

Cecile Young, Acting Executive Commissioner

Open Enrollment

For

Department of State Health Services Newborn Screening Program Benefits Contractors

Enrollment Number: HHS0001837

Enrollment Period Opens: July 16, 2018

Enrollment Period Closes: August 31, 2024

NIGP Class/Item Code:

948-07	948-48
948-32	948-55
948-33	948-72
948-47	948-74

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1 GENERAL INFORMATION

1.1 Scope

The State of Texas, by and through the Department of State Health Services ("DSHS" or "System Agency") seeks contractors to provide Newborn Screening ("NBS") Program Benefits services, such as Dietary Supplements, Medications, Vitamins, 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, Texas Administrative Code, Title 25, Chapter 37, and the specifications contained in this open enrollment.

1.2 Point of Contact

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

Sara Mosqueda, Contract Manager 1100 W 49th St, MC 1990 Austin, TX 78756 512-776-2956 (phone) 512-776-7391 (fax) sara.mosqueda@dshs.texas.qov

And:

Susana Garcia 1100 W 49th St, MC 1990 Austin, TX 78756 512-776-2118 (phone) 512-776-7391 (fax) susana.garcia@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 Department of State Health Services ("DSHS") or Texas Health and Human Services Commission ("HHSC") Procurement and Contracting Services ("PCS").

1.3 Procurement Schedule

All dates are subject to change at HHSC's discretion. Applications must be received by the DSHS Point 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.

NBS Benefits OE Announcement 07-16-18

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Procurement Schedule				
Open Enrollment Period Opens	7/16/2018			
Open Enrollment Period Closes	5:00 PM CST 8/31/2023			
OE Posted on <u>HHS Open Enrollment</u> <u>Opportunities</u>	On or After 7/16/2018			
Anticipated Contract Start Date	September 1, 2018 or Approximately Ten Days (10) after all screening requirements are met.			

1.4 Background

1.4.1 Overview of the 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 Service Agencies (HHS Agencies). HHSC's acting chief executive officer is Cecile Young.

As a result of the consolidation pursuant to the 78th Texas Legislature, Regular Session (2003), House Bill 2292, 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.

1.4.2 Program Overview

In 2005, during the Regular Session of the 79th Legislature, House Bill 790 was passed requiring expansion of the newborn screening panel to the American College of Medical Genetics (ACMG) recommended core panel, as funds allowed. Effective December 2006, the Newborn Screening 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. Two additional conditions were added in 2009 and 2012 and, on May 26, 2015, twenty-four (24) secondary conditions were added. The program now screens for a total of 53 conditions by dried bloodspots.

The legislation resulted in the adoption of Texas Administrative Code (TAC), Title 25, Chapter 37 – Maternal and Infant Health Services, Subchapter D - Newborn Screening Program (§§37.51-37.63), which details the disorders for which newborns are screened; responsibilities of providers and parents; screening procedures; the

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provisions of follow-up care; and the provision of services to provide through program benefits for specified populations.

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

The Program provides services to eligible clients in accordance with 25 TAC §§37.51-37.63. The services covered by the Program fall into four categories of contractors:

- 1 Physician Specialists;
- 2 Laboratories;
- 3 Pharmacies; and
- 4 Manufacturers or Retailers of Medical Foods (such as Low Protein Foods, formulas, Vitamins, and Dietary Supplements).

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

- 1 Clinical evaluations and follow-up care
- 2 Confirmatory, follow-up and monitoring; laboratory testing;
- 3 Medications;
- 4 Vitamins;
- 5 Dietary Supplements; and
- 6 Medical Foods (Low Protein Foods and formulas).

1.5. Eligible Applicants

To be eligible to apply for a contract and receive an award through this open enrollment, Applicants shall:

1.5.1. 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

1.5.2. 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://www.sam.gov/portal/SAM/?portal:componentId=3c9caa24-5c93-4ce9-877a-

<u>b244446a54e9&interactionstate=JBPNS_rO0ABXc0ABBfanNmQnJpZGdlVmlld0lkAAAAAQATL2pzZi9uYXZpZ2F0aW9uLmpzcAAHX19FT0ZfXw**&portal:type=action#111#1</u>

