

Texas Vendor Drug Program
Pharmacy Provider Enrollment Agreement

Pharmacy Provider Enrollment Agreement

DOCUMENT HISTORY LOG

STATUS	REVISION	EFFECTIVE	DESCRIPTION
Revision	1.3	Oct. 19, 2018	Document formatting
Revision	1.2	July 1, 2016	<p>Part 1. Provider Information</p> <ul style="list-style-type: none"> Added Limited Distribution Drug Provider section <p>Part 2. Definitions</p> <ul style="list-style-type: none"> Added definitions of "Breach," " Covered Limited Distribution Drug," "Discovery/Discovered," and Limited Distribution Drug Provider." <p>Part 3. Terms and Conditions</p> <ul style="list-style-type: none"> Amended "Authority to Dispense Covered Drugs" Inserted "Authority to Dispense Covered Limited Distribution Drugs" D.8. Term and Termination Inserted failure to keep Application Information updated as condition of termination D.10. Term and Termination Inserted bankruptcy language as condition of termination. F.6. Notice to HSSC. Added to Notification requirement bankruptcy language. Added same language to Chart as item 10. O. Inserted New Section "HIPAA Provisions - Provider's Breach Notice, Reporting and Correction Requirements." P. Remedies Moved from T. to P. Deleted from T-2 language from second sentence following "payment." S. Assignment Moved from M to S. Changed "will" to "shall." Y. Acknowledgment and Certifications - Combined language from Number 7 with Number 2 requiring maintaining current Application information and amending breach language to "constitute grounds for Termination in accordance with Section D of this Agreement." Y.3. Amended language to pertain only to falsification, omissions or misrepresentations in Application. Y.4. Amended language to pertain only to falsification, omissions or misrepresentations in filed claims. Y.5. Deleted language relating to bankruptcy. Former Number 6 is now Number 5. Y.6. Former Number 7 is now Number 6.
Revision	1.1	Dec. 29, 2015	<p>O. Deceptive Trade Practice Act Violations</p> <ul style="list-style-type: none"> Inserted "Practice" into section header
Baseline	1.0	Nov. 12, 2015	Initial publication.

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HHSC Number:
(For Internal Use)

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Part 1: Provider Information

Name of Enrolling Provider					
Doing-Business-As (DBA) Name (if different than the enrolling provider)					
Vendor ID Number	Medicare Provider ID (if applicable)			National Provider Identifier	
Physical Address (where covered drugs are dispensed): Pharmacy providers MUST enter the physical address where covered drugs are dispensed to recipients. If the accounting, corporate, or mailing address is entered into this physical address field, the application will be denied.					
Number	Street	Suite	City	State	ZIP
Accounting/Billing Address (if applicable)					
Number	Street	Suite	City	State	ZIP
Limited Distribution Drug Provider: Do not complete this section if the pharmacy is dispensing Covered Drugs that are not classified as Covered Limited Distribution Drugs. Check the box and complete this section if the pharmacy will be dispensing only the specified Covered Limited Distribution Drugs.					
<input type="checkbox"/> The pharmacy's reimbursement pursuant to this Agreement is limited to the following Covered Limited Distribution Drug(s):					

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Part 2: Definitions

Application means the Medicaid/CHIP Vendor Drug Program Pharmacy Provider Enrollment Application Form.

Breach means the term as defined in 45 C.F.R. §164.402, and as amended.

CHIP means the Children's Health Insurance Program administered in accordance with Title XXI of the Social Security Act.

CMS means the United States Centers for Medicare and Medicaid Services.

CSHCN means the Children with Special Health Care Needs Services Program administered in accordance with Title V of the Social Security Act.

Covered Drug means the term as explained in Section 354.1831 of Title 1 of the Texas Administrative Code.

Covered Limited Distribution Drug means a Covered Drug that is classified by the U.S. Food and Drug Administration (FDA) as a limited distribution drug.

Date of Service means the date the Provider prepares, packages, compounds and/or labels the Covered Drug.

Discovery/Discovered mean the terms as defined in 45 C.F.R. §164.410, and as amended.

HHSC means the Texas Health and Human Services Commission.

HHSC Confidential Information means any communication or record (whether oral, written, electronically stored or transmitted, or in any other form) provided to or made available to the Provider electronically or through any other means that consists of or includes any or all of the following:

- a) Protected Health Information in any form, including without limitation, Electronic Protected Health Information or Unsecured Protected Health Information;
- b) Sensitive Personal Information defined by Texas Business and Commerce Code Chapter 521;
- c) Federal Tax Information;
- d) Personally Identifiable Information;
- e) Social Security Administration Data, including without limitation, Medicaid information; and
- f) All information designated as confidential under the constitution and laws of the State of Texas and of the United States, including the Texas Health & Safety Code and the Texas Public Information Act, Texas Government Code, Chapter 552.

