

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES**

**OPEN ENROLLMENT (OE)**

**for**

**Newborn Screening Program Benefits Contractors**

**OE Number: HHS0014639**

**Enrollment Period Opens: April 9, 2024**

**Enrollment Period Closes: August 31, 2030**

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

**948-07 948-48**

**948-32 948-55**

**948-33 948-72**

**948-47 948-74**

**Date of Release: April 9, 2024**

**Response Due: August 31, 2030, 5:00 p.m. CST**

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# GENERAL INFORMATION

## Scope

The State of Texas, by and through the Texas Department of State Health Services (“**DSHS**” or “**System Agency**”) seeks contractors to provide Newborn Screening (“**NBS**”) Program Benefits Program services, such as Dietary Supplements, Vitamins, Medications, Medical Foods (Formulas), Low Protein Foods, and follow-up care at no cost or reduced cost, to eligible clients who have a heritable congenital disorder detected through the DSHS NBS Program in accordance with Texas Health and Safety Code, Chapter 33 and Texas Administrative Code, Title 25, Chapter 37, and the specifications contained in this open enrollment.

## Points of Contact

The DSHS Points of Contact for inquiries concerning this open enrollment are:

Tamara Johnson, Contract Manager

[tamara.johnson@dshs.texas.gov](mailto:Tamara.Johnson@dshs.texas.gov)

And:

Newborn Screening Open Enrollment Program

NBSOE@dshs.texas.gov

Applicant must direct all communications relating to this open enrollment to the DSHS Points of Contact named above unless specifically instructed to an alternate contact by Texas Department of State Health Services (“**DSHS**”) or Texas Health and Human Services Commission (“**HHSC**”) Procurement and Contracting Services (“**PCS**”).

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

## Procurement Schedule

All dates are subject to change at HHSC's discretion. Applications must be received by the DSHS Points of Contact identified in subsection 1.2 by the open enrollment closing period provided in the Procurement Schedule below. Late applications will be deemed non-responsive and will not be considered.

| **Procurement Schedule** | |
| --- | --- |
| Open Enrollment (OE) Period Opens  (Posted to HHS OE Opportunities webpage) | **April 9, 2024** |
| OE Period Closes  (Final date for RECEIPT of Applications) | **5:00 pm CST**  **8/31/2030** |
| OE Posted on [HHS Open Enrollment Opportunities](https://resources.hhs.texas.gov/open-enrollments/) | **On or After**  **April 9, 2024** |
| Anticipated Contract Start Date | ***September 1, 2024 or Approximately Ten Days (10) after all screening requirements are met.*** |

Applications must be received by the Texas Department of State Health Services (DSHS) prior to the closing date of August 31, 2030 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. DSHS is not responsible for lost, misdirected or late applications.

The dates in the Schedule of Events are tentative. DSHS 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. The e-mail subject line should contain the OE number and title as indicated on the cover page. The Applicant is solely responsible for ensuring requests are received timely by DSHS. DSHS is not responsible for lost, misdirected or late emails.

## Background

### Overview of the Texas Health and Human Services Commission (HHSC)

Since 1991, the Texas Health and Human Services Commission (HHSC) has overseen and coordinated the planning and delivery of health and human service programs in Texas. HHSC is established in accordance with Texas Government Code, Chapter 531, and is responsible for the oversight of all Texas Health and Human Services Agencies (HHS Agencies). The HHSC chief executive commissioner is Cecile Erwin Young.

As a result of the consolidation pursuant to House Bill 2292, 78th Texas Legislature, Regular Session, 2003, some of the contracting and procurement activities for the HHS Agencies have been assigned to the Procurement and Contracting Services (PCS) Division of HHSC. As such, PCS will administer the initial stages of the procurement process, including enrollment announcement and publication.

### Program Overview

House Bill 790, 79th Legislature, Regular Session, 2005, required expansion of the Texas newborn screening panel to include disorders listed in the core uniform panel of newborn screening conditions recommended in the 2005 American College of Medical Genetics (ACMG) report, "Newborn Screening: Toward a Uniform Screening Panel and System," as funds allowed. Effective December 2006, the Newborn Screening (NBS) Program began screening for 27 disorders. Increasing the panel from 7 to 27 disorders led to an increase in the number of presumptive positive screens as well as a greater need for confirmatory testing, evaluation, and treatment services. One additional condition was added in 2009 and another in 2012. In 2015, 24 secondary conditions were added. Also in 2015, the Legislature amended Texas Health and Safety Code, Chapter 33, requiring the Texas newborn screening panel to include disorders listed as core and secondary conditions in the Advisory Committee on Heritable Disorders in Newborns and Children Recommended Unform Screening Panel, as funds allow and excluding galactose epimerase and galactokinase. The NBS Program now screens for a minimum of 55 conditions by dried bloodspots and as of 2023 two other point-of-service tests, Critical Congenital Heart Disease and Newborn Hearing Screening.

