

**TEXAS HEALTH AND HUMAN SERVICES COMMISSION**

**OPEN ENROLLMENT (OE)**

**for**

**Kidney Health Care Program (KHC)
Drug Rebate Agreement**

**OE No. HHS0012325**

**NIGP Class/Item No(s):**

***#963-42 Incentives, Rebates and Refunds***

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# SECTION 1. SCHEDULE OF EVENTS

|  |  |
| --- | --- |
| **Enrollment Period Opens****(Posted to HHS OE Opportunities webpage)** | **July 1, 2022** |
| **Enrollment Period Closes****(Final date for Receipt of Applications)** | **July 1, 2027 at 5:00PM CST** |
| **Anticipated Contract Start Date** | **The effective date of a Contract, if any, awarded to an Applicant will be determined at the sole discretion of HHSC.** |

Applications must be **received** by the Texas Health and Human Services Commission (HHSC) prior to the closing date as indicated in this Schedule of Events or as changed via an Addendum posted to the HHS Open Enrollment Opportunities webpage. Every Applicant is solely responsible for ensuring its Application is received before the submission period closes. HHSC is not responsible for lost, misdirected, or late applications.

The dates in the Schedule of Events are tentative. HHSC reserves the right to modify these dates at any time by posting an Addendum to the HHS Open Enrollment Opportunities webpage.

By submitting an Application, the Applicant represents and warrants that any individual submitting the Application and any related documents on behalf of the Applicant is authorized to do so and to bind the Applicant under any resulting contract.

Withdrawal of Application:

Applications may be withdrawn from consideration or amended at any time prior to the “Enrollment Period Closes” date by emailing a request to the Point of Contact, Section 4.1. The e-mail subject line should contain the Open Enrollment (OE) number and title as indicated on the cover page.The Applicant is solely responsible for ensuring requests are received timely by HHSC. HHSC is not responsible for lost, misdirected, or late emails.

# SECTION 2. OVERVIEW

## 2.1 Introduction

The Texas Health and Human Services Commission (HHSC) is an agency within the Texas Health and Human Services (HHS) System.

HHSC is seeking Applications to establish Contract(s) for the Kidney Health Care (KHC) Program for pharmaceutical rebate services. KHC is a State Pharmaceutical Assistance Program (SPAP) for Texas residents diagnosed with end-stage renal disease (ESRD) who are receiving kidney dialysis or have had a kidney transplant. KHC is 100% state-funded and helps ease medical expenses and transportation costs for many Texas residents with ESRD.

KHC is considered a payor of last resort. All benefits, apart from outpatient pharmacy drug claims, are administered and paid by HHSC. Prescriptions are processed as real-time, point-of-service adjudications through the Texas Vendor Drug Program claims system. The KHC’s drug formulary is comprised of medications related to end-stage renal disease, and rebate revenue is returned to the program to help fund the drug benefit for dialysis and kidney transplant clients.

To be considered for an award, Applicants must submit a comprehensive Application that meets all the requirements of this OE and includes all requested documentation.

## 2.2 Legal Authority

The Health and Human Services Commission is posting this Open Enrollment pursuant to 1 Tex. Admin. Code, Part 15, Chapter 391, Subchapter A, Rule 391.103(a).

Any Contract awarded under this Open Enrollment will be awarded pursuant to Section 12.0125, Texas Health and Safety Code, and 42 U.S.C. 1396r-8.

## 2.3 No Guarantee of Volume or Usage

HHSC does not guarantee any volume or usage under any Contract resulting from this Open Enrollment. Additionally, all Contracts resulting from this Open Enrollment are subject to appropriations, the availability of funds, and termination. For the avoidance of doubt, Manufacturers will not be compensated by HHS Agencies under any Contract resulting from this Open Enrollment.

# SECTION 3. DEFINITIONS AND ACRONYMS

Unless the context clearly indicates otherwise, throughout this Open Enrollment, the definition given to a term below applies whenever the term appears in this Open Enrollment, in any Application submitted in response to this Open Enrollment, and in any Contract awarded as a result of this Open Enrollment. All other terms have their ordinary and common meaning.