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- **1.5.3.** 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;
- **1.5.4.** Be free of exclusions with the US Department of Health and Human Services, Office of Inspector General. https://exclusions.oig.hhs.gov/
- **1.5.5.** 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;
- **1.5.6.** If applying to be a Physician Specialist under the Program, meet the following requirements:
 - a) Be currently licensed as a Medicaid Provider in Texas; and
 - b) 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
 - c) Board Certified/Board Eligible in Adult and Pediatric Endocrinology (Adult-Endocrinology, Diabetes, and Metabolism), or Pediatric Endocrinology; or
 - d) Board Certified/Board Eligible in Adult and Pediatric Hematology (Adult-Hematology) or Pediatric Hematology (Hematology/Oncology); or
 - e) Board Certified/Board Eligible in Adult and Pediatric Pulmonology: or
 - f) Board Certified/Board Eligible in Allergy and Immunology.
- **1.5.7.** If applying to be a laboratory under the Program, meet the following requirements:
 - 1.5.7.1. Be certified by Clinical Laboratory Improvement Amendments (CLIA); Must provide a copy of the CLIA certification attached to the Application; and
 - **1.5.7.2.** Have the capacity to conduct confirmatory testing and follow-up testing for patients identified through the Texas Newborn Screening Program as being at risk for a hereditary metabolic, endocrine, or hematologic disorder.
- **1.5.8.** If applying to be a pharmacy under the Program, meet the following requirement: Must be able to dispense Medications, Medical Foods, Vitamins and Dietary Supplements prescribed by an enrolled Physician Specialist; and provide a copy of licensure with the enrollment Application identifying pharmacy classification in one of the following:
 - 1.5.8.1. Class A (may include compounding pharmacies);
 - 1.5.8.2. Class C (institutional):
 - 1.5.8.3. Class D (clinical); or
 - 1.5.8.4. Class E (mail-order).

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- **1.5.9.** If applying to be a Manufacturer or Retailer of Medical Foods, meet the following requirements:
 - Be a manufacturer or retailer of Medical Foods (Low Protein Foods and formulas), Dietary Supplements and Vitamins that are prescribed by an enrolled physician specialist;
 - b) Provide a catalog of low protein food products (if applicable); and
 - c) 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.

1.6. Strategic Elements

1.6.1. Contract Type and Term

DSHS will 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, 2018 or upon execution, and will end on August 31, 2020, 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-year terms or as necessary to complete the mission of the procurement. The 2 additional two-year terms are as follows:

Renewal 1: September 1, 2020 through August 31, 2022 Renewal 2: September 1, 2022 through August 31, 2024

1.6.2. 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 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 2.14(see below); the Data Use Agreement for Contractors who access agency confidential information and who are not exempt (https://hhs.texas.gov/doing-business-hhs/business-contracting-opportunities); and the successful Applicant's application.

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1.6.3. Security and Privacy Initial Inquiry (SPI)

The Applicant must submit the Information Security and Privacy Initial Inquiry (SPI) form with their Application to this open enrollment. The SPI form is available at: https://hhs.texas.gov/doing-business-hhs/business-contracting-opportunities

1.7. Amendments and Announcements Regarding this Open Enrollment

HHSC will post all official communication regarding this open enrollment on the <u>HHS Open Enrollment Opportunities</u> page. HHS 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 <u>HHS Open Enrollment Opportunities</u> page. Applicant must check <u>HHS Open Enrollment Opportunities</u> frequently for changes and notices of matters affecting this open enrollment.

Applicant's failure to periodically check <u>HHS Open Enrollment Opportunities</u> 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 Point 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 HHS of any ambiguity, conflict, discrepancy, omission or other error in the open enrollment.

1.8. Delivery of Notices

Any notice required or permitted under this announcement by one party to the other party must be in writing 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 HHS. It is the Applicant's responsibility to monitor this email address for Application-related information.

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2. STATEMENT OF WORK

2.1. Contractor Requirements

- 2.1.1 Contractor must provide services in accordance with the NBS Program Benefits Contractor Procedures Manual, which can be found at http://www.dshs.texas.gov/newborn/benefits.aspx, as revised, and applicable rules and regulations, as amended, including but not limited to Health and Safety Code Section 33.032 and 25 Texas Administrative Code Sections 37.51-37.64.
- 2.1.2 Contractor must ensure initial benefits eligibility screening is conducted in accordance with the NBS Benefits Contractor Procedural Manual and as directed by DSHS prior to providing services.
- 2.1.3 Contractor must comply with all documentation requirements set forth in the NBS Benefits Contractor Procedural Manual and as required by applicable federal and state laws and regulations.
- 2.1.4 Physician Specialist contractors shall:
 - **2.1.4.1** Provide medical services to eligible clients, including but not limited to evaluations and management of metabolic, pulmonology, or immunologic, endocrine, and hematological disorders, diagnostic laboratory tests, and follow up care.
 - **2.1.4.2** Provide services within the scope of the physician's license, certification, registration, or other legal authorization, at the location and in the manner specified in the contract.
 - **2.1.4.3** 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 Medical Foods. The client shall be responsible for obtaining the prescribed Treatment or lab tests from the enrolled providers. The Physician Specialist contractor shall coordinate clients' services including providing follow-up to ensure client services have been provided.
- 2.1.5 Laboratory Services contractors shall:
 - **2.1.5.1** 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.