Index means the Texas Drug Code Index issued by HHSC.

KHC means the Kidney Health Care Program administered in accordance with Texas Health and Safety Code Chapters 42 and 1001.

Limited Distribution Drug Provider means a Provider that is limited to dispensing only Covered Limited Distribution Drug(s) specified in Part I of this Agreement to eligible recipients of the Vendor Drug Program.

Manual means the Texas Vendor Drug Program Pharmacy Provider Procedure Manual issued by HHSC, as modified.

MFCU means the Medicaid Fraud Control Unit of the Texas Office of the Attorney General.

Medicaid means the Medical Assistance Program administered in accordance with Title XIX of the Social Security Act.

OIG means the HHSC Office of Inspector General.

Program Requirements means the Vendor Drug Program requirements included in the Manual, Index, and all federal and state laws, rules, regulations, policies, and procedures governing the Vendor Drug Program, as amended or modified. This includes all notices, bulletins, and information packages issued by HHSC concerning the Vendor Drug Program.

Provider means the pharmacy provider identified in Part 1 Section 2 of the Application and Part 1 of this Agreement.

Recipient means a person authorized to receive benefits under the Vendor Drug Program administered by HHSC.

SAO means the Texas State Auditor's Office.

Subcontractor means those persons or entities who provide medical goods or services for which the Provider bills the Vendor Drug Program or who provide billing, administrative, or management services in connection with Covered Drugs.

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Healthy Texas Women (HTW) means the state program administered by HHSC as authorized by Health and Safety Code, Chapter 31 and Subchapter B of Chapter 39 of Title 25 of the Texas Administrative Code (formerly the Texas Women's Health Program, or TWHP).

Vendor Drug Program (VDP) means the Texas Vendor Drug Program, an outpatient drug program administered by HHSC for Medicaid, CHIP, CSHCN, KHC, and HTW.

Part 3: Terms and Conditions

The Provider agrees to comply with the following terms and conditions of this Agreement.

- A. **Vendor Drug Program Administration.** HHSC is the State of Texas agency responsible for administering the Vendor Drug Program for the State of Texas.
- B. **Authority to Dispense Covered Drugs.** The Provider is authorized to dispense Covered Drugs to Recipients of the Vendor Drug Program on a vendor basis in accordance with the terms and conditions of this Agreement. Providers authorized only as a Limited Distribution Drug Provider may dispense only Covered Limited Distribution Drugs as specified under this Agreement.
- C. **Authority to Dispense Covered Limited Distribution Drugs.** The Limited Distribution Drug Provider is authorized to only dispense Covered Limited Distribution Drugs specified in Part I of this Agreement to Recipients of the Vendor Drug Program in accordance with the terms and conditions of this Agreement. Limited Distribution Drug Providers may **only** dispense and seek payment for those drugs specified in Part I "Limited Distribution Drug Provider" above.
- D. **Term and Termination of the Agreement.** This Agreement is effective on the date indicated in Part 4, and supersedes all prior pharmacy provider agreements between the Parties. The Agreement will expire on the date indicated in Part 5, unless terminated sooner as described herein. Either party may terminate this Agreement by providing written notice of its intent to terminate at least thirty (30) calendar days before the termination date.

HHSC, upon written notice of its intent to terminate, may terminate all or part of the Agreement for the following reasons:

1. The Provider loses its billing privileges or is excluded or debarred from participation in any program established under a state or federal government pursuant to the following provisions of the Social Security Act: Title XVIII (Medicare), Title XIX (Medicaid), Title XX (Block Grants to States for Social Services) or Title XXI (CHIP), or the Provider is convicted of an offense involving fraud (see 42 U.S.C. §1320a-7 and Executive Order 12549);
2. the Provider loses its Texas State Board of Pharmacy license or certificate for any reason;
3. the Provider becomes ineligible to participate in the Vendor Drug Program for any reason;
4. the Provider fails to comply with the terms of this Agreement and/or standards for participation in the Vendor Drug Program;
5. the MFCU or the OIG determines that the Provider has or may be placing the health and safety of a Recipient at risk;
6. a change in federal or Texas law requires a reduction or termination of the Vendor Drug Program, or funding is not available for Vendor Drug Program services or benefits;
7. HHSC determines that the Provider has had no claims activity with the Vendor Drug Program within a twelve-month period;
8. the Provider files or is the subject of a bankruptcy petition;
9. the Provider fails to keep current the information contained in its Application; or
10. HHSC determines the termination is in the best interest of the State of Texas.