|  |  |
| --- | --- |
| Term | Definition  |
| **Act** | Means the Social Security Act. |
| **Addendum** | A written clarification or revision to this Open Enrollment. All Addenda will be posted to the HHS Open Enrollment Opportunities web page. |
| **Application** | All information and materials submitted by an Applicant in response to this Open Enrollment. |
| **Applicant** | Any person or entity that submits an Application in response to this Open Enrollment.  |
| **Average Manufacturer Price (AMP)** | Will have the meaning set forth in section 1927(k)(1) of the Act as implemented by 42 CFR 447.504. |
| **Best Price** | Will have the meaning set forth in section 1927(c)(1)(C) of the Act as implemented by 42 CFR 447.505. |
| **Centers for Medicare & Medicaid Services (CMS)** | The agency of the U.S. Department of Health and Human Services having the delegated authority to operate the Medicaid Program. |
| **Contract** | Any Contract(s) awarded resulting from this Open Enrollment Drug Rebate Agreement. |
| **Contractor****(Manufacturer)** | Each Applicant, if any, awarded a Contract as a result of this Open Enrollment. May also be referred to as Manufacturer as defined below. Unless the context clearly indicates otherwise, all terms and conditions of this Open Enrollment and resulting Contract that refer to Applicant apply with equal force to Contractor (also referred to as “Manufacturer”). |
| **Covered Outpatient Drug** | Will have the meaning set forth in sections 1927(k)(2), (k)(3) and (k)(4) of the Act as implemented by 42 CFR 447.502 and, for purposes of this Agreement, are limited to drugs purchased on behalf of a client of the KHC. |
| **HHS Agency** | The Health and Human Services Commission (HHSC) and the Texas Department of State Health Services (DSHS) may be identified separately as an ‘HHS Agency’ or collectively as the ‘HHS Agencies’ in this Open Enrollment or any resulting Contract(s). |
| **HHS Open Enrollment Opportunities webpage**  | The HHS webpage where Open Enrollments are posted: <https://apps.hhs.texas.gov/pcs/openenrollment.cfm> |
| **Kidney Health Care Program (KHC)** | The HHSC program established to provide adequate kidney care and treatment for the citizens of the State of Texas and to carry out the purposes and intent of the Texas Kidney Health Care Act (Chapter 42, Texas Health and Safety Code). |
| **Manufacturer** | Means a manufacturer of prescription drugs as defined by [Section 1927(k)(5)](http://www.ssa.gov/OP_Home/ssact/title19/1927.htm) of the Social Security Act (42 U.S.C. §1396r-8(k)(5)), including a subsidiary or affiliate of a manufacturer.  |
| **National Drug Code (NDC)** | Will have the meaning as set forth in 42 CFR 447.502. |
| **Office of Management and Budget (OMB)** | OMB's prominent function is to produce the President of the United State's budget, but it also examines agency programs, policies, and procedures to ensure compliance with the President's policies and coordination with inter-agency policy initiatives. |
| **Open Enrollment (OE)** | This document, including all exhibits, attachments, and addenda, as applicable, posted on the HHS Open Enrollment Opportunities webpage. |
| **Program Utilization Information** | The total number of units of each dosage form (i.e., powder, pill) and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a Rebate Period under the KHC, other than units dispensed to KHC beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act; Program Utilization Data is supplied on the CMS-R-144 form (that is, the state rebate invoice). |
| **Quarter** | The calendar quarter unless otherwise specified. |
| **Rebate Contract Administrator** | HHSC’s KHC contracted designee for the administration and collection of drug rebates. |
| **Rebate Payment** | Means, with respect to the Manufacturer’s Covered Outpatient Drugs, the quarterly payment by the Manufacturer to HHSC, which is calculated by multiplying the URA for a Covered Outpatient Drug by the applicable Program Utilization Data. |
| **Rebate Period** | Will have the meaning as set forth in 42 CFR 447.502. |
| **Statement of Work** | The description of services and deliverables in this Open Enrollment that the Contractor (Manufacturer) is required to provide under the Contract. |
| **Unit** | Drug unit in the lowest dispensable amount. The Manufacturer will specify the unit information associated with each covered outpatient drug per the instructions provided in CMS-367c. |
| **Unit Rebate Amount (URA)** | The unit amount computed by CMS to which the Program Utilization Data is applied by HHSC in invoicing the Manufacturer for the KHC Rebate Payment due. |
| **U.S.C** | Means the United States Code. |

# SECTION 4. GENERAL INFORMATION

## 4.1 Sole Point of Contact

All questions, requests for clarification, or other communication about this OE shall be made in writing only to the HHSC sole point of contact listed below.

Attempts to ask questions by phone or in person will not be allowed or recognized as valid.

Jennifer Curtiss, MEd, CTCM

OPSH Contract Specialist

Email: jennifer.curtiss@hhs.texas.gov

**Applications should NOT be submitted to this address. See Section 13 for submission requirements.**

**Do not contact other HHS Agency personnel regarding this OE.**

**This restriction, as to only communicating in writing with the HHSC sole point of contact identified above, does not preclude discussions between Applicant and agency personnel for the purposes of conducting business unrelated to this OE.**

**Failure of an Applicant or its representatives to comply with these requirements may result in disqualification of the submitted Application.**

## 4.2 Changes, Modifications, and Cancellation

HHSC reserves the right to change, amend, modify, or cancel this OE at any time.

All Applications, including those submitted after cancellation of the OE, become the property of HHSC upon receipt.

### Advertisement of Changes, Modifications or Cancellation

If HHSC determines that the OE needs to be changed or modified, either an addendum will be posted on the OE Opportunities webpage or the OE will be canceled. The action to be taken will be determined at the sole discretion of HHSC. Furthermore, if the OE will be canceled, HHSC will determine, in its sole discretion, if a new OE will be posted.

No HHS Agency will be responsible or liable in any regard for the failure of any individual or entity to receive notification of any posting to the OE Opportunities webpage.

It is the responsibility of each Applicant to monitor the OE Opportunities webpage for any Addenda or additional information regarding this OE. Failure to monitor the OE Opportunities webpage will in no way release or relieve any Applicant or Contractor of its obligations to fulfill the requirements as posted.

## 4.3 Offer Period

By submitting an Application in response to this OE, Applicant agrees that its Application will remain a firm and binding offer to enter into a Contract under all terms and conditions of this OE for at least 240 days from the date of Application submission, as stated in Exhibit A, HHS Solicitation Affirmations, unless withdrawn by the Applicant before the Enrollment Period closes.

An Applicant may extend the time for which its Application will be honored and include the extended period in the Application.

## 4.4 Costs Incurred

HHSC accepts no obligations for costs incurred in preparing, submitting, and screening an Application, including, but not limited to, costs or expenses related to Contract execution.

Applicants understand that issuance of this OE or retention of Applications in no way constitutes a commitment by HHSC to award a Contract. All Applications shall be prepared simply and economically, providing a straightforward, concise delineation of the Applicant’s capabilities to satisfy the requirements of this OE and submitted at the sole expense of the Applicant.

## OE Questions or Clarifications

### 4.5.1 Questions and Requests for Clarification

Written questions and requests for clarification regarding this OE are permitted if submitted by e-mail to the Sole Point of Contact, Section 4.1.

Responses to questions and requests for clarification will not be posted. However, if HHSC determines, based on a question, request for clarification, or any other factor (including, but not limited to, notices of ambiguity, conflict, or discrepancy as referenced in Section 4.5.3, below), that the OE needs to be amended or clarified, either an Addendum will be posted on the OE Opportunities webpage or the OE will be canceled. The action to be taken will be determined at the sole discretion of HHSC. Furthermore, if the OE will be canceled, HHSC will determine, in its sole discretion, if a new OE will be posted.