The legislation resulted in the adoption of 25 Texas Administrative Code, Chapter 37, Subchapter D, Sections 37.51-37.63, relating to the NBS Program and details the disorders for which newborns are screened, responsibilities of providers and parents, screening procedures, the provisions of follow-up care, and the provisions of services the NBS Program provides through benefits for specified populations.

DSHS, to meet an increased need for services, entered into an open enrollment process to procure the services from public and private entities. The NBS Program Benefits Program (the “**Program**”) began operating in March 2007. The Program offers reimbursement to enrolled entities for the provision of specified services to eligible clients as Program funding allows.

The Program provides services to eligible clients in accordance with 25 Texas Administrative Code, Sections 37.51-37.63. The services covered by the Program fall into four categories of contractors:

1. Entity;
2. Laboratories;
3. Pharmacies that provide medications, Medical Foods (Formulas), dietary supplements and vitamins; and
4. Manufacturers or Retailers of low protein foods.

The services that are provided under the Program include but are not limited to:

1. Clinical evaluations and follow-up care;
2. Laboratory procedures including confirmatory, follow-up and monitoring testing;
3. Medications;
4. Vitamins;
5. Dietary Supplements;
6. Medical Foods (Formulas; and
7. Low Protein Foods

## Eligible Applicants

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. Applicant requirements apply with equal force to Contractors and Providers awarded contracts under this OE.

Applicants shall:

#### Be an entity free to participate in state contracts and not be debarred by the Texas Comptroller of Public Accounts:

#### <https://comptroller.texas.gov/purchasing/programs/vendor-performance-tracking/debarred-vendors.php>;

#### Be free to participate in federal contracts with the System of Award Management (SAM). Applicant is ineligible to apply for funds under this OE if currently debarred, suspended, or otherwise excluded or ineligible for participation in Federal or State assistance programs. Search the federal excluded list at the following website: <https://sam.gov/portal>;

#### Be authorized as a public or private entity to do business in Texas with the Secretary of State. See: <https://direct.sos.state.tx.us/acct/acct-login.asp>;

#### Be free of exclusions with the United States Department of Health and Human Services, Office of Inspector General. <https://exclusions.oig.hhs.gov/>

#### Be free from negative reports in the Vendor Performance Tracking System on the Centralized Master Bidders List (CMBL): <https://mycpa.cpa.state.tx.us/tpasscmblsearch/index.jsp>;

* + 1. If applying to be an Entity, you must have a physician specialist(s) that meet(s) the following Program requirements:
       1. Be currently licensed as a Medicaid Provider in Texas; and
       2. Be Board Certified/Board Eligible, which includes active candidates of the American Board of Medical Genetics and Genomics, in Medical Biochemical Genetics, or Clinical Biochemical Genetics; (Medical Geneticists who are physicians and boarded in Clinical Genetics are eligible, but must be able to document having been active in the management of patients with inborn errors of metabolism at least 25% of their time in the past two (2) years prior to submitting an application); or
       3. Board Certified/Board Eligible in Adult and Pediatric Endocrinology (Adult-Endocrinology, Diabetes, and Metabolism), or Pediatric Endocrinology; or
       4. Board Certified/Board Eligible in Adult and Pediatric Hematology (Adult-Hematology) or Pediatric Hematology (Hematology/ Oncology); or
       5. Board Certified/Board Eligible in Adult and Pediatric Pulmonology; or
       6. Board Certified/Board Eligible in Allergy and Immunology.
       7. Board Certified/Board Eligible in a specialty approved by the NBS Program Medical Director or designee.
    2. If applying to be a laboratory under the Program, meet the following requirements:
       1. Be certified by Clinical Laboratory Improvement Amendments (CLIA); Must provide a current copy of the CLIA certification attached to the Application; and
       2. Have the capacity to conduct confirmatory testing and follow-up testing for patients identified through the Texas NBS Program as being at risk for a hereditary metabolic, endocrine, or hematologic disorder.
    3. If applying to be a pharmacy under the Program, meet the following requirement: Must be able to dispense Medications, Medical Foods (Formulas), Vitamins and Dietary Supplements prescribed by an enrolled Physician Specialist on behalf of the contracted Entity; and provide a copy of licensure with the enrollment Application identifying pharmacy classification in one of the following:
       1. Class A (may include compounding pharmacies);
       2. Class C (institutional);
       3. Class D (clinical); or
       4. Class E (mail-order).
    4. If applying to be a Manufacturer or Retailer of Low Protein Foods, meet the following requirements:
       1. Be a manufacturer or retailer of Low Protein Foods prescribed by an enrolled physician specialist on behalf of the contracted Entity;
       2. Provide the Program a sample of the catalog of low protein food products (if applicable); and
       3. Provide the tax ID number and license/permit number, as appropriate, as part of its application.