The Parties are still responsible for any continuing obligations under this Agreement upon termination, including but not limited to equitable settlement of any accrued interests, records retention, and recoupment.

- E. **Agreement and Documents Constituting Agreement.** This Agreement incorporates by reference the terms of the Program Requirements and the Provider Application, including all revisions thereto. The Provider has a duty to become educated and knowledgeable about the Program Requirements and will ensure that the Provider and its employees, agents, and subcontractors who act on the Provider's behalf in fulfillment of the Provider's responsibilities under this Agreement comply with these Program Requirements. HHSC will maintain a link to current copies of the Manual and Index on its website (txvendordrug.com).
- F. **Notice to HHSC.** The Provider will provide HHSC or its designated representative written notice of the following in accordance with the timeframes described in this section:
 1. Changes to the information provided in the Application, including but not limited to, information on ownership and control, information related to business transactions, and information on persons convicted of crimes in accordance with the requirements of 42 C.F.R. Part 455;
 2. an action under §1128(a) or (b) of the Social Security Act or Executive Order 12549 taken against the Provider, or any other person defined under the provisions of §1128(a) or (b) of the Social Security Act, that could result in exclusion from Medicaid;

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3. the suspension or placement of any restriction on the Provider's license or certificate to provide pharmacy services, including complete information regarding any such suspension or restriction;
4. changes to or correction of the information provided in this Agreement's certifications regarding debarment, suspension, drug free workplaces, delinquent child support payments, and federal lobbying;
5. notice of the Provider's intent to terminate this Agreement; and
6. notice if the Provider files or is the subject of a bankruptcy petition.

The Provider will provide the notice described above to HHSC no later than the following dates:

Triggering Event		Notice Due
1.	Change in Ownership or Control	15 business days before change in ownership or control
2.	Conviction of Provider or Provider's Principals	10 business days after conviction
3.	Action that could result in exclusion from Medicare or Medicaid Programs	10 business days after receipt of the notice of action
4.	Suspension or Restriction of Provider's License or Certificate	10 business days after the suspension or restriction
5.	Debarment, Suspension, or Drug-free Workplace Certifications	Immediately following discovery that the certification was erroneous when submitted or becomes erroneous by reason of changed circumstances
6.	Child Support Certification	10 business days following discovery that the certification was erroneous when submitted or becomes erroneous by reason of changed circumstances
7.	Federal Lobbying Certification	10 business days following discovery that the certification was erroneous when submitted or becomes erroneous by reason of changed circumstances
8.	Change to Any Other Information in the Application	10 business days after change
9.	Intent to Terminate	30 calendar days before the effective date of termination
10.	Notice of bankruptcy petition	15 calendar days after the Provider files or is the subject of a bankruptcy petition and copy HHS on all Provider's pleadings on the case.

Notice to HHSC:

Texas Health and Human Services Commission
 Attn: Medicaid/CHIP Contract Compliance and Support (H-330)
 4900 North Lamar Blvd.
 Austin, TX 78751

The Provider agrees to supply the above-referenced information to the following entities at their request: CMS, United States Department of Health and Human Services; Comptroller General of the United States; HHSC; OIG; MFCU; SAO; Texas Department of Aging and Disability Services; Texas Department of State Health Services; a state or federal law enforcement agency; a special or general investigating committee of the Texas Legislature; any state or federal entity identified by HHSC; and any other entity identified by the above-referenced entities.

G. Claims Submission. The Provider will submit claims for payment in accordance with Program Requirements. The Provider understands that payment of claims may be from federal and state funds and that any falsification or concealment of material fact may be prosecuted under federal and state laws. The Provider agrees that information contained in all claims data submitted by or on behalf of the Provider:

1. Is true, complete and accurate;
2. can be verified by reference to source documentation maintained by the Provider;
3. is subject to audit, review, and inspection in accordance with the Manual, and Index, and updates or revisions thereto; and
4. will be for pharmacy services provided at the physical address identified in Part 1 of this Agreement. The Provider may not submit claims pursuant to this Agreement for prescriptions filled at other locations owned by the Provider.