###  Question and Clarification Format

Questions and requests for clarification must include the following information:

* the OE Number
* the question or request for clarification, providing the following information:
* OE language, topic, section heading
* Section, Paragraph, and Page number(s) or Exhibit/Attachment

The requestor must provide the following contact information:

* Company Name
* Company Representative Name
* Phone Number
* E-Mail address

### Ambiguity, Conflict, Discrepancy

Applicants must notify the Sole Point of Contact, Section 4.1, of any ambiguity, conflict, discrepancy, exclusionary specification, omission, or other error in the OE. Notices must be submitted in the same manner for submitting questions.

Each Applicant submits its Application at its own risk.

If an Applicant fails to properly and timely notify the Sole Point of Contact, Section 4.1, of any ambiguity, conflict, discrepancy, exclusionary specification, omission, or other error in the OE, the Applicant, whether awarded a Contract or not:

1. shall have waived any claim of error or ambiguity in the OE and any resulting contract,
2. shall not contest the interpretation by HHSC of such provision(s), and
3. shall not be entitled to additional compensation, relief, or time by reason of ambiguity, conflict, discrepancy, exclusionary specification, omission, or other error or its later correction.

# SECTION 5. CONTRACT TERM

## 5.1 Term of Contract

HHSC may award one or more Contracts under this OE.

Any Contract resulting from this OE will be effective on the signature date of the latter of the Parties to sign the agreement and will expire 5 years after the effective date, unless terminated earlier pursuant to the terms and conditions of the Contract, and Section 5.3.

## 5.2 Extension Option

HHSC, at its sole option and subject to availability of funding, may extend the Contract beyond the initial term for up to one year as necessary to ensure continuity of service, to process a new OE to award new Contract(s), for purposes of transition, or as otherwise determined to serve the best interest of the State of Texas.

## 5.3 Termination

HHSC may terminate the Contract for any reason with prior written notice to the Contractor. Unless otherwise specified in HHSC’s notice of termination, the Contract will terminate at the end of the Quarter then in effect.

The Contractor may terminate the Contract for any reason, and such termination will become effective the later of:

* the first day of the first Rebate Period beginning ninety (90) days after the Contractor gives written notice requesting termination, or
* the ending date of the term of the Agreement if a non-renewal notice has been given in writing to the KHC Program, KHCRebates@hhs.texas.gov.

Any non-renewal or termination will not affect rebates due before the effective date of termination.

# SECTION 6. MINIMUM QUALIFICATIONS

To be eligible to apply for a Contract and receive an award, Applicant(s) must be eligible, qualified, and meet all requirements of this OE.

## 6.1 Required Qualifications

1. Applicants must meet the definition of a Manufacturer as defined in this open enrollment agreement, Section 3.
2. Applicants must have entered and have in effect a federal rebate agreement with Texas Medicaid.
3. Prior to submitting application, applicants must receive written verification from the KHC Program Pharmacist, KHC@hhsc.state.tx.us, that Manufacturer’s drugs meet program criteria.

1. Criteria include, but may not be limited to, that the drugs be:

* + - 1. Appropriate for the treatment of clients with ESRD and kidney transplant recipients.
			2. Appropriate for the inclusion on the KHC formulary.
			3. Included on the Medicaid formulary.

2. Determination of whether the criteria in 6.1(c)(1) is met is at the sole discretion of KHC program.

1. Applicants must complete and submit Attachment A, Attestation of Required Qualification and Applicant Information with their Application.

# SECTION 7. STATEMENT OF WORK

## 7.1 Project Overview

In 1999, the Texas Legislature mandated the KHC program to develop a drug manufacturer rebate program, obligating the program to take rebates into consideration before adding any new drugs to the formulary. The rebate agreement mirrors the federal rebate program that the Texas Medicaid program uses with regard to the formula for calculating and collecting rebates. CMS Release 59, dated June 23, 2003, clarified that KHC meets the criteria and qualifies as a State Pharmacy Assistance Program. The rebate agreement partnership enables KHC to expand the formulary and make additional drugs available for Texas residents diagnosed with end stage renal disease who are receiving dialysis or have had a kidney transplant.

## 7.2 Contractor Responsibilities

In order for HHSC to include the Contractor's Covered Outpatient Drugs on the KHC formulary, the Contractor agrees to the following:

1. The Contractor will accurately calculate and report information and pay rebates to HHSC in accordance with the terms of the Contract.
2. Beginning with the Rebate Period following the Contract effective date and in accordance with the specifications pursuant to OMB-approved CMS-367a form, the Contractor will report quarterly pricing data to CMS for all Covered Outpatient Drugs in accordance with 42 CFR 447.510. The Contractor agrees that HHSC or the Rebate Contract Administrator may use the information the Contractor provides to CMS, including the Unit Rebate Amount, for KHC invoices.
3. The Contractor will submit a revised Attachment A with additional labeler codes to be included in the OE rebate agreement upon written approval by HHSC.
	1. Revised Attachment A must include KHC Program Pharmacist verification of manufacturer drug meeting KHC Program criteria (see section 6.1 Required Qualifications).
4. The Contractor will comply with all applicable state and federal law and regulations.
5. If either Party discovers an error in the Rebate Payment, it shall notify the other Party of such error. The Parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the Parties will resolve their dispute in accordance with the terms of Section 7.4.
6. Any undisputed overpayment shall be deducted from one or more subsequent Rebate Payment(s) payable under the Contract. In the event that no subsequent Rebate Payments are payable, HHSC will refund any such overpayment to Contractor within thirty (30) days of the Parties’ acknowledgement of the overpayment.
7. Contractor will remit any undisputed underpayment to HHSC within thirty (30) days of the Parties’ acknowledgement of such underpayment.
8. The Contractor shall maintain documentation for all payments made to HHSC under the Contract. The books, records, and documents of the Contractor, insofar as they relate to work performed or money remitted under this Agreement, shall be maintained for a period of seven full years from the later of the date of the Agreement terminates or all issues that arise from any litigation, claim, negotiation, audit, open records request, administrative review, or other action involving the Agreement are resolved. The records shall be subject to audit, at any reasonable time and upon reasonable notice, by HHSC, the Comptroller of Public Accounts, or their duly appointed representatives.
9. The Contractor may audit the books, records, and documents of HHSC that relate to the generation of a quarterly invoice under the Contract. HHSC shall retain all records in accordance with HHSC's records retention policy.

