1, 82nd Legislature, Regular Session, 2011 (Article II, Health and Human Services Commission, Rider 72), requires vitamins and minerals to be added to the VDP formulary so that all VDP-enrolled pharmacies can be reimbursed for this CCP benefit. Removing subsection (b) will allow HHSC to add vitamins and minerals to the VDP formulary and reimburse all VDP-enrolled pharmacies for this benefit for Medicaid clients under age 21.

Section-by-Section Summary

The proposed amendment deletes subsection (b) to allow for all VDP-enrolled pharmacies to receive reimbursement for vitamins and minerals, a current CCP benefit.

Fiscal Note

Greta Rymal, Deputy Executive Commissioner for Financial Services, has determined that during the first five-year period the proposed rule is in effect, there is an estimated cost in general revenue of $17,738 for state fiscal year (SFY) 2012; $332,798 for SFY 2013; $474,792 for SFY 2014; $508,027 for SFY 2015;

$543,589 for SFY 2016; and $581,640 for SFY 2017. The proposed rule will not result in any fiscal implications for local health and human services agencies. Local governments will not incur additional costs.

Small and Micro-business Impact Analysis

Ms. Rymal has also determined that there will be no effect on small businesses or micro businesses to comply with the proposed rule, as they will not be required to alter their business practices as a result of the amended rule. There are no anticipated economic costs to persons who are required to comply with the proposed rule. There is no anticipated negative impact on local employment.

Public Benefit

Billy Millwee, Deputy Executive Commissioner for Health Services Operations, has determined that for each year of the first five years the section is in effect, the public will benefit from the adoption of the rule. The anticipated public benefit of enforcing the proposed rule will be increased access to vitamins and minerals for Medicaid clients under age 21.

Regulatory Analysis

HHSC has determined that this proposal is not a "major environmental rule" as defined by §2001.0225 of the Texas Government Code. A "major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

Takings Impact Assessment

HHSC has determined that this 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 §2007.043 of the Government Code.

Public Comment

Written comments on the proposal may be submitted to Stacey Johnston, Policy Analyst, Medicaid/CHIP Division, Texas Health and Human Services Commission, P.O. Box 85200, Austin, TX 78708-5200, Mail Code H310; by fax to (512) 491-1953; or by e-mail to Stacey.Johnston@hhsc.state.tx.us within 30 days of publication of this proposal in the *Texas Register.*

Statutory Authority

The amendment is proposed under Texas Government Code §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; Texas Human Resources Code §32.021 and Texas Government Code §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas.

The amendment affects Texas Human Resources Code Chapter 32 and Texas Government Code Chapters 531 and 533. No other statutes, articles, or codes are affected by this proposal.

*§354.1831. Covered Drugs.*

(a) Only those drugs 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) Except for vitamins K and D3, prenatal vitamins, fluoride preparations, and products containing iron in its various salts, the Commission does not reimburse for vitamins and legend and nonlegend multiple ingredient antianemia products.~~]

(b) [~~(c)~~] 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.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on March 30, 2012.

TRD-201201645
Steve Aragon
General Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: May 13, 2012
For further information, please call: (512) 424-6576



## SUBCHAPTER F. PHARMACY SERVICES

The Texas Health and Human Services Commission (HHSC) proposes to amend §354.1901, concerning Pharmacy Claims; §354.1921, concerning Addition of Drugs to the Texas Drug Code Index; §354.1923, concerning Review and Evaluation; and §354.1927, concerning Retention and Deletion of Drugs.

Background and Justification

HHSC is clarifying the Medicaid Vendor Drug Program (VDP) drug pricing rules and, thereby, standardizing pharmaceutical manufacturers' price reporting. These rule changes will improve administrative efficiency by clarifying pharmaceutical manufacturers' responsibilities and improving the drug price reporting process. The benefits of clarifying these rules, and the resulting standardization of pharmaceutical companies' price reporting, have been confirmed by feedback from stakeholders.

The proposed amendments are consistent with, and help carry out, the federal mandate to reimburse providers at HHSC's best estimate of prices generally and currently paid (42 C.F.R. §447.502 and 42 C.F.R. §447.512). The proposed amendments also are in accordance with HHSC's approved Medicaid State Plan. The integrity of HHSC's regulatory system depends on pharmaceutical manufacturers reporting their market prices accurately and in good faith. This regulatory system fails if manufacturers do not report accurate market prices to HHSC.

Federal law requires HHSC to reimburse Medicaid pharmacies at HHSC's best estimate of provider acquisition cost (EAC). Reported manufacturer prices are the foundation of HHSC's calculation of EAC, and manufacturers have a legal obligation to know HHSC's price reporting requirements. Drug manufacturers must therefore provide complete and accurate pricing information. Failure to do so could result in liability under the Texas Medicaid Fraud Prevention Act (Texas Human Resources Code, Chapter 36 or other laws.