The Provider further agrees to refund to the Vendor Drug Program any overpayment, duplicate payment, or erroneous payment made by the Vendor Drug Program to which the Provider is not entitled. The Provider authorizes HHSC to recoup from any source of payment flowing from HHSC to the Provider.

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- H. **Fraud, Waste and Abuse.** The Provider will comply with all Texas and federal laws that regulate fraud, waste, and abuse in health care and the Vendor Drug Program. This includes, without limitation, the following obligations:
1. To keep and maintain all the records necessary for the purchasing and dispensing of Recipient prescriptions, and furnish all reports in such form and scope as HHSC may require. This includes without limitation:
 - a. All prescription documents, medication invoices, and medication acquisition documents;
 - b. all records pertinent to the services for which a claim was submitted, or the claims presented for payment for such services; and
 - c. all other records required to be maintained by HHSC's standards of participation in the Vendor Drug Program, as described in the Manual and all applicable federal and state laws.
 2. To cooperate with and assist HHSC, the MFCU, the CMS, the SAO and any State of Texas or federal agency charged with the duty of identifying, investigating, sanctioning, or prosecuting fraud, waste, or abuse in the Vendor Drug Program or the audit of claims submitted for payment. The Provider must grant any of these entities and/or their agents, and ensure that their employees, subcontractors and agents grant these entities and/or their agents:
 - a. Access to its premises, including immediate access to the files of prescriptions and to the drug acquisition records that pertain to the Vendor Drug Program for review and/or audit;
 - b. access to a sample of the de-identified prescription files of the Provider's customers who are not enrolled in the Vendor Drug Program for the purpose of determining a pharmacy provider's usual and customary price. For purposes of this requirement, the Provider may de-identify prescription files for these customers by removing "individually identifiable health information," as defined by 45 C.F.R. §160.103. "Individually identifiable health information" does not include information concerning the drug type, quantity, or dosage; National Drug Code (NDC) number; or drug pricing information;
 - c. access to all records maintained pursuant to this Agreement, including without limitation those maintained pursuant to 42 C.F.R. §431.107, and copies of such records free of charge;
 - d. access to employees, subcontractors, agents, witnesses and Recipients for purposes of investigating, sanctioning, or prosecuting fraud, waste or abuse upon request. The Provider must comply with requests for interviews in the form and the manner requested by the investigating entity. The Provider will ensure by contract or other means that its employees, agents and subcontractors cooperate fully in any investigation.; and
 - e. permission to interview the Provider's employees, agents and subcontractors without coercion by Provider and without the presence of the Provider or the Provider's representative or legal counsel unless the interviewee voluntarily agrees to such presence or representation. The Provider must not retaliate against an interviewee who declines such presence or representation. Nothing in this Agreement limits an interviewee's right to counsel of his or her choice; and
 3. To cooperate in HHSC's regular reviews of Recipient records, general audits and utilization reviews.
- I. **Records Retention.** The records and documents referenced in Part 3, Subpart G of this Agreement must be retained for a minimum of five years from the Date of Service. If any litigation, audit, review, or dispute resolution begins before the five-year period expires, the Provider must maintain all records until the process is concluded. Further, if any litigation, audit, review, or dispute resolution begins at a time when the Provider would have been otherwise authorized to destroy the records (e.g., five years and a day after the Date of Service) and Provider still has the records, Provider must maintain those records until the process concludes. For purposes of record retention, the process is concluded only after HHSC provides written notification that the process and issue is permanently resolved.
- J. **SAO Authority.** In accordance with the requirements of Texas Government Code § 2262.154, the Provider understands and agrees that the acceptance of funds under this Agreement acts as acceptance of the authority of the SAO, or any successor agency, to conduct an investigation in connection with those funds. The Provider further agrees to cooperate fully with the SAO or its successor in the conduct of the audit or investigation, including providing all records requested. The Provider will ensure that this clause concerning the authority to audit funds received indirectly by subcontractors through Provider and the requirement to cooperate is included in any subcontract it awards.
- K. **Payment in Full.** The Provider agrees to accept the vendor payment in effect on the date of service as payment in full for Covered Drugs provided to a Recipient. The Provider will not make additional charges to the Recipient, any member of his or her family, or any other source for supplementation of payment. These restrictions do not apply to copayments or cost-sharing amounts authorized by HHSC, or to amounts collected pursuant to HHSC's third-party recovery rules.
- L. **Recipient Rights.** The Provider will:
1. Not exclude, deny or withhold aid, care, services, or other benefits available under the Vendor Drug Program to any Recipient or otherwise discriminate against a person because of that person's race, color, national origin, gender, age, disability, political or religious beliefs.