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- **2.1.5.2** Maintain CLIA certification for the duration of the Contract.
- **2.1.5.3** Comply with the laboratory procedures requirements set forth in the NBS Benefits Program Contractor Procedures Manual.
- 2.1.6 Pharmacy Services contractors shall:
 - **2.1.6.1** Provide Medications, Vitamins, Dietary Supplements, and Medical Foods prescribed by enrolled health care providers specializing in metabolic, endocrine, and hematologic, pulmonology, or immunologic disorders, necessary for Treatment and management of diagnosed disorders;
 - **2.1.6.2** 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 physician specialist, client, and the NBS Benefits program of the delay, the reason for the delay and the estimated time the item will be shipped.
 - **2.1.6.3** 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 to continue to receive NBS Benefits.
- 2.1.7 Manufacturers or Retailers of Medical Foods or Low Protein Foods contractors shall:
 - **2.1.7.1** 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;
 - 2.1.7.2 As applicable, provide Medical Foods (such as formulas), Vitamins, and Dietary Supplements prescribed by health care providers specializing in metabolic, endocrine, and hematologic, pulmonology, or immunologic disorders, necessary for Treatment and management of diagnosed disorders, and
 - **2.1.7.3** Medical Foods contractors shall provide the prescribed Medical Foods, Vitamins, and Dietary Supplements as specified by the physician specialist's prescription.
 - 2.1.7.4 Low Protein Food contractors must provide modified foods which are low in protein. Low Protein Foods are defined as follows additional information regarding Low Protein Foods can be found in the NBS Benefits Program Contractor Procedures Manual at http://www.dshs.texas.gov/newborn/benefits.aspx):

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- **2.1.7.4.1** Must be lacking in the compounds which cause complications of the metabolic disorder;
- 2.1.7.4.2 Must be products listed in enrolled providers' catalog;
- **2.1.7.4.3** Are not generally available in grocery stores, health food stores, or pharmacies;
- 2.1.7.4.4 Are not used as food by the general population; and
- 2.1.7.4.5 Are not foods covered under the Food Stamps program.
- **2.1.7.5** 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 physician specialist, client, and the NBS Program Benefits of the delay, the reason for the delay and the estimated time the item will be shipped.
- **2.1.7.6** Ensure that products provided to clients and billed to the NBS Program Benefits are listed in the enrolled provider's pre-approved Texas NBS Program Benefits catalog.
- **2.1.7.7** 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 receive NBS Benefits.

2.2 Eligible Population

- **2.2.1** Contractor shall provide Program services only to clients who meet the eligibility criteria set forth in *25 TAC 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:
 - 2.2.1.1 Children 0-2 years of age
 - 2.2.1.2 Children 3-5 years of age
 - 2.2.1.3 Children 6-21 years of age
 - 2.2.1.4 Pregnant women
 - 2.2.1.5 Women of child bearing age
 - 2.2.1.6 Other adults (female or male)

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2.3 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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3 PAYMENT

3.1 Payment

3.1.1 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.

3.1.2 Method of Payment

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

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

3.2 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 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 NBS 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.

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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4 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) is not required with their Application at the time of submission.

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5 INFORMATION AND SUBMISSION INSTRUCTIONS

5.1 Open Enrollment Cancellation/Partial Award/Non-Award

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

5.2 Right to Reject Applications or Portions of Applications

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

5.3 Joint Applications

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

5.4 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 Point of Contact, as designated in <u>subsection 1.2</u>.

5.5 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.

5.6 Application Submission Instructions

Applicant must submit an original application and three (3) electronic copies of all required documents as scanned versions (.pdf) on separate portable media devices, such as flash drives or compact discs.

5.6.1 These devices and their content must be compatible with Microsoft Office 2010. Applicants must ensure there are no encryptions on these devices, so as to prevent DSHS from opening the documents. **The electronic Application submission must be organized as directed in subsection 5.7 of this open enrollment**. If Applicant is having difficulty providing an electronic Application submission, contact the DSHS Point of Contact identified in <u>subsection 1.2</u> of this open enrollment for hard copy submittal accommodations.

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- 5.6.2 It is the Applicant's responsibility to appropriately mark and deliver the Application and related materials in response to this open enrollment by the Application due date.
- **5.6.3** Submission of an Application does not execute a Contract.