Applicant is not considered eligible to apply unless the Applicant meets the applicable eligibility requirements listed above at the time the open enrollment application is submitted. Applicant must continue to meet these conditions throughout the selection and funding process. DSHS expressly reserves the right to review and analyze the documentation submitted and to request additional documentation and determine the Applicant’s eligibility to receive a contract.

## Strategic Elements

#### **Contract Type and Term**

DSHS plans to award one (1) or more contracts under this open enrollment. The initial contract term will begin on the effective date stated in the contract, which is anticipated to be September 1, 2024 or upon execution, and will end on August 31, 2026, unless sooner terminated or extended as set forth in the resulting contract.

Based upon the availability of federal and state funds, DSHS may renew the awarded contracts for two (2) additional two (2)-year terms or as necessary to complete the mission of the procurement. The two (2) additional two (2)-year terms are as follows:

Renewal 1: September 1, 2026 through August 31, 2028

Renewal 2: September 1, 2028 through August 31, 2030

#### **Contract Elements**

The term “Contract” means the Contract awarded as a result of this enrollment and all exhibits thereto. At a minimum, the following documents will be incorporated into the Contract: this open enrollment and all attachments and exhibits hereto; any modifications, addendum or amendments issued in conjunction with this enrollment; HHSC's Uniform Terms and Conditions (UTCs), Version 3.4; the Data Use Agreement for Contractors who access agency confidential information and who are not exempt (<https://www.hhs.texas.gov/business/contracting-hhs>); and the successful Applicant’s Application.

#### **Security and Privacy Inquiry (SPI)**

#### The Applicant must submit the Information Security and Privacy Inquiry (SPI) form with their Application to this open enrollment. The SPI form is available at:

<https://www.hhs.texas.gov/business/contracting-hhs/vendor-resources>

## Amendments and Announcements Regarding this Open Enrollment

HHSC will post all official communication regarding this open enrollment on the [HHS Open Enrollment Opportunities](https://resources.hhs.texas.gov/open-enrollments/) page. HHSC reserves the right to revise the open enrollment at any time and to make unilateral amendments to correct grammar, organization and clerical errors. It is the responsibility of each Applicant to comply with any changes, amendments, or clarifications posted to the [HHS Open Enrollment Opportunities](https://resources.hhs.texas.gov/open-enrollments/) page. Applicant must check [HHS Open Enrollment Opportunities](https://resources.hhs.texas.gov/open-enrollments/) frequently for changes and notices of matters affecting this open enrollment.

Applicant’s failure to periodically check [HHS Open Enrollment Opportunities](https://resources.hhs.texas.gov/open-enrollments/) will in no way release the Applicant from “addenda or additional information” resulting in additional costs to meet the requirements of the open enrollment.

All questions and comments regarding this open enrollment should be sent to the DSHS Points of Contact identified in subsection 1.2. Questions must reference the appropriate page and section number. HHSC will post subsequent answers to questions to the HHS Open Enrollment Opportunities page as appropriate. HHSC reserves the right to amend answers prior to the open enrollment closing date.

Applicants should notify HHSC of any ambiguity, conflict, discrepancy, omission, or other error in the open enrollment.

## Delivery of Notices

Any notice required or permitted under this announcement by one party to the other party must be done via email and correspond with the contact information noted in subsection 1.2 of this open enrollment. At all times, Applicant will maintain and monitor at least one active email address for the receipt of Application-related communications from HHSC. It is the Applicant’s responsibility to monitor this email address for Application-related information and inform HHSC if the active email address changes.