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2. Provide services to Recipients in the same manner, by the same methods, and at the same level and quality provided to the general public. Provider agrees to grant Recipients and HHSC all discounts and promotional offers provided to the general public. Provider understands and agrees that free services to the general public must not be billed to the State or its agents for Recipients, and discounted services to the general public must not be billed to the State or its agents as a full price, but rather the Provider agrees to bill only the discounted amount that would be billed to the general public.
 3. Not charge or pursue payment from a Recipient or any person who is financially responsible for a Recipient for anything other than a copayment or cost-sharing amount specifically authorized by HHSC.
 4. Ensure any personal or medical information regarding a Recipient in the Provider's custody will be maintained in a manner that protects the Recipient's rights of privacy and confidentiality under all applicable Texas and federal laws.
 5. Ensure a Recipient is free to seek and obtain medical, dental, or pharmacy services from a provider of his or her choice.
 6. Ensure that a Recipient's acceptance of any service is voluntary.
 7. Neither solicit, pay, nor offer inducements, remuneration, or other compensation to a Recipient in violation of state or federal anti-kickback laws, or in violation of HHSC's advertising rules (see e.g., 1 Tex. Admin. Code Part 15, Chapter 354, Subchapter F).
 8. Provide language assistance that may be required for effective communication with Recipients who demonstrate limited English Proficiency to ensure they have equal access to Vendor Drug Program services.
- M. **Compliance with laws.** The Provider will comply with all laws, rules and regulations applicable to this Agreement, as amended or modified, including without limitation:
1. State and federal anti-discrimination laws -- Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d et. seq.); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794 et. seq.); the Americans with Disabilities Act of 1990 (42 U.S.C. § 12101 et. seq.).
 2. Environmental protection laws -- Clean Air Act and Federal Water Pollution Control Act regulations (Executive Order 11738) and state Clean Air Implementation Plans (42 U.S.C. § 7401 et seq.); Pro-children Act of 1994 (20 U.S.C. § 6081 et seq.); National Environmental Policy Act of 1969 (42 U.S.C. § 4321 et seq. and Executive Order 11514); Safe Drinking Water Act of 1974 (21 U.S.C. §349; 42 U.S.C. §§ 300f through 300j-9);
 3. Immigration and Nationality Act (8 U.S.C. § 1101, et seq.) regarding employment verification and retention of verification forms for any individuals hired on or after November 6, 1986 who will perform any labor or services under this Agreement;
 4. Health Insurance Portability and Accountability Act (HIPAA) of 1996 (the Parties understand that they are not "business associates" as defined by 45 C.F.R. Parts 160 and 164);
 5. Debarment and suspension and drug-free workplace (45 C.F.R. Part 76);
 6. Delinquent child support payments (Tex. Fam. Code § 231.006);
 7. All federal and state lobbying laws, including, 31 U.S.C. § 1352;
 8. Employee education about false claims recovery (Section 1902(a)(68) of the Social Security Act), which requires compliance by entities that receive annual Medicaid payments of at least \$5,000,000.
 9. Texas Health and Safety Code Chapter 85 and HHSC's rules relating to workplace and confidentiality guidelines regarding HIV and AIDS.
 10. Texas and federal laws, rules and regulations establishing Medicaid or other programs under the Vendor Drug Program as the payor of last resort as described in the manual.
 11. Texas State Board of Pharmacy rules and regulations in effect at the time the prescription is serviced.
- N. **Confidential Information.** Any HHSC Confidential Information received by the Provider under this Agreement may be disclosed only in accordance with applicable law. By signing this agreement, the Provider certifies that the Provider is, and intends to remain for the term of this agreement, in compliance with all applicable state and federal laws and regulations with respect to privacy, security, and breach notification, including without limitation the following:

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1. The relevant portions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. Chapter 7, Subchapter XI, Part C;
2. 42 C.F.R. Part 2 and 45 C.F.R. Parts 160 and 164;
3. The relevant portions of The Social Security Act, 42 U.S.C. Chapter 7;
4. The Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988, 5 U.S.C. § 552a;
5. Internal Revenue Code, Title 26 of the United States Code including IRS Publication 1075;
6. OMB Memorandum 07-16;
7. Texas Business and Commerce Code Chapter 521;
8. Texas Health and Safety Code, § 81.006 and Chapters 181 and 611;
9. Texas Human Resources Code § 12.003;
10. Texas Government Code, Chapter 552, as applicable;
11. Title 3 of the Texas Occupations Code, as applicable;
12. Constitutional and Common Law Privacy; and
13. Any other applicable law controlling the release of information created or obtained in the course of providing the services described in this Agreement.