## 7.3 HHSC Responsibilities

1. HHSC will employ best efforts to ensure that KHC reports Program Utilization Information to the Contractor, within 60 days of the last day of each Rebate Period, using the same format as the CMS-R-144 Medicaid Drug Rebate State Reporting Forms. This process may be executed by an entity contracted with the State (also known in this document as the Rebate Contract Administrator).
2. HHSC or the Rebate Contract Administrator may, at its own option, compute the total rebate amount anticipated, based on its own records, but it will remain the responsibility of the Contractor to correctly calculate the rebate amount based on its correct determination under 42 U.S.C. §1396r-8, et seq.

## 7.4 Rebate Invoice Dispute Resolution

1. In the event the Contractor discovers a potential discrepancy with Program Utilization Data on the rebate invoice, which the Contractor and HHSC in good faith are unable to resolve prior to the payment due date, the Contractor will submit a Reconciliation of State Invoice (ROSI) form, the CMS-304, to HHSC. If such a discrepancy is discovered for a prior Rebate Period's invoice, the Contractor will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS-304a, to HHSC.
2. If the Contractor disputes in good faith any part of the Program Utilization Data on the rebate invoice, the Contractor shall pay HHSC for the rebate units not in dispute within the required due date in Section 7.6 of this Agreement. Upon resolution of the dispute, the Contractor will either pay the balance due, if any, plus interest at the rate calculated in accordance with applicable Texas law for interest owed on rebates in the Medicaid Vendor Drug Rebate Program, or be issued a credit by HHSC by the due date of the next quarterly payment.
3. Nothing in this section shall preclude the right of the Contractor to audit the Program Utilization Data reported (or required to be reported) by HHSC. The Contractor and HHSC will use best efforts to develop mutually beneficial audit procedures.
4. Adjustments to Rebate Payments will be made if information indicates that either Program Utilization Information or Unit Rebate Amounts were greater or lesser than the amount previously specified.

## 7.5 Performance Criteria

HHSC will look solely to the Contractor(s) for the performance of all contractual obligations resulting from an award based on this OE.

No Contractor will be relieved of its obligations for any nonperformance by its subcontractors. The Contractor must ensure that its subcontractors abide by all requirements, terms, and conditions of this Contract. Unless the context clearly indicates otherwise, every requirement and every prohibition set forth in this OE and any resulting contract that applies to a Contractor applies with equal force to its employees, agents, representatives, and subcontractors.

### 7.5.1 Specific Performance Standards

Contractor shall comply with all obligations and duties under the Contract, including submitting payments within required timeframes.

## 7.6 Payment Requirements

1. Beginning with the Quarter in which the Contract is effective, the Contractor will calculate and report to CMS all required pricing data on every Covered Outpatient Drug by NDC in accordance with section 1927 of the Act and as implemented by 42 CFR 447.510.
2. Except as otherwise provided in the Contract, the Contractor must make a Rebate Payment within 38 days after receiving a rebate invoice from HHSC so long as the invoice contains, at a minimum, the number of units paid by NDC in accordance with 1927(b)(1) of the Act. To the extent that changes in product, pricing, or related data cause increases to previously submitted total rebate amounts, the Contractor will be responsible for timely payment of those increases in the same 38-day time frame as the current rebate invoice.
3. The Contractor will continue to make a Rebate Payment on each of its Covered Outpatient Drugs for as long as:
	1. the Contractor has legal ownership of the Covered Outpatient Drug's NDC number, even when the Rebate Payment is made after the term Contract has expired; and
4. Program Utilization Information reports that payment was made to a provider for that Covered Outpatient Drug, regardless of whether the Contractor continues to market that drug.
5. If there are no sales by the Contractor during a Rebate Period, the Rebate Contract Administrator will use the Unit Rebate Amount reported in the prior Rebate Period in calculating rebates.
6. The Contractor will keep written or electronic records of the data and any other material from which the calculations of AMP and Best Price were derived in accordance with 42 CFR 447.510 and the Contract and make such records available to HHSC upon request. In the absence of specific guidance in section 1927 of the Act, federal regulations, and the terms of the Contract, the Contractor may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the purpose of section 1927 of the Act, federal regulations, and the terms of the Contract. The Contractor must maintain a record (written or electronic) explaining these assumptions in accordance with the recordkeeping requirements in 42 CFR 447.534. The Contractor will make these records available to HHSC upon request.
7. The Contractor may not report or recalculate pricing changes or dispute utilization or pricing data farther back than the effective date of the Contract or 12 quarters from the quarter in which the data were due to CMS, whichever is the shorter time period, unless CMS or the Office of the Inspector General (OIG) or its designee reviews pricing data and determines that adjustments or revisions are necessary.

## 7.7 Data Use Agreement (DUA) and Confidentiality

By submitting an Application and, if applicable, signing a Contract resulting from this OE, Applicant agrees to the terms of the Data Use Agreement, Exhibit B. The Applicant must complete, sign, and return with its Application Exhibit B, and Attachment 2, Security and Privacy Initial Inquiry (SPI).

The Contractor will comply with the Data Use Agreement in any resulting Contract to safeguard HHS Confidential Information.

Information disclosed by the Contractor in connection with the Contract is confidential and, notwithstanding other laws, will not be disclosed by HHSC in a form which reveals the Contractor or prices charged by the Contractor, except as authorized under section 1927(b)(3)(D) of the Act.