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# STATEMENT OF WORK

## Statement of Work to be Conducted

* + 1. Contractor Responsibilities
    2. Contractor must provide services in accordance with the NBS Benefits Contractor Procedures Manual, which can be found online at <https://www.dshs.texas.gov/newborn-screening-program/newborn-screening-benefits-program>, as revised, and applicable rules and regulations, as amended, including but not limited to Texas Health and Safety Code, Section 33.032, and 25 Texas Administrative Code, Sections 37.51-37.64.

* + 1. Contractor must verify initial benefits eligibility screening is conducted in accordance with the NBS Benefits Contractor Procedures Manual and as directed by DSHS prior to providing services.
    2. Contractor must comply with all documentation requirements set forth in the NBS Benefits Contractor Procedures Manual and as required by applicable federal and state laws and regulations.
    3. Physician Specialists providing services on behalf of the Entity shall:
       1. Provide medical services to eligible clients, including but not limited to evaluations and management of metabolic, pulmonology, immunologic, endocrine, and hematological disorders, diagnostic laboratory tests and follow-up care.
       2. Provide services within the scope of the physician’s license, certification, registration, or other legal authorization, at the location(s) authorized by the Entity to serve patients and in the manner specified in the contract.
       3. Ensure that prescribed Treatment is provided to the client utilizing a provider who is enrolled in the NBS Benefits Program. The NBS Benefits Program will maintain a list of enrolled laboratories, pharmacies and manufactures or retailers of Low Protein Food. The client shall be responsible for obtaining the prescribed Treatment or lab tests from the enrolled providers. The Physician Specialist on behalf of the Entity shall coordinate clients’ services including providing follow-up to ensure client services have been provided.
    4. **Laboratory Providers (contractors) shall:**
       1. Conduct confirmatory testing and follow-up testing for individuals identified through the DSHS Newborn Screening Program as being at risk for a hereditary metabolic, endocrine, hematologic, pulmonology, or immunologic disorders.
       2. Maintain CLIA certification for the duration of the Contract.
       3. Comply with the laboratory procedures requirements set forth in the NBS Benefits Program Contractor Procedures Manual.
    5. **Pharmacy Providers (contractors) shall:**
       1. Provide Medications, Vitamins, Dietary Supplements, and Medical Foods (Formula) prescribed by enrolled health care providers specializing in metabolic, endocrine, and hematologic, pulmonology, or immunologic disorders, necessary for Treatment and management of diagnosed disorders.
       2. Provide Medical Foods, Formulas, Vitamins, and Dietary Supplements as specified by the physician specialist’s prescription.
       3. Ensure items are shipped to the client within 24 hours of Contractor’s receiving the prescription. If problems arise with this time frame the Contractor shall notify the Dietitian or physician specialist providing services on behalf of the Entity, the client, and the Program of the delay, the reason for the delay and the estimated time the item will be shipped.
       4. Ensure that with each order clients are informed of the number of refills available for each item and the date of expiration of services so that the client is reminded of the need to submit a renewal application to the physician specialist providing services on behalf of the Entity to continue to receive NBS Benefits.
    6. **Manufacturers or Retailers of Low Protein Foods contractors shall:**
       1. As applicable, provide Low Protein Foods that are specially formulated and intended for the dietary management of a disorder identified by the DSHS NBS Program for individuals with distinctive nutritional needs that cannot be met by normal diet alone;
       2. Low Protein Food contractors must provide modified foods which are low in protein and also ensure the patient is receiving nutrional requirement of enough calories in diet. Low Protein Foods are defined in the NBS Benefits Program Contractor Procedures Manual at <https://www.dshs.texas.gov/newborn-screening-program/newborn-screening-benefits-program>):
          1. Must be lacking in the compounds which cause complications of the metabolic disorder;
          2. Must be products listed in enrolled providers’ catalog;
          3. Are not generally available in grocery stores, health food stores, or pharmacies;
          4. Are not used as food by the general population; and
          5. Are not foods covered under the Food Stamps program.
       3. Ensure items are shipped to the client within 24 hours of receiving the order from the client. If problems arise with this time frame, the applicant shall notify the dietitian or Physician Specialist providing services on behalf of the Entity, the client, and the Program of the delay, the reason for the delay and the estimated time the item will be shipped.
       4. Ensure that products provided to clients and billed to the Program are listed in the enrolled provider’s pre-approved Texas NBS Program Benefits catalog.
       5. Ensure that with each order clients are informed of the number refills available for each item and the date of expiration of services so that the client is reminded of the need to submit a renewal application to the physician specialist to continue to receive NBS Benefits.