Organization of (Electronic or Paper) Submission of Application

Applicant must organize its scanned and signed Application packets in the following order and format. Each (flash drive, compact disc, E-mail or paper) submission of the Application packet must include the following five (5) file folders with the respective listed documents included, and the documents must be in the following order, and labeled accordingly

- Form A: Face Page:
- Form B: Newborn Screening Program Benefits Open Enrollment Application

Form B-1: Physician Specialist

Form B-2: Laboratory Provider

Form B-3: Pharmacy Provider

Form B-4: Medical Foods Provider

- Form C: Contact Person Information Form
- Form D: Exceptions Form
- Form E: Security and Privacy Inquiry (SPI)

5.8 Electronic (or Paper) Copy

Label the Electronic Media Device (flash drive or compact disc), E-mail Application submittal or Paper copy of the Application.

- 5.8.1 Each (flash drive, compact disc, E-mail submission or paper copy) must be labeled with the:
 - Name of the Organization;
 - Organization's point of contact;
 - Organization's point of contact's job title;
 - Organization's point of contact's telephone number and Email address;
 - HHSC Procurement number of this open enrollment; and
 - Date of submission.

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5.9 Delivery of Applications

5.9.1 Submit all copies of the Application to the DSHS Contract Management Section(CMS) at the location provided below. All required documents must be received by PCS by the due date and time listed in the Procurement Schedule in subsection 1.3 of this open enrollment.

Delivery Option

Physical Address for Delivery

(Operating Hours - 8:00 A.M. to 5:00 P.M.)

Department of State Health Services
Attn: Sara Mosqueda, Contract Manager
Tower Building
1100 W. 49th St.
Mail Code: 1990
Austin, Texas 78756

Or email to <u>NBSOE@dshs.texas.gov</u> and to <u>sara.mosqueda@dshs.texas.gov</u>

5.9.2 DSHS will date and time-stamp all submissions when received. The clock in the DSHS office is the official timepiece for determining compliance with the deadlines in this procurement. DSHS reserves the right to reject late submissions. It is the Applicant's responsibility to appropriately mark and deliver the Application to DSHS by the specified time and date. All Applications must be submitted by hand delivery, by courier, scanned email, or mail.

DSHS will not accept Applications by any other method of delivery (e.g., telephone or facsimile).

5.9.3 All Applications become the property of HHS after submission.

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6 ELIGIBILITY DETERMINATION

6.1 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.

6.2 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:

- **6.2.1** The Applicant fails to meet major open enrollment specifications, including:
 - **6.2.1.1** The Applicant fails to submit the required Application, supporting documentation, or forms.
 - **6.2.1.2** The Applicant is not eligible under <u>subsection 1.5</u> of this open enrollment.
 - **6.2.1.3** Applicant does not accept the payment rate established in this open enrollment.
- **6.2.2** The Application is not signed.
- 6.2.3 The Applicant's response is not clearly legible. Typewritten is preferred.
- **6.2.4** The Application is not received by the closing of the open enrollment period provided in <u>subsection 1.3</u> of this open enrollment.

6.3 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 <u>subsection 1.2</u>. DSHS may request modifications to the Application at any time.

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6.4 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.

6.5 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:

- **6.5.1** Past business history, practices, and conduct;
- 6.5.2 Ability to supply the goods and services; and
- **6.5.3** 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.

6.6 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 <u>subsection 1.2</u> of this open enrollment. The debriefing provides information to the Applicant on the strengths and weaknesses of their Application.

6.7 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 <u>Texas</u> Administrative Code (TAC) Rule §391.403.

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7 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).

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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.

Subcontractor – A written agreement between the DSHS contractor and a third party to provide all or a specified part of the services, goods, work, and materials required in the original contract. The contractor remains entirely responsible to DSHS for performance of all requirements of the contract with DSHS. The contractor must closely monitor the subcontractor's performance. Subcontracting can be done only when expressly allowed in the program attachment.

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.

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Newborn Screening Program Benefits 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 by enteral 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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8 ATTACHMENTS AND FORMS

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

8.1 Required Forms and Open Enrollment Application

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

Form A: Face Page	Form A_FY2019_DSHS NBS
Form B: Open Enrollment Application	Form B_FYZ019_DSHS NBS
Form B-1: Physician Specialist	Form B-1_FY2019_DSHS N
Form B-2: Laboratory Provider	Form B-2_FY2019_DSHS NI
Form B-3: Pharmacy Provider	Form B-3_FY2019_DSH5 N
Form B-4: Medical Foods Provider	Form B-4_FY2019_DSHS NI
Form C: Contact Person Information	Form C_FY2019_DSHS NBS
Form D: Exceptions Form	Form D_FY2019_DSHS NBs
Form E: Security and Privacy Inquiry (SPI)	hhs-spi-v2-1.pdf

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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:

W
General Affirmations, docx
C_vendor-UTC.pdf
W attempt
Governmental UTC.docx
W
DSHS Vendor Supplemental Speci
w
DSHS Interagency Interlocal Suppleme
data-use-agreemen t_v.8.4_3.15.18_priva
gov-data-use-agree ment_v.8.3_4.1.15.pc