The Contractor will hold Program Utilization Data confidential. If the Contractor audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or Contract, the Contractor will observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data.

Notwithstanding the nonrenewal or termination of the Contract for any reason, these confidentiality provisions will remain in full force and effect.

## 7.8 Notice of Criminal Activity

At the time of submission, Applicants shall provide confirmation that the Applicant, any person with ownership or controlling interest in Applicant, and Applicant’s agents, employees, subcontractors and volunteers who will be providing the required services:

1. have not engaged in any activity that does or could constitute a criminal offense equal to or greater than a Class A misdemeanor or grounds for disciplinary action by a state or federal regulatory authority; and
2. have not been placed on community supervision, received deferred adjudication, or been indicted for or convicted of a criminal offense relating to involvement in any financial matter, federal or state program, or sex crime.

This is a continuing disclosure requirement; prior to Contract award, if any, Applicants must notify the HHSC Sole Point of Contact within five days of the date Applicant learns of actions set forth in subsections (a) and (b) above. Additionally, this is a continuing disclosure requirement for each Contractor, during the term of the Contract, to immediately report, in writing, to the HHSC contract manager when Contractor learns of or has any reason to believe it or any person with ownership or controlling interest in Contractor, or any of Contractor’s agents, employees, subcontractors or volunteers has: engaged in any activity that does or could constitute a criminal offense equal to or greater than a Class A misdemeanor or grounds for disciplinary action by a state or federal regulatory authority; or been placed on community supervision, received deferred adjudication, or been indicted for or convicted of a criminal offense relating to the involvement in any financial matter, federal or state program, or sex crime.

Contractor shall not permit any person who engaged, or was alleged to have engaged, in any activity subject to reporting under this section to perform direct client services or have direct contact with clients, unless otherwise directed in writing by the HHSC contract manager.

Key personnel with misdemeanor offenses must receive prior approval by the HHS Agency before being allowed to work under this contract.

HHSC, at its sole discretion, may terminate any Contract if Contractor, its agents, employees, subcontractors, or volunteers are arrested, indicted, or convicted of any criminal activity.

## 7.9 Notice of Insolvency or Indebtedness

At the time of submission, Applicants shall provide with the Application detailed written descriptions of any insolvency, incapacity, and outstanding unpaid obligations of Applicant owed to the Internal Revenue Service (IRS) or the State of Texas, or any agency or political subdivision of the State of Texas. This is a continuing disclosure requirement; prior to Contract award, if any, Applicants must notify the HHSC Sole Point of Contact within five days of the date Applicant learns of such financial circumstances after submission of the Application. Additionally, Contractors are under a continuing obligation to notify the HHSC contract manager, as applicable, within five days of the date Contractor learns of such financial circumstances after Contract award.

## 7.10 Terms and Conditions

Submission of an Application in response to this OE constitutes acceptance of all Terms and Conditions attached to, referenced, or set forth in the OE. Applicant shall not submit additional or different terms and conditions.

Any term, condition, or other part of an Applicant’s submitted Application that has been rejected by HHSC, that is not accepted in writing by HHSC, or that conflicts with applicable law, this OE, any resulting Contract, or applicable terms and conditions, will not constitute part of the Contract.

## 7.11 Standards of Conduct for Contractors

Pursuant to 1 TAC 391.405(a), contractors, respondents, and vendors interested in working with HHS are required to implement standards of conduct to apply to all matters involving, or related to, those solicitations and Contract(s) between themselves and HHS. These standards must adhere to ethics requirements adopted in rule, in addition to any ethics policy or code of ethics approved by the HHSC Executive Commissioner and must be at least as restrictive as those applicable to HHS personnel in the applicable ethics law and policy provisions.

The standards of conduct must include the ten standards of ethical conduct set forth in Section I of the HHS Ethics Policy and requirements to comply with ethical standards set forth in federal and state law (including, but not limited to, 1 TAC Chapter 391, Subchapter D).

The standards of conduct, together with the responsibilities and restrictions incorporated herein, also apply to subcontractors of Contractors, applicants, and vendors.

Standards of conduct of any Contractor, applicant, or vendor may be reviewed and/or audited by the State Auditor and HHSC. Additionally, pursuant to 1 TAC 391.405(a), HHS may examine an applicant’s standards of conduct in the evaluation of a bid, offer, proposal, quote, or other applicable expression of interest in a proposed purchase of goods or services.

Any vendor or Contractor that violates a provision of 1 TAC Chapter 391, Subchapter D, may be barred from receiving future Contracts or have an existing Contract canceled. Additionally, HHSC may report the Contractor’s actions to the Comptroller of Public Accounts for statewide debarment, or law enforcement.

# SECTION 8. HHSC CONTRACT ADMINISTRATION

HHSC will designate a Contract Manager and provide the manager’s contact information to the Contractor.

After award of any Contract resulting from this OE, all communications related to the Contract will be processed through the designated Contract Manager. Additional requirements apply to legal notices, which must be provided to the HHS Chief Counsel as well as the Contract Manager.

# SECTION 9. INSURANCE REQUIREMENTS

## 9.1 Insurance Coverage

For the duration of any Contract resulting from this OE, Applicant shall acquire insurance with financially sound and reputable independent insurers, in the type and amount customarily carried within the industry. Failure to maintain insurance coverage or acceptable alternative methods of insurance shall be deemed a breach of Contract.

# SECTION 10. CONFIDENTIAL OR PROPRIETARY INFORMATION

## 10.1 Public Information Act

**Applicant Requirements Regarding Disclosure**

Applications and contracts are subject to the Texas Public Information Act (PIA), Texas Government Code [Chapter 552](http://www.statutes.legis.state.tx.us/DocViewer.aspx?K2DocKey=odbc%3a%2f%2fTCAS%2fASUPUBLIC.dbo.vwTCAS%2fGV%2fS%2fGV.552%40TCAS2&QueryText=552&HighlightType=1), and may be disclosed to the public upon request. Other legal authority also requires HHSC to post certain Contracts and Applications on HHSC’s website and to provide such information to the Legislative Budget Board for posting on its website.