In 2003, the United States Department of Health and Human Services, Office of Inspector General (HHS/OIG) published its "OIG Compliance Program Guidance for Pharmaceutical Manufacturers." HHS/OIG's guidance can be found in the *Federal*

*Register,* 68 FR 86 (2003-5-5). This guidance raised concerns that some pharmaceutical manufacturers were illegally manipulating published average wholesale prices (AWPs) in order to increase reimbursements paid to their customers by federally funded health care programs. Similar to the recommendation in HHS/OIG's guidance, HHSC suggests that manufacturers review their AWP reporting practices to ensure that their AWPs are an accurate reflection of true market prices.

HHSC's acceptance and use of manufacturer reported pricing information, or HHSC's use of pricing information obtained from pricing compendiums, including published AWP, is not confirmation by HHSC that the pricing information is true and correct or that the pricing information is an accurate representation of drug manufacturers' actual market prices.

Concurrently, amendments to §355.8541 and §355.8542 related to pharmacy services reimbursement are being proposed elsewhere in this issue of the *Texas Register.*

Section-by-Section Summary

Throughout the rules, minor language changes are proposed for clarification.

The proposed amendment to §354.1901 makes the following changes:

(1) Subsection (a) clarifies that when providers are submitting a claim for the original dispensing of a drug and for subsequent refills, providers must indicate on the pharmacy claim, not the prescription, the usual and customary price and the purchasing method in addition to the National Drug Code. It also clarifies that all drug purchases through a central purchasing agreement or from a central purchasing entity must be billed to HHSC as direct price to chain pharmacy.

(2) Subsection (e) clarifies that the appropriate drug costs are determined by HHSC and are based on estimated acquisition costs.

The proposed amendment to §354.1921 makes the following changes:

(1) Subsection (a) clarifies that a drug company also includes a repackager or private labeler in addition to a manufacturer.

(2) Subsection (b) clarifies that a drug company must apply to add a drug to the Texas Drug Code Index (TDCI) by completing each section of the Certification of Information for the Addition of a Drug Product on the Texas Drug Code Index (Certification of Information) instead of completing what was formerly known as a questionnaire. This includes completing all of the price certification sections in the Certification of Information.

(3) Subsection (c) lists requirements for drug companies with drugs listed on the TDCI, including: updating HHSC with any changes to the formulation, product status, or availability; submitting changes to the prices reported in the price certification section of the Certification of Information form; submitting price updates in a timely manner; and updating average manufacturer price (AMP) prices on a quarterly basis. The remaining subsections are relettered.

(4) Subsection (d) clarifies that when sources other than drug companies request the addition of a drug to the TDCI, HHSC may request that the manufacturer submit a Certification of Information.

(5) Subsection (e) clarifies that drug companies and other sources are entitled to receive notification as to whether a Certification of Information has been approved or denied, and that if the Certification of Information has been denied, the notice will state the reason(s) for the denial.

(6) Subsection (f) clarifies that pricing information reported by a drug company must not be disclosed by HHSC or its designee in a format that discloses the identity of a manufacturer or the prices charged, except as necessary to permit the Attorney General to enforce state and federal laws.

(7) Subsection (g) adds the following definitions: average manufacturer price (AMP), average wholesale price (AWP), customary prompt pay discount, direct price to chain pharmacy (with exclusions), direct price to long term care pharmacy (with exclusions), direct price to pharmacy (with exclusions), gross amount due, "may apply to the Commission," National Drug Code (NDC), pharmacy, price concession, price to wholesaler/distributor (with exclusions), reliable sources, reported manufacturer pricing, warehouse purchases, weighted AMP, and wholesaler cost.

The proposed amendment to §354.1923 makes the following changes:

(1) Subsection (a) clarifies that HHSC reviews Certifications of Information to determine the need for a drug to be added to the TDCI and to determine the need for restrictions. Paragraph (3)(A) clarifies the relevant information that HHSC considers in determining the need to have the drug placed on the TDCI. Paragraph (3)(B) adds the comparison of the cost of a drug to pharmacies to the drug company's price for the same drug in other packaging sizes as a consideration when determining the need to add a drug to the TDCI. The remaining subparagraphs are relettered.

(2) Subsection (b) clarifies the reasons that HHSC may return a Certification of Information, and subsection (b)(4) further clarifies that wholesale estimated acquisition cost, direct price to chain pharmacy, and direct estimated acquisition cost are determined based on reported manufacturer pricing and a review of published and non-published prices.

(3) Subsection (c) adds medical foods and nutritional supplements to the list of drug classes that HHSC may deny from being added to the TDCI.

The proposed amendment to §354.1927 reorganizes the structure of the rule and makes the following changes:

(1) Paragraph (2) clarifies that if a drug company does not provide HHSC with the information required under §354.1921(c), or if the drug violates state or federal law, HHSC may request that the U.S. Department of Health and Human Services (HHS) allow deletion of the drug from the TDCI.