## Eligible Population

* + 1. Contractor shall provide Program services only to clients who meet the eligibility criteria set forth in 25 Texas Administrative Code, Section 37.61, Eligibility Requirements for the Newborn Screening Program Benefits, as amended, and must prioritize services among eligible individuals in the following order depending on available funding:
       1. Children 0-2 years of age
       2. Children 3-5 years of age
       3. Children 6-21 years of age
       4. Pregnant women
       5. Women of child bearing age
       6. Other adults (female or male)

## Performance Measures

#### DSHS will monitor Contractor’s performance of the requirements as stated in the Statement of Work and compliance with the Contract’s terms and conditions.

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# PAYMENT

## Payment

#### **Availability of Funds**

#### Contract awards resulting from this open enrollment are contingent upon the availability of funding.

#### If funding for these Contracts become unavailable during any budget period, DSHS may immediately terminate or reduce the amount of the resulting Contract at the discretion of DSHS. Contractor will have no right of action against DSHS if DSHS cannot perform its obligations under this Contract due to a lack of funding for any activities or functions outlined within this open enrollment.

#### Contractor may not use funds received from DSHS to replace any other federal, state, or local source of funds awarded under any other contract.

#### **Method of Payment**

DSHS will reimburse contractors only for allowable services to eligible clients in accordance with payment procedures and rates listed in the Newborn Screening Program Benefits Contractor Procedures Manual located at:

<http://www.dshs.texas.gov/newborn/benefits.aspx>, as amended, as funding allows.

## Invoicing Process

Requests for reimbursement must be submitted to DSHS in aggregate each month within thirty (30) days following the end of the month for which services are being billed or within sixty (60) days in cases of potentially Medicaid or Children’s Health Insurance Program (CHIP) eligible individuals who are denied eligibility by DSHS. In billing DSHS, contractor shall certify that all billed services have been provided only to individuals determined eligible for the NBS Program Benefits, in accordance with the Newborn Screening Program Benefits Contractor Procedures Manual located at <http://www.dshs.texas.gov/newborn/benefits.aspx>, as amended, and shall attach applicable documentation of services provided. DSHS reserves the right to request additional documentation.

Contractor shall submit to DSHS detailed and accurate invoice(s) which include the information below. Each invoice must be submitted by e-mail, using the State of Texas Purchase Voucher (Form B-13).

The e-mail address for submitting an invoice is: [NBSBenefits@dshs.texas.gov](mailto:NBSBenefits@dshs.texas.gov).

The invoice shall include, at a minimum:

1. Contractor’s Name;
2. Remit to Address;
3. Federal ID or Texas CPA Payee ID;
4. Accounts Receivable telephone number;
5. Contract Number;
6. Identification of services provided; and
7. Service date(s).

No payment will be made under this Contract without submission of detailed, accurate invoices submitted as outlined and approved by DSHS.

#### Failure to submit invoices on time may be considered a contract compliance issue and will be used in evaluating whether to renew or terminate the Contract.

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# HISTORICALLY UNDERUTILIZED BUSINESSES (HUB)

In accordance with CPA’s Contract Management Guide, open enrollment contracts may be exempt from competitive bidding. The HHSC HUB Program Office has determined that the HUB requirements are not applicable because this is a non-competitive open enrollment; and therefore the submission of a [**HUB Subcontracting Plan (HSP)**](http://www.window.state.tx.us/procurement/prog/hub/hub-forms/HUBSubcontractingPlan.doc) is not required with their Application at the time of submission.

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# INFORMATION AND SUBMISSION INSTRUCTIONS

## Open Enrollment Cancellation/Partial Award/Non-Award

At its sole discretion, DSHS may cancel this open enrollment.

## Right to Reject Applications or Portions of Applications

At its sole discretion, DSHS may reject any and all responses or portions thereof.

## Joint Applications

DSHS will not consider joint or collaborative responses that require it to contract with more than one Applicant in a single contract.