Under the PIA, certain information is protected from public release. If Applicant asserts that information provided in its Application is exempt from disclosure under the PIA, Applicant must:

1. **Mark Original Application:**
2. Mark the original Application, on the top of the front page, with the words “CONTAINS CONFIDENTIAL INFORMATION” in large, bold, capitalized letters (the size of, or equivalent to, 12-point Times New Roman font or larger); and
3. Identify, adjacent to each portion of the Application that Applicant claims is exempt from public disclosure, the claimed exemption from disclosure (NOTE: no redactions are to be made in the original Application);
4. **Certify in Original Application - HHS Solicitation Affirmations (attached as Exhibit A to this OE):** certify, in the designated section of the HHS Solicitation Affirmations, Applicant’s confidential information assertion and the filing of its Public Information Act Copy; and
5. **Submit Public Information Act Copy of Application:**  submit a separate “Public Information Act Copy” of the original Application (in addition to the original and all copies otherwise required under the provisions of this OE). The Public Information Act Copy must meet the following requirements:
6. The copy must be clearly marked as "Public Information Act Copy" on the front page in large, bold, capitalized letters (the size of, or equivalent to, 12-point Times New Roman font or larger);
7. Each portion Applicant claims is exempt from public disclosure must be redacted; and
8. Applicant must identify, adjacent to each redaction, the claimed exemption from disclosure. Each identification provided as required in subsection (c) of this section must be identical to those set forth in the original Application as required in section a.(2), above. The only difference in required markings and information between the original Application and the “Public Information Act Copy” of the Application will be redactions - which can only be included in the “Public Information Act Copy.” There must be no redactions in the original Application.

**By submitting an Application to this OE, Applicant agrees that, if Applicant does not mark the original Application, provide the required certification in the HHS Solicitation Affirmations, and submit the Public Information Act Copy, Applicant’s Application will be considered to be public information that may be released to the public in any manner including, but not limited to, in accordance with the Public Information Act, posted on HHSC’s and/or DSHS’s public website, and posted on the Legislative Budget Board’s website.**

**If Applicants submit partial, but not complete, information suggesting inclusion of confidential information and failure to comply with the requirements set forth in this section, HHSC, in its sole discretion, reserves the right to (1) disqualify all Applicants that fail to fully comply with the requirements set forth in this section, or (2) to offer all Applicants that fail to fully comply with the requirements set forth in this section additional time to comply.**

Applicant should not submit a Public Information Act Copy indicating that the entire Application is exempt from disclosure. Merely making a blanket claim that the entire Application is protected from disclosure because it contains any amount of confidential, proprietary, trade secret, or privileged information is not acceptable, and may make the entire Application subject to release under the PIA.

Applications should not be marked or asserted as copyrighted material. If Applicant asserts a copyright to any portion of its Application, by submitting an Application, Applicant agrees to reproduction and posting on public websites by the State of Texas, including HHSC and all other state agencies, without cost or liability.

HHSC will strictly adhere to the requirements of the PIA regarding the disclosure of public information. As a result, by participating in this OE process, Applicant acknowledges that all information, documentation, and other materials submitted in the Application in response to this OE may be subject to public disclosure under the PIA. HHSC does not have authority to agree that any information submitted will not be subject to disclosure. Disclosure is governed by the PIA and by rulings of the Office of the Texas Attorney General. Applicants are advised to consult with their legal counsel concerning disclosure issues resulting from this process and to take precautions to safeguard trade secrets and proprietary or otherwise confidential information. HHSC assumes no obligation or responsibility relating to the disclosure or nondisclosure of information submitted by Applicants.

For more information concerning the types of information that may be withheld under the PIA or questions about the PIA, refer to the *Public Information Act Handbook* published by the Office of the Texas Attorney General, or contact the attorney general’s Open Government Hotline at (512) 478-OPEN (6736) or toll-free at (877) 673-6839 (877-OPEN TEX). The *Public Information Act Handbook* may be accessed at:

<https://www.texasattorneygeneral.gov/open-government/members-public>

## 10.2 Applicant Waiver – Intellectual Property

**Submission of any document to any HHS agency in response to this OE constitutes an irrevocable waiver, and agreement by the submitting party to fully indemnify the State of Texas, HHS from any claim of infringement by HHS regarding the intellectual property rights of the submitting party or any third party for any materials submitted to HHS by the submitting party.**

# SECTION 11. BINDING OFFER

All Applications should be responsive to the OE as issued or amended through written and posted Addenda, not with any assumption that HHSC will negotiate any or all terms, conditions, or provisions of the OE. Furthermore, all Applications constitute binding offers. **Any Application that includes any type of disclaimer or other statement indicating that the Application submitted in response to this OE does not constitute a binding offer may be disqualified.**

# SECTION 12. REQUIRED APPLICATION DOCUMENTS

|  |
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| **Documentation Required for Submission** All documentation listed must be returned for a complete Application. Provide the documentation in the same sequence as outlined below by using the Item number(s) and title(s) as necessary.  |
| **1. Exhibit A – HHS Solicitation Affirmations*** Must be completed and signed.
* Important Note: Applications received without the signed Exhibit A will be disqualified.
 |
| **2. Exhibit B - DUA, – Attachment 2, Security and Privacy Initial Inquiry – completed and signed** |
| **3. Attachment A - Required Qualifications and Applicant Information – Reference Section 6*** Applicant must complete Attachment A and provide documentation to confirm that Applicant meets the minimum requirements, including:
	+ Attestation of Federal Rebate Agreement with Texas Medicaid
	+ Verification of Manufacturer Drug Meeting KHC Program Criteria

Applicant must complete the following contract information in Attachment A. * Legal Entity Name
* Manufacturer Labeler Code(s)
* Manufacturer Physical Address

