

PDMP INTEGRATION TERMS & CONDITIONS AGREEMENT

THIS AGREEMENT is entered into by and between

(referred to as " Organization") and The Pennsylvania Department of Health Prescription Drug Monitoring Program (referred to as "PDMP"), and the Organization and the PDMP collectively referred to as the "Parties."

NOW THEREFORE, the Parties, intending to be legally bound, agrees as follows:

1. Definitions.

- 1.1. **Protected Health Information ("PHI")** means individually identifiable information received from or on behalf of the PDMP.
- 1.2. **Privacy Rule** means the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR Parts 160 and Part 164, Subparts A and E, and any amendments thereto.
- 1.3. **Affiliate** means any entity that directly, or indirectly, is controlled by, is under common control with, or controls, a party. "Control" means the ownership of or exercise of voting control or direction over shares, securities or other voting instruments of such entity carrying fifty percent (50%) or more of the unrestricted voting rights, or ownership or exercise of other rights or powers entitling the holder thereof to direct, cause the direction of, or to manage the business of such entity.
- 1.4. **Authorized Users** means prescribers or dispensers, as defined by act of October 27, 2014 (P.L.2911, No.191), known as the "Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act" (Act 191 of 2014), within the Organization's organization or health care entities that have a member or client relationship with the Organization, which is described in a valid agreement between such prescribers, dispensers or entities and The Organization, and that, in accordance with the terms of this Agreement:
 - 1.4.1. Comply with applicable Requirements;
 - 1.4.2. Are validly licensed;
 - 1.4.3. Are validly authorized by the Organization to access PDMP Data in accordance with Act 191 of 2014;
 - 1.4.4. Access or use PDMP Data for health care decision-making related to such patient, in accordance with applicable law; and

- 1.4.5. Properly authenticate to the applicable PDMP, as required, when seeking to query one or more state's PDMPs.
- 1.5. **Employee** means an employee of each party, including contractors engaged to augment staff and/or perform duties traditionally performed by employees under such party's direct supervision.
- 1.6. **Application** means a data communication service (including but not limited to an Application Programming Interface (API)), that facilitates the transmission of requests for, and retrieval of, controlled substance prescription related services and information, for authorized end users.
- 1.7. **PDMP Data** means prescription history information maintained by PDMPs.
- 1.8. **Requirements** means applicable laws and/or rules established, from time to time, by a state related to its PDMP including, but not limited to, PDMP access or permitted use(s) of PDMP Data, and/or rules issued by the federal government. "Requirements" may relate to one or more state PDMPs, as the context requires.
- 1.9. **Application Information** means data that is input, transmitted, or output via the Application, including but not limited to user data, search criteria, PDMP Data, and any other controlled substance prescription related information from the Application.
- 1.10. **Breach** means a confirmed incident in which sensitive, confidential or otherwise protected data has been accessed and/or disclosed in an unauthorized fashion
2. **Permitted Use.** The Organization agrees that it shall not receive, create, use or disclose PHI or confidential information except as follows:
 - 2.1. **Covered Functions.** To facilitate the transmission of PHI from the PDMP to The Organization in accordance with Act 191 of 2014.
 - 2.2. **Disclosure Restrictions.** If necessary, for the proper management and administration of The Organization or to carry out legal responsibilities of The Organization. PHI may only be disclosed to another person/entity for such purposes if disclosure is permitted or required by law.
3. **USE RESTRICTIONS.**
 - 3.1. **Access and Use Policies.** The Organization will maintain and enforce policies and procedures to limit access and use of the Application and Application Information as follows:
 - 3.1.1. Only Authorized Users may access or use the Application;
 - 3.1.2. Authorized Users may only access or use the Application and patient-related Application Information in accordance with the terms and conditions of this Agreement;