(2) Paragraph (5) clarifies that HHSC deletes from the TDCI drugs for which federal matching funds are no longer available.

(3) Paragraph (6) clarifies additional conditions under which HHSC may delete a drug from the TDCI.

(4) Deletes the provision in former subsection (b) that drug companies are entitled to notification and an opportunity to request reconsideration of HHSC's decision to delete a drug from the TDCI.

Fiscal Note

Greta Rymal, Deputy Executive Commissioner for Financial Services, has determined that during the first five-year period the proposed amendments are in effect there will be no fiscal im-

pact to state government. The amendments will not result in any fiscal implications for local health and human services agencies. Local governments will not incur additional costs.

Small and Micro-business Impact Analysis

Ms. Rymal has also determined that there is no potential impact to small or micro-businesses to comply with the proposed rule amendments because the amendments clarify VDP's existing price reporting requirements. There are no anticipated economic costs to persons who are required to comply with the amendments. There is no anticipated negative impact on local employment.

Public Benefit

Billy Millwee, Deputy Executive Commissioner for Health Services Operations, has determined that for each year of the first five years the proposed amendments are in effect, the public will benefit from the adoption of the amendments. The anticipated public benefit, as a result of enforcing the amendments, is improved administrative efficiency achieved by clarifying pharmaceutical manufacturers' responsibilities and improving the drug price reporting process.

Regulatory Analysis

HHSC has determined that this proposal is not a "major environmental rule" as defined by §2001.0225 of the Texas Government Code. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

Takings Impact Assessment

HHSC has determined that this 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 §2007.043 of the Government Code.

Public Comment

Written comments on the proposal may be submitted to Michelle Erwin, Senior Policy Analyst, at 11209 Metric Blvd., MC H310, Austin, Texas 78758; by fax to (512) 491-1953; or by e-mail to michelle.erwin@hhsc.state.tx.us within 30 days of publication of this proposal in the *Texas Register.*

Public Hearing

A public hearing is scheduled for May 8, 2012, from 9:00 a.m. to 10:00 a.m. (central time) at the Health and Human Services Building H, Lone Star Conference Room, located at 11209 Metric Boulevard, Austin, Texas. Persons requiring further information, special assistance, or accommodations should contact Leigh Van Kirk at (512) 491-2813.

## DIVISION 6. PHARMACY CLAIMS

### 1 TAC §354.1901

Statutory Authority

The amendments are proposed under Texas Government Code §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas.

The amendments affect the Human Resources Code, Chapter 32, and the Texas Government Code, Chapter 531. No other statutes, articles, or codes are affected by this proposal.

*§354.1901. Pharmacy Claims.*

(a) To receive payment from the Health and Human Services Commission (Commission), the provider must submit a pharmacy claim through the electronic adjudication system. A separate entry is submitted for each prescription or refill. For the original dispensing and each subsequent refill, the provider indicates on the corresponding pharmacy claim submitted to the Commission [~~prescription~~] the usual and customary price, the purchasing method, [~~and reimbursement method (wholesale estimated acquisition cost, direct estimated acquisition cost, or maximum allowable cost)~~] and the National Drug Code (NDC) [~~number (NDC), which is submitted to the Commission on the corresponding pharmacy claim~~]. All drug purchases through a central purchasing agreement or from a central purchasing entity must be billed to the Commission as Direct Price to Chain Pharmacy, as required by §355.8541 of this title (relating to Legend and Nonlegend Medications). Claims received over 90 days after the date of service are rejected. For claims on behalf of an individual who has applied for Medicaid coverage but has not yet been assigned a recipient number on the date of service, the filing period does not commence until the date the individual has been assigned a number. The requirements in §354.1863 of this subchapter [~~title~~] (relating to Prescription Requirements) are also waived for retroactive claims. The provider must ensure, however, that a prescription submitted for a prior eligibility period [~~claim~~] conformed to Texas State Board of Pharmacy and [~~Texas Health and Human Services~~] Commission regulations on the date of service, or a claim cannot be submitted.

(b) Providers must dispense the quantity prescribed or ordered by the prescriber except as limited by the policies and procedures described in the Commission's Pharmacy Provider Handbook. Where the actual quantity dispensed deviates from the prescribed quantity, the provider must bill for the amount actually dispensed. The quantity of drugs must be entered in the metric decimal quantity field. The quantity shown as the metric decimal quantity unit must be calculated after referencing the pricing unit shown in the Texas Drug Code Index.

(c) If all necessary information is not supplied, a claim will not [~~cannot~~] be processed or paid.

(d) The provider must submit claims as the prescription is dispensed through the on-line system. Providers [~~; however, some providers~~] who supply a large volume of medications to nursing facility recipients may submit these claims through their data transmission company after the point of sale.