Titles of personnel for contact information: * Person Authorized to Sign Contract
* Primary Contact for Questions Regarding Application
* Primary Contact for Contract Management
* Alternate Contact for Contract Management

Provide this information for each contact listed above: * Name and Title
* Mailing Address
* Phone Number
* E-mail Address
 |
| **4. Notice of Criminal Activity – Reference Section 7.8**Provide confirmation that the Applicant, any person with ownership or controlling interest, their agent, employee, subcontractor or volunteer who will be providing the required services are not: 1. Engaged in any activity that could constitute a criminal offense equal to or greater than a Class A misdemeanor or grounds for disciplinary action by a state or federal regulatory authority; or
2. Been placed on community supervision, received deferred adjudication, or been indicted for or convicted of a criminal offense relating to involvement in any financial matter, federal or state program, or sex crime.
 |
| **5. Notice of Insolvency or Indebtedness – Reference Section 7.9**Provide with the Application detailed written descriptions of any insolvency, incapacity, and outstanding unpaid obligations of Applicant owed to the Internal Revenue Service (IRS) or the State of Texas, or any agency or political subdivision of the State of Texas. |
| **6. Public Information Act Copy of Application, if applicable** |

# SECTION 13. APPLICATION SUBMISSION REQUIREMENTS

The Application must be submitted in accordance with this section and Section 12.

The complete Application must be submitted to:

HHSC Office of Primary and Specialty Health (OPSH)

Email:KHCRebates@hhs.texas.gov

Subject: KHC OE HHS0012325

Each Applicant is solely responsible for ensuring its Application is submitted in accordance with all OE requirements and ensuring timely receipt by HHSC.

**In no event will HHSC be responsible or liable for any delay or error in submission or delivery.**

The Application must be submitted by e-mail.

## 13.1 E-Mail Submission

Each Applicant is solely responsible for ensuring its Application is submitted in accordance with all OE requirements, including, but not limited to, the Section 12, Required Application Documents and ensuring timely e-mail receipt by HHSC.

The Application, including all documentation outlined in Section 12, must be sent in its entirety in one or more e-mails.

**In no event will HHSC be responsible or liable for any delay or error in delivery. Applications must be RECEIVED by HHSC before the OE period closes as identified in Schedule of Events, Section 1, or subsequent Addenda.**

The e-mail subject line should contain the OE number, title as indicated on the cover page, and number of e-mails if more than one (e.g., E-mail 1 of #, etc.). The Applicant is solely responsible for ensuring that Applicant’s complete electronic Application is sent to, and **actually received by**, HHSC at the proper destination server before the submission deadline.

The Application documentation must not be encrypted so as to prevent HHSC from opening the documents.

IMPORTANT NOTE: HHSC recommends a 10MB limit on each attachment. This may require Applicants to send multiple e-mails to HHSC at KHCRebates@hhs.texas.gov to ensure all documentation contained in an Application is received.

All documents should be submitted in Microsoft office® formats (Word® and Excel®, as applicable) or in a form that may be read by Microsoft office® software. Any documents with signatures shall be submitted as an Adobe® portable document format (pdf) file. HHSC is not responsible for documents that cannot be read or converted. Unreadable applications may be, in HHSC’S sole discretion, rejected as nonresponsive.

Please be aware Internet Service Providers may limit file sizes on outgoing emails; therefore, it is recommended Applications not contain graphics, pictures, letterheads, etc., which consume a lot of space. These typically include \*.tif/\*.tiff, \*.gif, & \*.bmp file extensions, but may use others, as well. HHSC’s firewall virus protection runs at all times, so during times of new active virus alerts, incoming traffic may be delayed while virus software scans emails with attachments. HHSC takes no responsibility for e-mailed Applications that are captured, blocked, filtered, quarantined, or otherwise prevented from reaching the proper destination server by any HHSC anti-virus or other security software.

Applicants may email the Point of Contact, Section 4.1, to request confirmation of receipt.

## 13.2 Receipt of Application

All Applications become the property of HHSC upon receipt and will not be returned to Applicants.

HHSC will **not** be held responsible for any Application that is mishandled by the Applicant, any Applicant’s delivery or mail service, or for Applications sent by e-mail that are captured, blocked, filtered, quarantined, or otherwise prevented from reaching the proper destination server by any HHSC anti-virus or other security software.

Applications received after the OE Period closes will not be considered.

# SECTION 14. SCREENING OF APPLICATIONS

Neither issuance of this OE nor retention of Applications constitutes a commitment on the part of HHSC to award a Contract. HHSC maintains the right to reject any or all Applications and to cancel this OE if HHSC, in its sole discretion, considers it to be in the best interests of HHSC to do so.

Submission and retention of Applications by HHSC confers no legal rights upon any Applicant.

HHSC reserves the right to select qualified Applicants to this OE with or without discussion of the Applications with Applicants. It is understood by Applicant that all Applications, Contracts, and related documents are subject to the Texas Public Information Act.

## 14.1 Initial Screening of Applications

An initial screening of Applications will be conducted by HHSC to determine which Applications are deemed to be responsive and qualified for further consideration for award. This screening includes a review to determine that each Applicant meets the minimum requirements and qualifications, and that each Application includes all required documentation.

HHSC reserves the right to:

1. Ask questions or request clarification from any Applicant at any time during the OE and screening process, and
2. Conduct studies and other investigations as necessary to evaluate any Application.

**Informalities**

HHSC reserves the right to waive minor informalities in an Application. A "minor informality" is an omission or error that, in HHSC’s determination, if waived or modified when screening Applications, would not give an Applicant an unfair advantage over other Applicants or result in a material change in the Application or OE requirements.

HHSC, at its sole discretion, may give an Applicant the opportunity to submit missing information or make corrections. The missing information or corrections must be submitted to the Point of Contact e-mail address in Section 4.1 by the deadline set by HHSC. Failure to respond before the deadline may result in HHSC’s rejecting the Application and the Applicant not being considered for award.

