



November 5, 2021

Diona Kristian
Centers for Medicare and Medicaid Services
Center for Medicaid, and CHIP Services
Division of State Demonstrations and Waivers
7500 Security Boulevard
Mail Stop S2-02-26
Baltimore, MD 21244-1850

Dear Ms. Kristian,

The Health and Human Services Commission (HHSC) is submitting a request to the Centers for Medicare & Medicaid Services (CMS) for an amendment to the Texas Healthcare Transformation Quality Improvement Program (THTQIP) waiver under section 1115 of the Social Security Act.

Senate Bill 1096, 86th Legislature, Regular Session, 2019 (S.B. 1096) requires HHSC to exempt STAR Kids members from all preferred drug list (PDL) prior authorizations (PAs). Specifically, S.B. 1096 removes all the PDL PAs for all members of the STAR Kids program except those PAs based on evidence-based clinical criteria and nationally recognized peer-reviewed information and PAs designed to minimize waste, fraud, or abuse. This amendment will not result in any changes to the formulary. This amendment, if approved, will allow a member to be prescribed any Medicaid-covered drug regardless of whether the drug has preferred or non-preferred status.

HHSC is proposing to waive requirements in 42 Code of Federal Regulations (CFR) §440.240, related to comparability of services for groups, because only members of the STAR Kids program will be allowed this option. 42

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C.F.R. §440.240 requires the services available to any categorically needy beneficiary under the plan not be less in amount, duration, and scope than those services available to a medically needy beneficiary; and the services available to any individual in the following groups be equal in amount, duration, and scope for all beneficiaries within the group: (1) the categorically needy, and (2) a covered medically needy group. Because STAR Kids members would be able to obtain non-preferred drugs without a PA not based on clinical criteria or designed to minimize fraud, waste, or abuse, services provided would not be equal, and a waiver of comparability is necessary.

HHSC requests CMS approve this amendment package by March 5, 2022. Kathi Montalbano, Director of Policy Development Support, is the lead staff on this matter and can be contacted by telephone at (512) 438-4299 or by email at kathi.montalbano@hhs.texas.gov.

Sincerely,

Stephanie Stephens
State Medicaid Director

General Program Requirements

Texas Healthcare Transformation and Quality Improvement Program

Number: 11-W-00278/6

Demonstration Period: January 15, 2021 through September 30, 2030

Amendment Request: To waive Preferred Drug List (PDL) Prior Authorizations (PA) for STAR Kids members

Submitted: November 5, 2021

III. General Program Requirements

- 7) Amendment Process. Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the planned date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with the STCs, including but not limited to failure by the state to submit required elements of a complete amendment request as described in this STCs, reports or other deliverables required in the approved STCs in a timely fashion according to the deadlines specified herein. Amendment requests must include, but are not limited to, the following:**
 - a) An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS.**

Pursuant to STC. 12 Public Notice, Tribal Consultation, and Consultation with Interested Parties, the public notice for public comment about the changes requested in Amendment 20 was published in the Texas Register on April 23, 2021 (see attachment named TX Reg Public Notice). The Texas Register is published weekly and is the journal of state agency rulemaking for Texas. In addition to activities related to rules, the Texas Register publishes various public notices including attorney general opinions, gubernatorial appointments, state agency requests for proposals and other documents, and it is used regularly by stakeholders. HHSC publishes all Medicaid waiver submissions in the Texas Register in addition to many other notices. The publication is available online and in hard copy at the Texas State Library and Archives Commission, the State Law Library, the Legislative Reference Library located in the State Capitol building, and the University of North Texas libraries. All of these sites are located in Austin, except for the University of North Texas, which is located in Denton. Printed copies of the Texas Register are also available through paid subscription; subscribers include cities, counties and public libraries throughout the state.