(e) Overcharged prescription claims are not denied. The Commission pays the appropriate drug cost. The appropriate drug cost is the estimated acquisition cost, as determined by the Commission [~~(wholesale acquisition cost, direct acquisition cost, or maximum allowable cost) listed in the computer drug file~~], plus the provider's [~~assigned~~] dispensing fee [~~, is paid~~]. The amount claimed and the amount paid are shown on the payment register.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 2, 2012.

TRD-201201682

Steve Aragon
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: May 13, 2012
For further information, please call: (512) 424-6900

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# DIVISION 7. TEXAS DRUG CODE INDEX--ADDITIONS, RETENTIONS, AND DELETIONS

**1 TAC §§354.1921, 354.1923, 354.1927**

Statutory Authority

The amendments are proposed under Texas Government Code §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas.

The amendments affect the Human Resources Code, Chapter 32, and the Texas Government Code, Chapter 531. No other statutes, articles, or codes are affected by this proposal.

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

(a) A [~~Any~~] drug company that has a valid rebate agreement under 42 U.S.C. §1396r-8 may [~~the Social Security Act, §1927, is allowed to~~] apply to the Health and Human Services Commission (Commission) to add a drug to [~~for addition of a drug not currently listed in~~] the Texas Drug Code Index (TDCI). The term "drug company" includes [~~Drug companies include~~] any manufacturer, repackager, or private labeler [~~own label distributor, or re-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 Texas Drug Code Index (Certification of Information) provided by the Commission. [~~The drug company must complete the questionnaire provided by the Commission to request the addition of a drug to the TDCI. All questions on the questionnaire must be answered and all statements must be complete. For a multi-source drug, the drug company may reference the actual manufacturer's data, if the manufacturer's drug is listed in the TDCI.~~]

(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, as follows:

(A) by the 10th business day of each month, submit price updates, except Average Manufacturer Price (AMP) updates, to the Commission;

(B) when submitting price updates, include current information for each price on the Certification of Information that changed during the preceding month;

(C) update Average Manufacturer Price (AMP) prices quarterly; and

(D) if required by the Commission, update pricing on a more frequent basis as circumstances warrant.

(d) [~~(c)~~] 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 [~~requests~~] the manufacturer [~~to~~] submit a Certification of Information [~~the questionnaire~~] as described in subsection (b) of this section.

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

(f) [~~(e)~~] Notwithstanding any other state law, pricing information reported by a drug company [~~disclosed by manufacturers or labelers~~] under this subchapter [~~title~~] is confidential and must [~~, except as necessary to permit the attorney general to enforce state and federal laws, may~~] not be disclosed by the Commission, its agents, contractors, or any other State agency in a format [~~form~~] 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) Average Manufacturer Price (AMP)--The average manufacturer price as defined in 42 USC §1396r-8(k)(1).

(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.

(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.

(4) Direct Price to Chain Pharmacy--The amount paid by a chain pharmacy for a product when purchased directly from a drug company, whether delivered directly to a chain warehouse facility or indirectly through 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.

(5) 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. 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.

(6) Direct Price to Pharmacy--The amount paid for a product by a pharmacy when purchased directly from a drug company. This 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;

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

(C) Direct Prices to a Chain Pharmacy or Direct Prices to Long Term Care Pharmacy.

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

(8) "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.

(9) 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.

(10) Pharmacy--An entity with an approved community pharmacy license or an institutional pharmacy license.

(11) 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.

(12) 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.

(13) 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.

(14) 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, Direct Price to Chain 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.

(15) Warehouse Purchases--Purchases through a central purchasing agreement or from a central purchasing entity. Warehouse purchases will be reimbursed at Direct Price to Chain Pharmacy.

(16) Weighted AMP (Average Manufacturer Price)--The Weighted AMP (Average Manufacturer Price) as contemplated in 42 U.S.C. §1396r-8(b)(3) and (e), and as reported by the Centers for Medicare & Medicaid Services.

(17) Wholesaler Cost--The net cost of a product to a wholesaler; equivalent to Price to Wholesaler/Distributor and cost to wholesaler.

*§354.1923. Review and Evaluation.*

(a) The Health and Human Services Commission (Commission) reviews Certifications of Information [~~each request~~] to determine the need for a drug to be added to the Texas Drug Code Index and to determine the need for restrictions, when appropriate. In determining need, the Commission considers the following:

(1) expansion [~~Expansion~~] of the prescriber's armamentarium by a new drug entity or an additional multiple source [~~multisource~~] drug;

(2) the predominant use of the drug in an outpatient setting;

(3) the cost of the drug to pharmacies compared to:

(A) relevant costs as published in price reporting compendia [~~wholesale estimated acquisition cost (WEAC) or direct estimated acquisition costs (DEAC) listed in the Redbook (Annual Pharmacists' Reference)~~];

(B) the drug company's prices for the drug in other packaging sizes;

(C) [~~(B)~~] the Average Manufacturer [~~Manufacturer's~~] Price (AMP) as defined by 42 U.S.C. 1396r-8(k), as amended; and

(D) [~~(C)~~] other generically equivalent drug products; and [~~.~~]

(4) whether [~~Whether~~] the drug is part of a category that is subject to inclusion in a preferred drug list (PDL) under §354.1924 of this division (relating to Preferred Drug List). If a drug is subject to inclusion in the PDL, the manufacturer or labeler's provision of supplemental rebates will be considered when determining whether the product is subject to prior authorization.