Note: Any disqualifying factor set forth in this OE does not constitute an informality (e.g., Exhibit A, HHS Solicitation Affirmations, and Exhibit B, Data Use Agreement, which must be signed and submitted with the Application).

## 14.2 Verification of Past Vendor Performance

HHSC reserves the right to conduct studies and other investigations as necessary to evaluate any Application. By submitting an Application, the Applicant generally releases from liability and waives all claims against any party providing information about the Applicant at the request of HHSC.

Applicants may be rejected as a result of unsatisfactory past performance under any contract(s) as reflected in vendor performance reports, reference checks, or other sources.

An Applicant’s past performance may be considered in the initial screening process and prior to making an award determination.

Reasons for which an Applicant may be denied a Contract include, but are not limited to:

1. Applicant has an unfavorable report or grade on the CPA Vendor Performance Tracking System (VPTS). VPTS may be accessed at: <https://comptroller.texas.gov/purchasing/programs/vendor-performance-tracking/>; or
2. Applicant is currently under a corrective action plan through HHSC, or,
3. Applicant has had repeated, negative vendor performance reports for the same reason; or
4. Applicant has a record of repeated non-responsiveness to vendor performance issues; or
5. Applicant has contracts or purchase orders that have been cancelled in the previous 12 months for non-performance or sub-standard performance.

In addition, HHSC may examine other sources of vendor performance which may include information provided by any governmental entity, whether an agency or political subdivision of the State of Texas, another state, or the federal government.

The performance information may include, but is not limited to:

* Notices of termination,
* Cure notices,
* Assessments of liquidated damages,
* Litigation,
* Audit reports, and
* Non-renewals of contracts.

Further, HHSC, at its sole discretion**,** may initiate investigations or examinations of vendor performance based upon media reports. Any negative findings, as determined by HHSC in its sole discretion**,** may result in HHSC’s removing the Applicant from further consideration for award.

# SECTION 15. AWARD PROCESS

## 15.1 Contract Award and Execution

HHSC, at its sole discretion, reserves the right to cancel this OE at any time or decline to award any Contracts as a result of this OE.

HHSC intends to award one or more Contracts as a result of this OE.

All awards are contingent upon approval of the HHSC Executive Commissioner or the HHSC Executive Commissioner’s designee.

## 15.2 Compliance for Participation in State Contracts

### 15.2.1 Required Pre-Award Verifications

In addition to the initial screening process, the following verification checks are required to be conducted for each Applicant to determine compliance for participating in State contracts.

The Applicant’s Legal Name and, if applicable, Assumed Business Name (D.B.A.) will be used to conduct these checks.

Applicants found to be barred, prohibited, or otherwise excluded from Contract award will be disqualified from further consideration.

1. **State of Texas Debarment**

Must not be debarred from doing business with the State of Texas through the Comptroller of Public Accounts (CPA): <https://comptroller.texas.gov/purchasing/programs/vendor-performance-tracking/debarred-vendors.php>

1. **System of Award Management (SAM) Exclusions List - Federal**

Must not be excluded from contract participation at the federal level. This verification is conducted through SAM, official website of the U.S. Government, which may be accessed at this link:

<https://sam.gov/content/entity-information>.

Note: If the link does not work, copy/paste the link into browser bar.

1. **Divestment Statute Lists**

Must not be listed on the Divestment Statute Lists provided by CPA which may be accessed at: <https://comptroller.texas.gov/purchasing/publications/divestment.php>

1. Companies that boycott Israel;
2. Scrutinized Companies with Ties to Sudan;
3. Scrutinized Companies with Ties to Iran;
4. Designated Foreign Terrorist Organizations; and
5. Scrutinized Companies with Ties to Foreign Terrorist Organizations.
6. **HHS Office of Inspector General**

Must not be listed on the HHS Office of Inspector General Texas Exclusions List for people or businesses excluded from participating as a provider: <https://oig.hhs.texas.gov/exclusions>

1. **U.S. Department of Health and Human Services**

Must not be listed on the U.S. Department of Health and Human Services Office of Inspector General’s List of Excluded Individuals/Entities (LEIE), excluded participation as a provider, unless a valid waiver is currently in effect: <https://exclusions.oig.hhs.gov/>

###  Additional Required Pre-Award Verifications

After the checks performed in Section 15.2.1, the following verifications will be conducted for each Applicant. The verifications will be based on the legal name and, if applicable, the Assumed Business Name (D.B.A.), and/or the Secretary of State (SOS) charter number, the Federal ID or Texas Payee ID numbers, or the CPA Franchise Tax number provided, as applicable, on Exhibit A, HHS Solicitation Affirmations.

The results of the checks below will be used to further consider an Applicant for award and may result in disqualification.

1. **Texas Franchise Tax Status**

The Texas franchise tax is a privilege tax imposed on each taxable entity formed or organized in Texas or doing business in Texas. Although not all entities are required to file or pay franchise taxes, HHSC will process a search of the Applicant through the CPA Franchise Tax system to verify the Applicant is in good standing.

Franchise tax checks may reveal as to applicable entities (1) debts or delinquencies owed to the state (implicating contracting limitations) and (2) forfeiture of the right to transact business in Texas.

1. **Texas Warrant Hold Status**

The check for warrant holds through the CPA is required to determine if an Applicant is on hold for any reason. [Texas Government Code Section 2252.903](https://statutes.capitol.texas.gov/Docs/GV/htm/GV.2252.htm#2252.903) requires agencies to verify the warrant hold status no earlier than the seventh day before and no later than the day of contract execution for transactions involving a written contract. In accordance with Section 3.3 of Exhibit C, Uniform Terms and Conditions, payments under any Contract resulting from this OE will be applied directly toward eliminating the Applicant’s debt or delinquency regardless of when it arises.

1. **Texas Secretary of State**

Must be registered, if required by law, with the Texas Secretary of State as a public or private entity eligible to do business in Texas: <https://direct.sos.state.tx.us/acct/acct-login.asp>