In accordance with the requirements included in STC 12, letters were sent on April 23, 2021, to Tribal Governments requesting comments, questions, or feedback on the amendment. (see attached copies of each Tribal letter sent). No comments, questions, or feedback on the project were received from the public or Tribal Governments during the public comment period or Tribal Consultation period.

b) A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation.

Senate Bill (S.B.) 1096, 86th Legislature, Regular Session, 2019, directs HHSC to seek a waiver of comparability to exempt STAR Kids members from all preferred drug list (PDL) prior authorizations (PA) to meet the requirements of Section 533.005, Government Code (a)(23)(L), as added by SB 1096, 86th Texas Legislature.

Specifically, section 533.005 removes all the PDL PAs for all members of the STAR Kids program except those PAs based on evidence-based clinical criteria and nationally recognized peer-reviewed information, and those PAs designed to minimize waste, fraud, or abuse. This amendment will not result in any changes to the formulary. This amendment will give a member the opportunity to be prescribed any drug whether it has preferred or non-preferred status, although a member will not have access to drugs not covered by Medicaid.

HHSC is proposing to waive requirements in 42 CFR §440.240 / section 1902(a)(10)(B), related to comparability of services for groups, because only members of the STAR Kids program will be allowed this option. 42 CFR §440.240 / section 1902(a)(10)(B) requires the services available to any categorically needy beneficiary under the plan are not less in amount, duration, and scope than those services available to a medically needy beneficiary; and the services must be available to any individual in the following groups are equal in amount, duration, and scope for all beneficiaries within the group: (1) The categorically needy and (2) A covered medically needy group.

There is no anticipated impact on enrollment, and there will not be beneficiary cost sharing for this benefit. This benefit would fall outside the current objectives and goals of the approved demonstration but will increase access to non-preferred prescribed drugs.

c) A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the

change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment.

Preferred drugs are medications recommended by the Texas Drug Utilization Review Board for their efficaciousness, clinical significance, cost effectiveness, and safety. The primary impact due to this change results in a loss of federal and supplemental rebate revenues given that the PDL process will not be applied for these members. However, budget neutrality (BN) does not consider rebate revenues so this aspect of the policy change has no impact to BN. The only potential impact to BN would be due to shift in utilization of prescribed drugs; that impact is unable to be estimated.

d) An up-to-date CHIP allotment worksheet, if necessary.

N/A

e) The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the Evaluation Design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

Texas Medicaid currently requires PA for prescription drugs not on the PDL, even when the recipients' primary health benefit plan previously provided coverage for the drug. Starting October 1, 2021, STAR Kids beneficiaries would receive coverage for any drug without a PDL PA, including non-preferred drugs. To implement this change, HHSC is requesting to waive CMS requirements in 42 CFR §440.240 / section 1902(a)(10)(B), related to comparability of services for groups.

The THTQIP evaluation design CMS approved on August 2, 2018, focusing on demonstration years 7-11, culminates in a Draft Evaluation Report due March 31, 2024, as required by STC 86. The CMS-approved THTQIP evaluation design includes 5 evaluation questions, and 13 evaluation hypotheses. HHSC anticipates the STAR Kids PDL PA exemption may result in increased utilization of prescription drugs, specifically non-preferred drugs. Increased utilization of prescription drugs may impact With Waiver and Without Wavier costs, which are used in the evaluation's assessment of Demonstration cost outcomes (Measure 5.2.1). Increased utilization of prescription drugs among STAR Kids beneficiaries may also impact measures assessed through the STAR Kids Add-On Component, which will be included in the Interim Evaluation Report #1 (due on March 31, 2024). Since cost outcomes and the STAR Kids Add-On Component reflect the entire MMC or STAR Kids populations, respectively, it is not possible to subset these measures by individuals most directly impacted by the amendment (e.g., individuals utilizing non-preferred drugs). Additionally, without a comparison group of STAR Kids

members not exposed to the PDL PA exemption, it is not possible to estimate the impact of this amendment on evaluation measures. However, the state will direct the external evaluator to interpret and present pertinent findings within the context of this amendment.