(b) The Commission may return a Certification of Information [~~returns a questionnaire~~] for any of the following reasons:

(1) discovery of false, erroneous, or incomplete information or documentation in the Certification of Information [~~on the questionnaire~~];

(2) failure of the drug company to provide the Commission with documentation of the:

(A) approved New Drug Application [~~new drug application (NDA)~~] or Abbreviated New Drug Application [~~abbreviated new drug application (ANDA)~~], if applicable; or

(B) Food and Drug Administration (FDA) approval for marketing;

(3) failure of the drug company to provide the Commission with the National Drug Code [~~national drug code (NDC)~~], as defined by and filed with the FDA, for the drug product as shown on the drug product container sold to the pharmacy; or

(4) failure of the drug company to provide the Commission with [~~the~~] current prices for the pricing points on the Certifica-

tion of Information. The Wholesale Estimated Acquisition Cost, Direct Price to Chain Pharmacy, and Direct Estimated Acquisition Cost are determined based on Reported Manufacturer Pricing and a review of published and non-published prices. [~~DEAC to a pharmacy, cost to a wholesaler, estimated wholesale cost to a pharmacy, or AMP. The allowable WEAC and DEAC are the costs to a pharmacy, as determined by review of published or non-published prices resulting from routine marketing practices. The drug company shall update the AMP each quarter at the same time the information is reported to the Secretary of Health and Human Services.~~]

(c) The Commission may deny a request if it determines that the drug is included in one or more of the following classes:

(1) amphetamines, when used for weight loss, and obesity control drugs;

(2) appliances;

(3) cosmetics;

(4) DESI-ineffective products;

(5) diagnostic aids;

(6) durable medical equipment (rental or purchase);

(7) elastic stockings;

(8) experimental drugs;

(9) fertility drugs;

(10) first aid supplies;

(11) immunizing agents;

(12) irrigating sets;

(13) IV sets;

(14) medical devices;

(15) medical supplies;

(16) oxygen;

(17) products unsuitable for use outside of physician offices or health care facilities;

(18) shampoos, unless medicated for parasite control;

(19) skin lotions and creams (nonlegend cosmetic types);

(20) soaps and soap substitutes;

(21) supports and suspensories;

(22) syringes and needles;

(23) unit-dose or convenience packaging; [~~and~~]

(24) vitamin and antianemia combinations; [~~.~~]

(25) medical foods; and/or

(26) nutritional supplements.

*§354.1927. Retention and Deletion of Drugs.*

[~~(a)~~] The Health and Human Services Commission (Commission) reviews the Texas Drug Code Index to evaluate the need for retaining or deleting drugs according to the following criteria.

(1) If the drug company fails to remove from pharmacies any drug recalled by the Food and Drug Administration (FDA) or fails to meet other federal requirements, the Commission has the right to request that the U.S. Department of Health and Human Services (HHS) allow deletion of the drug. If the drug company repeatedly fails to meet FDA or other federal requirements, the Commission may request permission to delete all drugs manufactured by the company.

(2) The Commission may request that HHS allow deletion of a drug if:

(A) the drug company or companies' actions with respect to a drug violate state or federal law; or

(B) the drug company fails to provide to the Commission the information required under §354.1921(c) of this division (relating to Addition of Drugs to the Texas Drug Code Index). If the Commission retains a drug for which the cost was not reported, the Commission establishes the cost.

[~~(2) If the drug company fails to provide the Commission the current drug costs that include the direct estimated acquisition costs (DEAC) to a pharmacy, the cost to a wholesaler, the Average Manufacturer's Price (AMP), and the estimated wholesale cost to a pharmacy, the Commission is allowed to request that HHS allow deletion of the drug. If the Commission retains a drug for which the cost was not reported, the Commission establishes the cost. The allowable wholesale estimated acquisition cost (WEAC) and DEAC are the costs to a pharmacy, as determined by review of published or nonpublished prices that result from routine marketing practices.~~]

(3) The Commission may delete [~~deletes~~] a legend drug if the same drug becomes available as an over-the-counter drug.

(4) Effective upon notification, the Commission deletes discontinued or permanently recalled drugs. This provision applies to:

(A) drugs permanently recalled by the manufacturer;

(B) drugs permanently recalled by the FDA; and

(C) drugs no longer manufactured.