- 3.1.3. Organization shall provide training to its Authorized Users on accessing and using the Application and Application Information;
 - 3.1.4. The Organization shall ensure that the Application and Application Information, and its systems used in connection therewith, are accessed and used in a secure manner in accordance with applicable law and the terms of this Agreement; and
 - 3.1.5. Copies of said policies and procedures shall be provided to the PDMP upon request.
- 3.2. **Storage of Application Information.** The Organization may store Application Information in the patient's medical record for the purposes of fulfilling applicable legal requirements in Act 191 of 2014.
- 3.3. **Credentialing and Validation.** The Organization shall ensure that its credentialing and identity validation processes adhere to all applicable state and federal laws and rules and requirements for credentialing and validation of the pharmacists or health care practitioners, its subordinates, and entities or users who seek to access or use the Application or Application Information, and employees and contractors who do not provide patient care but who seek to access or use the Application.
- 3.4. **Responsibility for Use.** The Organization shall be responsible if use of or access to the Application is improper or illegal or otherwise does not conform to the terms of this Agreement.
- 3.5. **Processes.** The Organization is responsible for adopting and enforcing reasonable processes designed to confirm Authorized Users and others comply with applicable law and Requirements to access, use, and maintain the security of the Application and Application Information. The Organization shall be responsible for its and its employees', staff's, contractors', and affiliates' compliance with the terms of this Agreement.
- 3.6. **Complaints and Investigations.** The Organization is responsible for investigating all complaints and claims that an Authorized User, Authorized Entity, or an Organization employee, agent, contractor, or affiliate failed to comply with laws or rules applicable to the Application or Application Information or any Requirement for access or use of Application Information. The Organization acknowledges that PDMP has the authority to investigate, take action, sanction, or discipline those who improperly access or use the Application or Application Information, including but not limited to Authorized Users. The Organization agrees to promptly report the results of its investigation to the PDMP.
- 3.7. **Compliance with Law.** The Organization is responsible for compliance with all local, state, and federal laws and rules applicable to PDMP Data, personally identifiable information, and health information organizations including, but not limited to, confidentiality, security, registration and licensure requirements.
- 3.8. **Conduct.** The Organization, The Organization employees, agents, contractors, affiliates, and Authorized Users shall not engage in unlawful, objectionable, or malicious conduct or

activities related to Application Information including, but not limited to, the transmission or distribution of viruses, computer worms, Trojan horses, malicious code, denial of service attacks, unsolicited commercial e-mail, or the like; the unauthorized entry to any other machine accessible via the Application; the unauthorized submission or transmission of data or material protected by a proprietary right of a third party; or the submission of otherwise objectionable information, material, or communications.

4. **Minimize Use of PHI.** The Organization agrees that it will not request, use or release more than the minimum necessary amount of PHI to accomplish the purpose of the use, disclosure or request.

5. **Unauthorized Disclosure and Incident Reporting and Remediation and Privacy and Security Breach Notification.**

5.1. **Incident Reporting.**

5.1.1. The Organization shall report to PDMP any use or disclosure of PHI which is not in compliance with the terms of this Agreement or applicable law of which it becomes aware; and

5.1.2. Within 24 hours of discovery of a reportable incident as described in 5.1.1 above, The Organization shall notify PDMP of the existence and nature of the incident as understood at that time. The Organization shall immediately investigate the incident and within 5 business days of discovery shall provide PDMP, in writing, a report describing the results of The Organization's investigation. The report shall be based on best available information known at the time. If the investigation is ongoing, the report should reflect that. The PDMP may request updates to the report, and the Organization will provide an addendum as soon as possible upon completion of the investigation. The report shall include:

5.1.2.1. What data elements were involved, the extent of the data involved in the incident, and the identification of affected individuals, if applicable;

5.1.2.2. A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI, or to have been responsible for the incident;

5.1.2.3. A description of where the PHI is believed to have been improperly transmitted, sent, or utilized, if applicable;

5.1.2.4. A description of the proposed plan for preventing similar future incidents, including ongoing risk remediation plan approval; and

5.1.2.5. Whether The Organization believes any federal or state laws requiring notifications to individuals are triggered.