The THTQIP Demonstration Extension evaluation design submitted to CMS on July 14, 2021 includes 1 evaluation question, 5 evaluation hypotheses, and 13 measures on the STAR Kids MMC program. HHSC determined not to include evaluation questions or measures related to STAR Kids prescription drug use. However, it is possible that increased utilization of prescription drugs among STAR Kids beneficiaries may indirectly impact proposed measures. Similar to the STAR Kids Add-On Component, all STAR Kids measures in the evaluation design submitted to CMS on July 14, 2021 reflect the entire STAR Kids population, so it is not possible to subset these measures by individuals most directly impacted by the amendment (e.g., individuals utilizing non-preferred drugs). Additionally, without a comparison group of STAR Kids members not exposed to the PDL PA exemption, it is not possible to estimate the impact of this amendment on evaluation measures. However, the state will direct the external evaluator to interpret and present pertinent findings within the context of this amendment. HHSC is not proposing changes to the evaluation reports, annual progress reports, or oversight, monitoring, and measurement of the provisions outlined in the STCs.

¹ Budget neutrality does not include rebate revenues in With Waiver and Without Waiver costs. The only potential impact to With Waiver and Without Wavier costs would be due to changes in utilization of prescribed drugs.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
WAIVER LIST**

NUMBER: 11-W-00278/6

TITLE: Texas Healthcare Transformation and Quality Improvement Program

AWARDEE: Texas Health and Human Services Commission

Title XIX Waivers

All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived in this list, shall apply to the Demonstration project beginning January 15, 2021, through September 30, 2030. In addition, these waivers may only be implemented consistent with the approved Special Terms and Conditions (STCs).

Under the authority of section 1115(a)(1) of the Social Security Act (the Act), the following waivers of State plan requirements contained in section 1902 of the Act are granted in order to enable Texas to carry out the Texas Healthcare Transformation and Quality Improvement Program section 1115 Demonstration.

1. Statewide **Section 1902(a)**

To enable the State to conduct a phased transition of Medicaid beneficiaries from fee-for-service to a managed care delivery system based on geographic service areas.

To the extent necessary, to enable the State to operate the STAR+PLUS program on a less than statewide basis.

2. Amount, Duration, ~~and~~ Scope of Services, and Comparability of Services for Groups
Section 1902(a)(10)(B) / **42 CFR 440.240**

To the extent necessary to enable the State to vary the amount, duration, and scope of services offered to individuals, regardless of eligibility category, by providing additional, or cost-effective alternative benefit packages to enrollees in certain managed care arrangements. To the extent necessary to enable the state to provide a greater duration of hospital services for individuals with severe and persistent mental illness.

To waive requirements related to comparability of services for groups to allow STAR Kids members access to any drug on the Medicaid formulary without requiring a Preferred Drug List (PDL) prior authorization (PA). To waive the requirement services available to any categorically needy beneficiary under the plan are not less in amount, duration, and scope than those services available to medically needy beneficiary; and the services must be available to any individual in

the following groups are equal in amount, duration, and scope for all beneficiaries within the group: (1) The categorically needy and (2) A covered medically needy group.

3. Freedom of Choice

Section 1902(a)(23)(A)

To the extent necessary, to enable the State to restrict freedom of choice of provider through the use of mandatory enrollment in managed care plans for the receipt of covered services. No waiver of freedom of choice is authorized for family planning providers.

4. Self-Direction of Care for HCBS Members

Section 1902(a)(32)

To permit section 1915(c)-like Home and Community Based Services (hereinafter HCBS) members to self-direct expenditures for HCBS long-term care and supports as specified in paragraph 28(k) of the STCs.

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

Public Notice

The Health and Human Services Commission (HHSC) is submitting a request to the Centers for Medicare & Medicaid Services (CMS) to amend the Texas Healthcare Transformation Quality Improvement Program (THTQIP) waiver under section 1115 of the Social Security Act. The current waiver is approved through September 2030. The proposed effective date for this amendment is October 1, 2021.