(5) The Commission deletes drugs for which federal matching funds are no longer available. [~~Federal matching funds are not available for:~~]

[~~(A) drugs for which a rebate is not available under Public Law 101-508; and~~]

[~~(B) drugs for which notice of opportunity for hearing has been published in the Federal Register.~~]

(6) The Commission may delete a drug if:

(A) there is no federal rebate for the drug;

(B) the drug no longer meets the definition of a covered, outpatient drug;

(C) the drug has been designated to an excludable class of drugs; or

(D) the classification of the drug changes to a class listed in §354.1923(c) of this division (relating to Review and Evaluation).

[~~(b) If a drug is deleted, the drug company is entitled to be notified and given an opportunity to request reconsideration of the decision, unless the deletion is based on criteria in subsection (a)(3)-(5) of this section.~~]

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 2, 2012.

TRD-201201683

Steve Aragon
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: May 13, 2012
For further information, please call: (512) 424-6900

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# CHAPTER 355. REIMBURSEMENT RATES
## SUBCHAPTER J. PURCHASED HEALTH SERVICES
## DIVISION 28. PHARMACY SERVICES: REIMBURSEMENT

**1 TAC §355.8541, §355.8542**

The Texas Health and Human Services Commission (HHSC) proposes to amend §355.8541, concerning Legend and Nonlegend Medications, and §355.8542, concerning Price Changes.

Background and Justification

HHSC is proposing to amend the Medicaid Vendor Drug Program (VDP) drug pricing rules to clarify them, thereby standardizing pharmaceutical manufacturers' price reporting. These proposed rule amendments will improve administrative efficiency by clarifying pharmaceutical manufacturers' responsibilities and improving the drug price reporting process. The benefits of clarifying these rules, and the resulting standardization of pharmaceutical companies' price reporting, have been confirmed by feedback received from stakeholders.

The amendments are consistent with, and help carry out, the federal mandate to reimburse providers at HHSC's best estimate of prices generally and currently paid (42 C.F.R. §447.502 and 42 C.F.R. §447.512). The amendments are also in accordance with HHSC's approved Medicaid State Plan.

Concurrently, amendments to §§354.1901, 354.1921, 354.1923, and 354.1927, related to pharmacy policy, are being published elsewhere in this issue of the *Texas Register.*

Section-by-Section Summary

The introductory sentence in §355.8541 is unnecessary and has been deleted. The rule has been relettered, and various language and formatting changes have been made throughout the rule for clarification. The proposed amendment to §355.8541 also makes the following changes:

(1) Subsection (a)(3) adds the Gross Amount Due as a basis of reimbursement to pharmaceutical providers.

(2) Subsection (b) clarifies that the estimated acquisition cost (EAC) is HHSC's best estimate of prices generally and currently paid in the market as required by federal law.

(3) Subsection (b)(1)(C) indicates that direct price to chain pharmacy (DPCP) is included in what defines the EAC.

(4) Subsection (b)(3) clarifies that drug purchases through a central purchasing agreement or from a central purchasing entity must be billed to HHSC as DPCP.

(5) Subsection (b)(4) clarifies that the wholesale estimated acquisition cost (WEAC) may be established using government sources in addition to market sources, and that these sources may include the weighted AMP and the National Average Drug Acquisition Cost, as published by the Centers for Medicare & Medicaid Services. First Alert is removed as one of the sources for determining WEAC.

(6) Subsection (b)(5) clarifies that WEAC may not exceed Wholesaler Costs, as supplied by drug companies, plus an amount that represents wholesaler operating costs and profits. It also clarifies that wholesaler operating conditions will be determined based on information supplied by drug companies, wholesalers, or other reliable sources.

(7) Subsection (b)(6) clarifies that the direct estimated acquisition cost (DEAC) is established using direct price information supplied by drug companies, and that 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.

(8) Subsection (b)(7) indicates that the DPCP is established by HHSC using price information supplied by drug companies.

(9) Subsection (c)(1)(C) adds the Gross Amount Due as a basis for reimbursement of nonlegend drugs.

(10) Subsection (c)(2) clarifies that no dispensing fee is added to the price of nonlegend drugs except as described in paragraph (3) of the subsection.

(11) Subsection (c)(3) clarifies that nonlegend drugs are to be reimbursed as stated under subsection (a) of the section if 50 percent of the EAC exceeds the original dispensing fee.

(12) Subsection (e) clarifies that terms used in §355.8541 have the same meaning as the terms defined in §354.1921(g).

The amendment to §355.8542 changes the name of the section from "Price Changes" to "Drug Price Effective Date." The amendment also clarifies that, subject to the requirements of Chapter 354, Subchapter F of this title (relating to Pharmacy Services), new prices and price updates are effective for reimbursement purposes on the day HHSC receives the new prices and price updates from drug companies, wholesalers, or other reliable sources.

Fiscal Note

Greta Rymal, Deputy Executive Commissioner for Financial Services, has determined that during the first five-year period the proposed amendments are in effect there will be no fiscal impact to state government. The amendments will not result in any fiscal implications for local health and human services agencies. Local governments will not incur additional costs.