The Provider further certifies that the Provider will comply with all amendments, regulations, and guidance relating to those laws, to the extent applicable. Provider will also ensure that any subcontractor of Provider who has access to HHSC Confidential Information will sign a HIPAA-compliant Business Associate Agreement with Provider, and Provider will submit a copy of that Business Associate Agreement to HHSC upon request.

O. HIPAA Provisions - Provider's Breach Notice, Reporting and Correction Requirements

1. Notification to HHSC.

- a. Provider will cooperate fully with HHSC in investigating, mitigating to the extent practicable and issuing notifications directed by HHSC, for any unauthorized disclosure or suspected disclosure of HHSC Confidential Information to the extent and in the manner determined by HHSC.
- b. Provider's obligation begins at discovery of unauthorized disclosure or suspected disclosure and continues as long as related activity continues, until all effects of the incident are mitigated to HHSC's satisfaction (the "incident response period").
- c. Provider will require that its subcontractors and providers comply with all of the following breach notice requirements.

2. Breach Notice.

- a. Initial Notice:
 - i. For federal information, including without limitation, Federal Tax Information, Social Security Administration Data, and Medicaid Member Information, within the first, consecutive clock hour of discovery, and for all other types of Confidential Information not more than 24 hours after discovery, or in a timeframe otherwise approved by HHSC in writing, initially report to HHSC's Privacy and Security Officers via email at: privacy@HHSCC.state.tx.us and to the HHSC division responsible for this Provider Agreement;
 - ii. Report all information reasonably available to Provider about the privacy or security incident; and
 - iii. Name, and provide contact information to HHSC for, Provider's single point of contact who will communicate with HHSC both on and off business hours during the incident response period.
- b. 48-Hour Formal Notice: No later than 48 consecutive clock hours after discovery, or a time within which discovery reasonably should have been made by Provider, provide formal notification to HHSC, including all reasonably available

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information about the incident or breach, and Provider's investigation, including without limitation and to the extent available:

- i. The date the incident or breach occurred;
- ii. The date of Provider's and, if applicable, subcontractor's discovery;
- iii. A brief description of the incident or breach; including how it occurred and who is responsible (or hypotheses, if not yet determined);
- iv. A brief description of Provider's investigation and the status of the investigation;
- v. A description of the types and amount of Confidential Information involved;
- vi. Identification of and number of all individuals reasonably believed to be affected, including first and last name of the individual and if applicable the, legally authorized representative, last known address, age, telephone number, and email address if it is a preferred contact method, to the extent known or can be reasonably determined by Provider at that time;
- vii. Provider's initial risk assessment of the incident or breach demonstrating whether individual or other notices are required by applicable law or this DUA for HHSC approval, including an analysis of whether there is a low probability of compromise of the Confidential Information or whether any legal exceptions to notification apply;
- viii. Provider's recommendation for HHSC's approval as to the steps individuals and/or Provider on behalf of Individuals, should take to protect the Individuals from potential harm, including without limitation Provider's provision of notifications, credit protection, claims monitoring, and any specific protections for a legally authorized representative to take on behalf of an Individual with special capacity or circumstances;
- ix. The steps Provider has taken to mitigate the harm or potential harm caused (including without limitation the provision of sufficient resources to mitigate);
- x. The steps Provider has taken, or will take, to prevent or reduce the likelihood of recurrence;
- xi. Identify, describe or estimate of the persons, workforce, subcontractor, or individuals and any law enforcement that may be involved in the incident or breach;
- xii. A reasonable schedule for Provider to provide regular updates to the foregoing in the future for response to the incident or breach, but no less than every three (3) business days or as otherwise directed by HHSC, including information about risk estimations, reporting, notification, if any, mitigation, corrective action, root cause analysis and when such activities are expected to be completed; and
- xiii. Any reasonably available, pertinent information, documents or reports related to an incident or breach that HHSC requests following discovery.

3. Investigation, Response and Mitigation:

- a. Provider will immediately conduct a full and complete investigation, respond to the incident or breach, commit necessary and appropriate staff and resources to expeditiously respond, and report as required to and by HHSC for incident response purposes and for purposes of HHSC's compliance with report and notification requirements, to the satisfaction of HHSC.
- b. Provider will complete or participate in a risk assessment as directed by HHSC following an incident or breach, and provide the final assessment, corrective actions and mitigations to HHSC for review and approval.
- c. Provider will fully cooperate with HHSC to respond to inquiries and/or proceedings by state and federal authorities, persons and/or incident about the incident or breach.
- d. Provider will fully cooperate with HHSC's efforts to seek appropriate injunctive relief or otherwise prevent or curtail such incident or breach, or to recover or protect any HHSC Confidential including complying with reasonable corrective action or measures, as specified by HHSC in a Corrective Action Plan.