Senate Bill 1096, 86th Legislature, Regular Session, 2019 directs HHSC to seek a waiver of comparability to exempt STAR Kids members from all preferred drug list (PDL) prior authorizations (PA) to meet the requirements of Section 533.005, Government Code (a)(23)(L), as added by SB 1096, 86th Texas Legislature.

Proposed Changes

Specifically, SB 1096 removes all the Preferred Drug List (PDL) prior authorizations (PAs) for all members of the STAR Kids program except those PAs based on evidence-based clinical criteria and nationally recognized peer-reviewed information, and those PAs designed to minimize waste, fraud, or abuse. This amendment will not result in any changes to the formulary. This amendment will give a member the opportunity to be prescribed any drug whether there is preferred or non-preferred status although a member will not have access to drugs not covered by Medicaid.

HHSC is proposing to waive requirements in 42 CFR §440.240, related to comparability of services for groups, because only members of the STAR Kids program will be allowed this option. 42 CFR §440.240 requires the services available to any categorically needy beneficiary under the plan are not less in amount, duration, and scope than those services available to a medically needy beneficiary; and the services must be available to any individual in the following groups are equal in amount, duration, and scope for all beneficiaries within the group: (1) The categorically needy and (2) A covered medically needy group.

Financial Analysis

Preferred drugs are medications recommended by the Texas Drug Utilization Review Board for their efficaciousness, clinical significance, cost effectiveness, and safety. The primary impact due to this change results in a loss of federal and supplemental rebate revenues absent a PDL for these members. However, budget neutrality (BN) does not consider rebate revenues so this aspect of the policy change has no impact to BN. The only potential impact to budget neutrality would be due to shift in utilization of prescribed drugs; that impact is unable to be estimated.

Evaluation Design

Per Standard Term and Condition 82 of the Ten-Year THTQIP Demonstration Extension, HHSC must submit a draft Evaluation Design to CMS by July 14, 2021 (180 calendar days after the approval of the demonstration). At time of writing, HHSC was still formulating evaluation design questions and hypotheses for the Ten-Year THTQIP Demonstration Extension. As a result, the impact of the STAR Kids PDL PA exemption on the forthcoming evaluation design is unknown.

HHSC anticipates the STAR Kids PDL PA exemption may result in increased utilization of prescription drugs. Increased utilization of prescription drugs may impact medication adherence measures, if such measures are included in the evaluation design, as well as With Waiver and Without Waiver costs, which may be used in the evaluation's assessment of Demonstration cost outcomes.

HHSC is not considering specific evaluation questions or hypotheses related to STAR Kids prescription drug use under the Ten-Year THTQIP Demonstration Extension evaluation. However, if evaluation measures are impacted by the STAR Kids PDL PA exemption, and contingent on data availability, HHSC will provide the external evaluator with vendor drug claims for STAR Kids members. This information will allow the external evaluator to identify influences associated with the STAR Kids PDL PA exemption and, if necessary, adjust analytic methods to account for impacts where possible.

Enrollment, Cost Sharing and Service Delivery

There is no anticipated impact on enrollment, and there will not be beneficiary cost sharing for this benefit. This benefit would fall outside the current objectives and goals of the approved demonstration but will increase access to non-preferred prescribed drugs. This amendment will allow a STAR Kids member to access any drug on the Medicaid formulary without requiring the prescriber to obtain a PDL PA except those PAs based on evidence-based clinical criteria and nationally recognized peer-reviewed information, and those PAs designed to minimize waste, fraud, or abuse.