Small and Micro-business Impact Analysis

Ms. Rymal also has determined that there is no potential impact to small or micro-businesses to comply with the proposed amendments, because the amendments clarify VDP's existing price reporting requirements. There are no anticipated economic costs to persons who are required to comply with the amendments. There is no anticipated negative impact on local employment.

Public Benefit

Billy Millwee, Deputy Executive Commissioner for Health Services Operations, has determined that for each year of the first five years the proposed amendments are in effect, the public will benefit from the adoption of the amendments. The anticipated public benefit, as a result of enforcing the amendments, is improved administrative efficiency achieved by clarifying pharma-

ceutical manufacturers' responsibilities and improving the drug price reporting process.

Regulatory Analysis

HHSC has determined that this proposal is not a "major environmental rule" as defined by §2001.0225 of the Texas Government Code. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

Takings Impact Assessment

HHSC has determined that this 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 §2007.043 of the Government Code.

Public Comment

Written comments on the proposal may be submitted to Michelle Erwin, Senior Policy Analyst, at 11209 Metric Blvd., MC H310, Austin, Texas 78758; by fax to (512) 491-1953; or by e-mail to michelle.erwin@hhsc.state.tx.us within 30 days of publication of this proposal in the *Texas Register.*

Public Hearing

A public hearing is scheduled for May 8, 2012, from 10:00 a.m. to 11:00 a.m. (central time) at the Health and Human Services Building H, Lone Star Conference Room, located at 11209 Metric Boulevard, Austin, Texas. Persons requiring further information, special assistance, or accommodations should contact Leigh Van Kirk at (512) 491-2813.

Statutory Authority

The amendments are proposed under Texas Government Code §531.033, which provides the Executive Commissioner of HHSC with broad rulemaking authority; and Human Resources Code §32.021 and Texas Government Code §531.021(a), which provide HHSC with the authority to administer the federal medical assistance (Medicaid) program in Texas.

The amendments affect the Human Resources Code, Chapter 32, and the Texas Government Code, Chapter 531. No other statutes, articles, or codes are affected by this proposal.

*§355.8541. Legend and Nonlegend Medications.*

[~~For all medication, legend and non-legend, covered by the Vendor Drug Program and appearing in the Texas Drug Code Index (TDCI) and updates, the following requirements must be met.~~]

(a) [~~(1)~~] Legend drug reimbursement [~~Reimbursement~~]. A pharmaceutical provider is reimbursed for legend drugs based on the lesser of the:

(1) [~~(A)~~] Health and Human Services Commission's (HHSC's) [~~the HHSC's~~] best estimate of acquisition cost (EAC) plus [~~the~~] HHSC's currently established dispensing fee per prescription; [~~or~~]

(2) [~~(B)~~] [~~the~~] usual and customary price charged the general public; or[~~.~~]

(3) Gross Amount Due, if provided.

(b) [~~(2)~~] Estimated acquisition cost (EAC). The EAC is HHSC's best estimate of prices generally and currently paid in the market.

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

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

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

(C) direct price to chain pharmacy (DPCP); or

(D) [~~(iii)~~] maximum allowable cost (MAC) for multiple source [~~multi-source~~] drugs.

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

(3) [~~(C)~~] All drug purchases through a central purchasing agreement or from a central purchasing entity must be billed to [~~the~~] HHSC as DPCP [~~warehouse purchases~~].

(4) [~~(D)~~] The WEAC is established by [~~the~~] HHSC 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); or

(E) National Average Drug Acquisition Cost (NADAC), as published by the CMS.

~~*[(i)* the current Redbook;]~~

~~*[(ii)* Redbook Update;]~~

~~*[(iii)* First Databank;]~~

~~*[(iv)* First Alert; or]~~

~~*[(v)* reported manufacturer pricing.]~~

(5) [~~(E)~~] The WEAC may not exceed the Wholesaler Cost [~~wholesaler cost~~], as supplied by a drug company, [~~the drug manufacturers~~] plus an amount representing wholesaler operating costs and profits [~~under current market conditions~~]. Wholesaler operating conditions may [~~Market conditions will be examined at least every two years. Market conditions will~~] be determined from information supplied to HHSC [~~the department~~] by drug companies, wholesalers, or other reliable sources[~~, which include, but are not limited to the manufacturer, the wholesaler, and contracted providers~~]. Exceptions to general pricing determinations may be made on certain drugs and/or drug categories based on information from these same [~~market~~] sources.

(6) [~~(F)~~] The DEAC is established by [~~the~~] HHSC using direct price information supplied by a drug company [~~drug manufacturers~~]. 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. [~~The TDCI is used as the reference for drugs included in the scope of benefits and for allowable package sizes. No acquisition cost is billed to the HHSC for samples dispensed.~~]

(7) The DPCP is established by HHSC using price information supplied by a drug company.

(c) [~~(3)~~] Nonlegend drugs.