4. Breach Notification to Individuals and Reporting to Authorities.

- a. HHSC may direct Provider to provide breach notification to individuals, regulators or third-parties, as specified by HHSC following a breach.

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- b. Provider must obtain HHSC's prior written approval of the time, manner and content of any notification to individuals, regulators or third-parties, or any notice required by other state or federal authorities. Notice letters will be in Provider's name and on Provider's letterhead, unless otherwise directed by HHSC, and will contain contact information, including the name and title of Provider's representative, an email address and a toll-free telephone number, for the Individual to obtain additional information.
- c. Provider will provide HHSC with copies of distributed and approved communications.
- d. Provider will have the burden of demonstrating to the satisfaction of HHSC that any notification required by HHSC was timely made. If there are delays outside of Provider's control, Provider will provide written documentation of the reasons for the delay.
- e. If HHSC delegates notice requirements to Provider, HHSC shall, in the time and manner reasonably requested by Provider, cooperate and assist with Provider's information requests in order to make such notifications and reports.

P. Remedies.

1. HHSC or another state or federal agency may, consistent with due process, assess a remedy, sanction, penalty, or other action authorized by law, including, but not limited to, payment hold, recoupment, administrative penalties, debarment, suspension, cancellation of contract, or exclusion from participation in the Vendor Drug Program.
2. HHSC reserves the right to suspend all or part of the payments under this Agreement if a review or audit indicates the Provider is not substantially complying with all program requirements, statutes or procedures. HHSC will provide the Provider written notice of the substantial non-compliance prior to suspending payment.

Q. Deceptive Trade Practice Act Violations. The Provider is under a permanent obligation to notify HHSC of Texas Deceptive Trade Practices Act violations (see Texas Business and Commerce Code, Chapter 17). The Provider will promptly disclose and fully inform HHSC of all instances whereby the Provider or its officers, while serving the Provider or as officers of another entity, are found liable of violating the Texas Deceptive Trade Practices Act.

R. HHSC Responsibilities. HHSC will:

1. Pay clean claims for Covered Drugs that are paid for by the VDP. HHSC will make payments on vendor basis, in amounts and under conditions determined by HHSC and established by administrative rule (see e.g., 1 Tex. Admin. Code Part 15, Chapter 354, Subchapter F, "Pharmacy Services," and 1 Tex. Admin. Code Part 15, Chapter 355, Subchapter J, Division 28, "Pharmacy Services: Reimbursement."). VDP is not responsible for claims that are billed to or paid by a managed care organization (MCO) that contracts with HHSC or the MCO's Subcontractor.
2. Pay clean claims in accordance with applicable federal and state laws, rules and regulations (see e.g., 42 U.S.C. § 1396a (a) (37) and 42 C.F.R. § 447.45). These laws and regulations give HHSC up to twelve (12) months to pay clean claims; however, HHSC will attempt to pay clean claims submitted electronically or on the VDP Pharmacy Claims Billing Request (Form 3700) on a weekly payment cycle, as described in the "Claims Payment" provisions of the Manual. HHSC is not required to pay Provider claims that are under investigation for fraud, abuse, or waste, or are on vendor hold. HHSC may place irregular or erroneous claims on vendor hold until it can adjust such irregularities or errors;
3. Make proper adjustments to Provider payments to compensate for prior overpayment or underpayment;
4. Provide reasonable notice of any impending change in the Provider's status as a participating provider of pharmaceutical services, including notice of cancellation of this Agreement if no claims are processed in a twelve-month period;
5. Provide public notice of any major changes in HHSC rules and regulations applicable to pharmacies and standards for participation in the Vendor Drug Program;
6. Work with the Texas Pharmaceutical Association, its local Pharmaceutical Association components, and the Provider to provide the best pharmaceutical services available within the limitations of the law and available funds; and
7. Provide an appeal in accordance with 1 Tex. Admin. Code § 354.1809 in the event HHSC suspends or cancels the Provider's participation in the Vendor Drug Program.