## Withdrawal of Applications

Applicants have the right to withdraw their Application from consideration at any time prior to Contract award, by submitting a written request for withdrawal to the DSHS Points of Contact, as designated in [subsection 1.2](#_Point_of_Contact).

## Costs Incurred

Applicants understand that issuance of this open enrollment in no way constitutes a commitment by the HHS agency to award a Contract or to pay any costs incurred by an Applicant in the preparation of an Application in response to this open enrollment. The HHS agency is not liable for any costs incurred by an Applicant prior to issuance of, or entering into a formal agreement, Contract, or purchase order. Costs of developing applications, preparing for or participating in oral presentations and site visits, or any other similar expenses incurred by an Applicant are entirely the responsibility of the Applicant, and will not be reimbursed in any manner by the State of Texas.

## Application Submission Instructions

#### The Application must be submitted in accordance with this section and Section 8.1.

The complete Application must be submitted to:

DSHS Newborn Screening and Open Enrollment Program

Email: [NBSOE@dshs.texas.gov](mailto:NBSOE@dshs.texas.gov) and to [tamara.johnson@dshs.texas.gov](mailto:tamara.johnson@dshs.texas.gov)

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

**In no event will DSHS** **be responsible or liable for any delay or error in**

**submission or delivery.**

The Application must be submitted by e-mail. Applications submitted by facsimile, or any other method not specified in this OE, will NOT be accepted or considered.

## Organization of E-mail Submission of Application

Applicant must organize its signed Application in the following order and format. Each E-mail submission of the Application must include the following five (5) files with the respective listed documents included, and the documents must be in the following order, and labeled accordingly:

* Form A: Newborn Screening Program Benefits Open Enrollment Application
* Form B-1: Entity
* Form B-2: Laboratory Provider
* Form B-3: Pharmacy Provider
* Form B-4: Low Protein Foods Provider
* Form C: Face Page
* Exhibit A: General Affirmations
* Exhibit D: Security and Privacy Inquiry (SPI)
* Exhibit E: Federal Assurances
* Exhibit F: Certification Regarding Lobbying
* Exhibit G: FFATA Certification

## 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 8.1, Required Forms and Open Enrollment Application and ensuring timely e-mail receipt by DSHS.

The Application, including all documentation outlined in Section 8.1, must be sent in its entirety in one or more e-mails.

**In no event will DSHS be responsible or liable for any delay or error in delivery. Applications must be RECEIVED by DSHS 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 DSHS at the proper destination server before the submission deadline.

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

IMPORTANT NOTE: DSHS recommends a 10MB limit on each attachment. This may require Applicants to send multiple e-mails to DSHS at [e-mail address] 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. DSHS is not responsible for documents that cannot be read or converted. Unreadable applications may be, in DSHS’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. DSHS’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. DSHS takes no responsibility for e-mailed Applications that are captured, blocked, filtered, quarantined or otherwise prevented from reaching the proper destination server by any DSHS anti-virus or other security software.

Applicants may email the Point of Contact, Section 1.2 to request confirmation of receipt.

## Verification of Past Vendor Performance

#### DSHS 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 DSHS.

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,

1. Applicant is currently under a corrective action plan through DSHS, OR,
2. Applicant has had repeated, negative vendor performance reports for the same reason, OR,
3. Applicant has a record of repeated non-responsiveness to vendor performance issues, OR,
4. Applicant has contracts or purchase orders that have been cancelled in the previous 12 months for non-performance or sub-standard performance.

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

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# ELIGIBILITY DETERMINATION

## Initial Compliance Screening

DSHS will perform an initial screening of all Applications received. Unsigned Applications and Applications that do not include all required forms and sections are subject to rejection without further evaluation.

If the Application passes the initial screening, the contract manager will contact the Applicant for further instructions or actions.

DSHS reserves the right to:

a. Ask questions or request clarification from any Applicant at any time during the OE and screening process, and

b. Conduct studies and other investigations as necessary to evaluate any Application.

**Informalities**:

DSHS reserves the right to waive minor informalities in an Application. A "minor informality" is an omission or error that, in DSHS’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.

DSHS, 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 by the deadline set by DSHS. Failure to respond before the deadline may result in DSHS’ 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., Exhibits, HHS Solicitation Affirmations, which must be signed and submitted with the Application).