(1) [~~(A)~~] Reimbursement for nonlegend drugs is based on the lesser of the:

(A) [~~(i)~~] [~~the~~] usual and customary price charged to the general public; [~~or~~]

(B) [~~(ii)~~] EAC, plus 50 percent [~~50 %~~] of the EAC; or[~~.~~]

(C) Gross Amount Due, if provided.

(2) [~~(B)~~] No dispensing fee is added to the price of nonlegend drugs paid under this subsection, except as described in paragraph (3) of this subsection[~~, and 50% of the EAC may not exceed the assigned dispensing fee~~].

(3) If 50 percent of the EAC exceeds the standard dispensing fee calculation, the nonlegend drug is reimbursed under subsection (a) of this section.

(d) [~~(4)~~] Public hearing [~~Hearing~~]. Notice of a public hearing to receive comments on proposed changes to general pricing determinations derived under this section will [~~these rules shall~~] be published in the *Texas Register* [~~Texas Register~~].

(e) [~~(5)~~] 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). [~~As used in the previous section, these terms shall be defined as follows:~~]

[~~(A) Reported Manufacturer Price--Information on pricing submitted to VDP by the manufacturer, including Average Wholesale Price, Average Manufacturer Price, wholesaler costs, direct prices and institutional or contract prices.~~]

[~~(B) Reliable Sources--Sources including other state/federal agencies and pricing services, as well as verifiable reports by contracted pharmacists and VDP field staff.~~]

[~~(C) Market Conditions--Conditions within the overall retail and wholesale pharmacy drug market place.~~]

[~~(D) Wholesaler Costs--The net cost of a product to a drug wholesaler or distributor.~~]

*§355.8542. Drug Price Effective Date [~~Price Changes~~].*

Subject to the requirements of Chapter 354, Subchapter F of this title (relating Pharmacy Services), new prices and price updates are effective for reimbursement purposes on the day the Health and Human Services Commission receives the new prices and price updates from drug companies, wholesalers, or other reliable sources. [~~Price changes for legend and nonlegend drugs are effective 30 days after receipt of the latest edition of the Redbook or Redbook Update in the Vendor Drug Program, Texas Department of Health.~~]

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on April 2, 2012.

TRD-201201686
Steve Aragon
Chief Counsel
Texas Health and Human Services Commission
Earliest possible date of adoption: May 13, 2012
For further information, please call: (512) 424-6900

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# TITLE 4. AGRICULTURE

# PART 1. TEXAS DEPARTMENT OF AGRICULTURE

## CHAPTER 9. SEED QUALITY

## SUBCHAPTER C. SEED TESTING

### 4 TAC §9.5

The Texas Department of Agriculture (the department) proposes new §9.5, concerning service testing fees. The new section is proposed due to farmer and rancher requests for germination and vigor tests and for red rice examinations of rice samples, as required by §10.15 of this title (relating to Genetic Seed Certification Standards). The new section is necessary to comply with changes made to the Seed Quality Program to cover the cost of providing germination tests, vigor tests and red rice examinations. The new section adds seed service testing fees for germination test, vigor test, and red rice examination.

Jeff Claxton, Coordinator for Seed Quality Program, has determined that for the first five-year period the new section is in effect, there will be fiscal implications for state government resulting from the collection of fees. There will be an estimated increase in state revenue of $12,000 annually due to the fees collected. The charging of a fee is necessary to enable the continued operation of a leaner, cost-efficient program due to a legislative requirement that this program generate revenue to completely offset its costs. There is no anticipated fiscal impact for local governments as a result of administering or enforcing the new section, as proposed.

Mr. Claxton also has determined that for each year of the first five years the proposed new section is in effect the public benefit anticipated as a result of enforcing the new section will be the availability of seed service testing for farmers and ranchers. There will be fiscal implications to farmers and ranchers requesting to have their seed tested and to producers who are required to have rice samples examined for red rice. The germination and vigor tests are on a voluntary basis and the anticipated economic cost to person required to comply with the new section as proposed will be dependent on the number of germination and vigor tests requested, as well as the number of seed components in a sample. For a person required to have a red rice examination under the certification regulations, the anticipated economic cost will be $35 per 10-pound sample of rice and $75 per 50-pound sample of rice seed.

Comments on the proposal may be submitted to Mr. Jeff Claxton, Coordinator for Seed Quality Program, Texas Department of Agriculture, P.O. Box 629, Giddings, Texas 78942. Comments must be received no later than 30 days from the date of publication of the proposal in the *Texas Register.*

New §9.5 is proposed under the Texas Agriculture Code, §61.009, which provides that at the request of a farmer or dealer, the department may conduct or provide for the testing of seed for purity and germination and may fix by rule and collect fees for testing.

The Texas Agriculture Code, Chapter 61, is affected by the proposal.

*§9.5. Service Testing Fees.*

(a) At the request of a farmer or dealer, the department will provide for the testing of seed for germination and/or vigor. The department will also conduct red rice examination for rice samples submitted to the department as required in §10.15 of this title (relating