S. Assignment. The Provider shall not transfer or assign this Agreement to another Provider or party.

T. Amendment. This Agreement may be amended by mutual agreement of the Parties. If federal or state laws or other requirements are amended or judicially interpreted to render the fulfillment of this Agreement unfeasible or impossible, or if the Parties are unable to agree on amendments necessary to enable the substantial continuation of this Agreement, the Parties may terminate this

Pharmacy Provider Enrollment Agreement

Agreement provided notice is given in accordance with Part 3, Subpart E. The Parties are still responsible for any continuing obligations under this Agreement upon termination, including but not limited to equitable settlement of any accrued interests, records retention, and recoupment.

- U. **Assignment to HHSC.** By signing this Agreement, the Provider hereby assigns to HHSC any and all claims for overcharges associated with this Agreement that arise under federal and Texas antitrust laws (see 15 U.S.C. §1 *et seq.* and Tex. Bus & Com. Code § 15.01 *et seq.*).
- V. **Electronic Signatures.** The Provider understands and agrees that any signature on a submitted document certifies, to the best of the provider's knowledge, the information in the document is true, accurate, and complete. Submitted documents with electronic signatures may be accepted by mail or fax when the sender has met the national and state standards for electronic signatures set by HHSC and the Texas Uniform Electronic Transactions Act The Provider understands and agrees that both the Provider and the Provider's representative whose signature is on an electronic signature method bear the responsibility for the authenticity of the information certified.
- W. **Compliance Program Requirement.** The Provider certifies that in accordance with requirement 1 Tex. Admin. Code § 352.5(b)(11), it has a compliance program containing the core elements as established by the Secretary of Health and Human Services referenced in §1866(j)(8) of the Social Security Act (42 U.S.C.§1395cc(j)(8)), as applicable.
- X. **Internal Review Requirement.** The Provider, in accordance with 1 Tex. Admin. Code § 352.5 (b)(1), has conducted an internal review to confirm that neither the Provider, nor any of its employees, owners, managing partners, or contractors (as applicable), have been excluded from participation in a program under Title XVIII, XIX, or XXI of the Social Security Act.
- Y. **Acknowledgement and Certifications.** By signing below, Provider acknowledges and certifies to all of the following:
 - 1. The Provider has carefully read and understands the requirements of this Agreement, and will comply with the requirements.
 - 2. The Provider has carefully reviewed all of the information submitted in connection with the Provider's Application to participate in the Vendor Drug Program, and certifies that said information is still current, complete, and correct as of the Effective Date of this Agreement. The Provider understands that the failure to keep the information contained in the Application current constitutes grounds for Termination in accordance with Section D of this Agreement.
 - 3. Provider understands and agrees that any falsification, omission, or misrepresentation in connection with the Application for enrollment may result in all paid services declared as an overpayment and subject to recoupment, and may also result in other administrative sanctions that include payment hold, exclusion, debarment, contract cancellation, and monetary penalties.
 - 4. Provider understands and agrees that any falsification, omission, or misrepresentation in connection with claims filed for services provided in relation to this Agreement may result in all paid services declared as an overpayment and subject to recoupment, and may also result in other administrative sanctions that include payment hold, exclusion, debarment, contract cancellation, and monetary penalties.
 - 5. Provider certifies that the Provider and its principals have not been excluded, suspended, debarred, revoked or any other synonymous action from participation in any program under Title XVIII (Medicare), Title XIX (Medicaid), or under the provisions of Executive Order 12549, relating to federal contracting. Provider further certifies that the Provider and its principals have also not been excluded, suspended, debarred, revoked or any other synonymous action from participation in any other state or federal health-care program. Provider agrees to fully comply at all times with the requirements of 48 C.F.R., Ch. 3, relating to eligibility for federal contracts and grants.
 - 6. The Provider hereby certifies that the Provider is eligible to participate in the VDP programs selected in Part 1 Section 4 of the Application and agrees to comply with the law, rules, and regulations for all the programs for which the Provider enrolls.

Pharmacy Provider Enrollment Agreement

Part 4: Effective Date: (to be completed by HHSC)

The effective date of this agreement is:

Assigned to HHSC Contract Manager:

Part 5: Expiration Date: (to be completed by HHSC)

This Agreement expires on , unless terminated sooner in accordance with Part 3, Subpart C.

Part 6: Applicant Signature

For applicants that are entities, corporations, facilities, groups, or organizations, and an authorized representative is completing this application with authority to sign on the applicant's behalf, the authorized representative must sign below and print their name and title where indicated.

Provider Name	
Signature	
Printed Name (if signed by an authorized representative)	
Title (if signed by an authorized representative)	
Date	