## Unresponsive Applications

Unless Applicant has taken action to withdraw the Application for this open enrollment, an Application will be considered unresponsive and will not be considered further when any of the following conditions occurs:

#### The Applicant fails to meet major open enrollment specifications, including:

#### The Applicant fails to submit the required Application, supporting documentation, or forms.

#### The Applicant is not eligible under [subsection 1.5](#_Eligible_Applicants) of this open enrollment.

#### Applicant does not accept the payment rate established in this open enrollment.

#### The Application is not signed.

#### The Applicant’s response is not clearly legible. Typewritten is preferred.

#### The Application is not received by the closing of the open enrollment period provided in [subsection 1.3](#_Procurement_Schedule) of this open enrollment.

## Corrections to Application

Applicants may amend their Application at any time prior to an unresponsive decision or Contract award decision by submitting a written amendment to the DSHS Point of Contact, as designated in [subsection 1.2](#_Point_of_Contact). DSHS may request modifications to the Application at any time.

## Review and Validation of Applications

The Applicant must provide full, accurate, and complete information as required by this open enrollment. Applications must contain original signatures on all forms requiring signatures.

## Additional Information

By submitting an Application, the Applicant grants DSHS the right to obtain information from any lawful source regarding the Applicant’s, its directors’, officers’, and employees:

#### Past business history, practices, and conduct;

#### Ability to supply the goods and services; and

#### Ability to comply with Contract requirements.

By submitting an Application, an Applicant generally releases from liability and waives all claims against any party providing DSHS information about the Applicant. HHSC may take such information into consideration in screening or the validation of information on Applications or supporting documentation.

## Debriefing

Any Applicant who is not awarded a Contract may request a debriefing by submitting a written request to the HHSC Point of Contact as provided in [subsection 1.2](#_Point_of_Contact) of this open enrollment. The debriefing provides information to the Applicant on the strengths and weaknesses of their Application.

## Protest Procedures

The protest procedure for an Applicant, who is not awarded a Contract to protest an award or tentative award made by any HHS agency, is allowed for competitive Procurements. This Procurement is non-competitive and cannot be protested as provided in [Texas Administrative Code (TAC) Rule §391.403](http://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=1&pt=15&ch=391&rl=403).

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# DEFINITIONS

Appendix – Additional information and/or forms that are available in the back of this solicitation document.

Applicant – A person or entity that submits a response to a solicitation. For purposes of this document, “applicant” is intended to include such phrases as “offeror”, “applicant”, “bidder”, “responder”, or other similar terminology employed by DSHS (or HHSC) to describe the person or entity that responds to a solicitation.

Budget Period – The duration of the budget (stated in the number of months the contract will reflect from begin date to end date of the term of the contract). Each renewal will have its own budget period.

Contract – A written document referring to promises or agreements for which the law establishes enforceable duties and remedies between a minimum of two parties. A DSHS contract is assembled using a core contract (base), one or more program attachments, and other required exhibits (general provisions, etc.).

Contract Term – The period of time during which the contract or program attachment will be effective from begin date to end, or renewal date. The contract term may or may not be the same as the budget period.

Debarment – An exclusion from contracting or subcontracting with state agencies on the basis of cause set forth in Title 34, Texas Administrative Code Chapter 20, Subchapter C, §20.105 et seq.

Effective Date – The date the contract term begins.

Fully Executed – When a contract is signed by each of the parties to form a legal binding contractual relationship. No costs chargeable to the proposed contract will be reimbursed before the contract is fully executed.

Project Period – The anticipated duration of the entire Project stated in total number of budget periods.

Scope of Work – A description of the services and/or goods, if any, for each service type, to be obtained as a result of this solicitation for a project period. The scope of work is a document written in the early stages of procurement to explain what DSHS plans to purchase.

Solicitation – The process of notifying prospective contractors of an opportunity to provide goods or services to the state (e.g., OE).

Statement of Work – A part of the contract that describes the services and/or goods to be delivered by the DSHS contractor specifying the type, level and quality of service, that directly relate to program objectives.

Supplant (verb) - To replace or substitute one source of funding for another source of funding. A recipient of contract funds under an OE must not use the funds to pay any costs that the recipient is already obligated to pay. If a contractor, prior to responding to an OE, had committed to provide funding for activities defined in the contract’s statement of work (i.e., as represented in the OE Budget Summary), then the contractor must provide the amount of funding previously committed in addition to the amount requested under the OE.