An individual may obtain a free copy of the proposed waiver amendment, ask questions, obtain additional information, or submit comments by May 24, 2021, regarding this amendment by contacting Luis Solorio by U.S. mail, telephone, fax, or email. The addresses are as follows:

U.S. Mail

Texas Health and Human Services Commission
Attention: Luis Solorio, Waiver Coordinator, Policy Development Support
PO Box 13247
Mail Code H-600
Austin, Texas 78711-3247

Email

TX_Medicaid_Waivers@hhsc.state.tx.us.

Telephone
(512) 487-3449

Fax
512-206-3975



April 23, 2021

Myra Sylestine
Health Director
Alabama-Coushatta Tribe of Texas
571 State Park Road, #56
Livingston, Texas 77351

Dear Ms. Sylestine:

The purpose of this letter is to notify members of the Alabama-Coushatta Tribe of Texas that the Health and Human Services Commission (HHSC) is submitting a request to the Centers for Medicare & Medicaid Services (CMS) to amend the Texas Healthcare Transformation Quality Improvement Program (THTQIP) waiver under section 1115 of the Social Security Act. The current waiver is approved through September 2030. The proposed effective date for this amendment is October 1, 2021.

Senate Bill 1096, 86th Legislature, Regular Session, 2019 (S.B. 1096) directs HHSC to seek a waiver of comparability to exempt STAR Kids members from all preferred drug list (PDL) prior authorizations (PAs) to meet the requirements of Section 533.005, Government Code (a)(23)(L), as added by S.B. 1096.

Proposed Changes

Specifically, S.B. 1096 removes all the PDL PAs for all members of the STAR Kids program except those PAs based on evidence-based clinical criteria and nationally recognized peer-reviewed information and those PAs designed to minimize waste, fraud, or abuse. This amendment will not result in any changes to the formulary. This amendment will give a member the opportunity to be prescribed any drug whether is the drug has preferred or non-preferred status, although a member will not have access to drugs not covered by Medicaid.

HHSC is proposing to waive requirements in 42 C.F.R. §440.240, related to comparability of services for groups, because only members of the STAR Kids program will be allowed this option. 42 C.F.R. §440.240 requires the services available to any categorically needy beneficiary under the plan not be less in amount, duration, and scope than those services available to a medically needy beneficiary; and the services available to any individual in the following groups be equal in amount, duration, and scope for all beneficiaries within the group: (1) The categorically needy and (2) A covered medically needy group.

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Financial Analysis

Preferred drugs are medications recommended by the Texas Drug Utilization Review Board for their efficaciousness, clinical significance, cost effectiveness, and safety. The primary impact due to this change results in a loss of federal and supplemental rebate revenues absent a PDL for these members. However, budget neutrality (BN) does not consider rebate revenues, so this aspect of the policy change has no impact to BN. The only potential impact to BN would be due to shift in utilization of prescribed drugs; that impact is unable to be estimated.

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HHSC anticipates the STAR Kids PDL PA exemption may result in increased utilization of prescription drugs. Increased utilization of prescription drugs may impact medication adherence measures, if such measures are included in the evaluation design, as well as With Waiver and Without Waiver costs, which may be used in the evaluation's assessment of Demonstration cost outcomes.

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Enrollment, Cost Sharing and Service Delivery

There is no anticipated impact on enrollment, and there will not be beneficiary cost sharing for this benefit. This benefit would fall outside the current objectives and goals of the approved demonstration but will increase access to non-preferred prescribed drugs. This amendment will allow a STAR Kids member to access any drug on the Medicaid formulary without requiring the prescriber to obtain a PDL PA

23rd April 2021

unless the PA is based on evidence-based clinical criteria and nationally recognized peer-reviewed information or is designed to minimize waste, fraud, or abuse.

To obtain a free copy of the proposed waiver amendment, ask questions, or request additional information regarding this amendment, please contact Dana Williamson by phone at (512) 462-6287, or by e-mail at TX_Medicaid_Waivers@hhsc.state.tx.us.

Sincerely,

Kathi Montalbano

Manager of Policy Development Support

Medicaid/CHIP Division, HHSC