Vendor – A type of contractor or subcontractor that provides services, and goods, if any, that assist in, but are not the primary means of, carrying out the DSHS-funded program. Under a vendor contract, the vendor will have few if any administrative requirements. (For example, a vendor might be required only to submit a summary report of services delivered and an invoice.) A vendor generally will deliver services to DSHS-funded clients in the same manner the vendor would deliver those services to its non-DSHS-funded clients.

A vendor contractor generally has most of the following characteristics: a) provides goods and services within normal business operations, b) provides similar goods and services to many different purchasers, c) operates in a competitive environment, d) is not subject to compliance requirements of the federal or state program, e) provides goods and services that are ancillary to the operation of the program. Note: Characteristics a, b, c, and d do not apply to vendor contractors that are universities.

Vendor Identification Number (Vendor ID No.) – Fourteen-digit number needed for any entity, whether vendor or subrecipient, to contract with the State of Texas and which must be set up with the State Comptroller’s Office. It consists of a ten-digit identification number (IRS number, state agency number, or social security number) +check digit + 3 digit mail code. The Vendor ID No. includes all the numbers in the TINs (defined above), including a three digit mail code for a total of 14-digits.

**Newborn Screening Program Benefits Program Additional Definitions**

Diagnosis – A disorder that has been confirmed to be present in a patient based on clinical evaluation and additional testing including any of the following, as necessary, laboratory testing (blood, urine, or tissue tests), physiologic tests or radiologic exams.

Diagnostic Services– Laboratory studies or tests, x-rays and other appropriate services, ordered by the patient’s health care practitioner(s) to evaluate an individual’s health status for diagnostic purposes.

Dietary Supplement – Dietary Supplement is a preparation intended to supplement the diet and provide nutrients, such as Vitamins, minerals, fiber, fatty acids, or amino acids, that may be missing or may not be consumed in sufficient quantities in a person's diet. It is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is labeled on the front panel as being a Dietary Supplement.

Low Protein Foods – Modified foods low in protein.

Medications – A substance or preparation used in treating disease. Medications can be used for maintenance of health and the prevention, alleviation, or cure of disease.

Medical Foods – A food which is formulated to be consumed or administered enterally administration under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation

Medical Management Services – Services include prescriptions for Medications, Medical Foods, Vitamins, Dietary Supplements and/or Low Protein Foods deemed necessary for the Treatment and management of the diagnosed disorder.

Prescription Drugs– Medically-necessary pharmaceuticals needed for the Treatment of a diagnosed condition.

Texas Resident – An individual who resides within the geographic boundaries of the state is considered a Texas Resident.

Treatment – Any specific procedure used for the management of a disease or pathological condition.

Vitamins - Vitamins are compounds that are necessary for growth and health. They are needed in small amounts only and are usually available in a person’s diet.

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# ATTACHMENTS AND FORMS

Applicants must complete and submit the forms in the format and order listed below.

## Required Forms and Open Enrollment Application

Applicants must complete and submit the forms in the format and order listed below, as applicable.

|  |
| --- |
| Form A: Open Enrollment Application |
| Form B-1: Entity Provider |
| Form B-2: Laboratory Provider |
| Form B-3: Pharmacy Provider |
| Form B-4: Low Protein Foods Provider |
| Form C: Face Page |
| Exhibit A: General Affirmations |
| Exhibit D: Security and Privacy Inquiry (SPI) |
| Exhibit E: Federal Assurances |
| Exhibit F: Certification Regarding Lobbying |
| Exhibit G: FFATA Certification |

A complete answer includes a written response and any supporting documents required by the form. In addition, “Not Applicable” is only an appropriate response when a given question or form does not apply to an Applicant’s organization.

**8.2 Exhibits**

Contractor must abide by the requirements contained in the following exhibits, as applicable:

|  |  |
| --- | --- |
| **Exhibit A: General Affirmations**  Must be completed and signed |  |
| **Exhibit B-1: Uniform Terms and Conditions (UTC) - Vendor** |  |
| **Exhibit B-2: Uniform Terms and Conditions (UTC) – State Governmental Body** |  |
| **Exhibit C: Data Use Agreement (DUA)** |  |
| **Exhibit D: Security and Privacy Inquiry (SPI)**  Must be completed and signed |  |
| **Exhibit E: Federal Assurances**  Must be completed and signed |  |
| **Exhibit F: Certification Regarding Lobbying**  Must be completed and signed |  |
| **Exhibit G: FFATA Certification**  Must be completed and signed |  |

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