5.1.3. Reporting and other communications made to the PDMP under this section must be made to the Director of the PDMP

- 5.2. **Subscribing Organization Mitigation.** In addition, Organization agrees to mitigate, to the extent practicable, any harmful effect that is known to Organization of a use or disclosure of PHI by Organization in violation of the requirements of this Agreement, and report its mitigation activity back to the PDMP. Organization shall preserve evidence.
- 5.3. **Coordination.** The Organization will coordinate with the PDMP to determine specific actions that will be required for mitigation of the Breach, which may include notification to the individuals, entities or other authorities. Notifications, if any, will be made at the direction of the PDMP or as otherwise required by law.
- 5.4. **Incident costs.** The Organization shall be responsible for all costs associated with the incident involving PHI under its care, custody, or control that arises out of a material breach of the obligations under this Agreement.
6. **Subcontractor Obligations.** The Organization shall require that all of its subcontractors and agents are bound by the same restrictions and obligations contained herein, including but not limited to the obligation to implement reasonable and appropriate safeguards to protect the information, whenever PHI is made accessible to such subcontractors or agents.
7. **INDEMNIFICATION.** The Organization shall indemnify and hold harmless the PDMP and its respective officers, directors, employees, members, and contractors, against any third party claim, including costs and reasonable attorneys' fees, in which any of the Parties are named as a result of: the exercise or practice of any right granted hereunder; (b) the breach of any material term or condition of this Agreement by The Organization, The Organization employees, agents, contractors, or affiliates, or Authorized Users; (c) any access or use of the Application or Application Information by The Organization, any user of The Organization, The Organization Employees, agents, contractors, or affiliates, or Authorized Users; (d) any medical services, products or medication offered or sold by The Organization, The Organization Employees, agents, contractors, or affiliates, or Authorized Users; (e) any act or omission of negligence or willful misconduct of The Organization or its affiliates; or (f) violations of applicable law or the Requirements by The Organization, or Authorized Users, in connection with the performance of this Agreement, including access or use of PDMP Data.
8. **LIMITATIONS OF LIABILITY.** THE PDMP SHALL NOT BE LIABLE IN ANY AMOUNT FOR ANY DIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, LOSS OF GOODWILL OR BUSINESS PROFITS, WORK STOPPAGE, DATA LOSS, COMPUTER FAILURE OR MALFUNCTION, OR EXEMPLARY OR PUNITIVE DAMAGES, HOWEVER ARISING, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
9. **Compliance and HHS Access.** The Organization shall make available to the PDMP and to the Secretary of the U.S. Department of Health and Human Services any and all internal practices, documentation, books, and records related to the use and disclosure of PHI received from the PDMP, or created or received by the Organization on behalf of the PDMP. Such access is for the purpose of determining the PDMP's compliance with HIPAA, regulations promulgated by the United States Department of Health and Human Services, and any amendment thereto. Any non-compliance by The Organization with the terms of this Agreement or the privacy and security

regulations shall be a breach of this Agreement if The Organization knew of the breach and failed to take immediate and reasonable steps to cure the non-compliance. The Organization agrees that PDMP has the right to immediately terminate this Agreement and seek relief, including the right to contract for replacement service through another entity at the same cost, with The Organization responsible for paying any difference in cost, if PDMP determines that The Organization has violated a material term of the Agreement.

10. **AMENDMENT.** This agreement may be amended by adding, removing, or changing any provision herein at the sole discretion of the PDMP by providing notice to the Organization. Such amendment shall be effective upon receipt of notice by Organization as provided herein.
11. **TERM AND TERMINATION.**
 - 11.1. **Term.** This Agreement shall be effective upon the signature of both parties and shall remain in effect unless other termination actions as set forth herein are initiated.
 - 11.2. **Termination.** Either party may terminate this Agreement without cause upon ninety (90) days written notice to the other party. The PDMP may terminate this Agreement if at any time it determines that The Organization has violated a material term of this Agreement. In the alternative, the PDMP may, at its sole discretion, take any action provided in this Agreement, may suspend this Agreement, or may allow The Organization a reasonable period of time to cure before termination, when such action is determined to be in the PDMP's best interest. Upon suspension of this Agreement, the PDMP may, at its sole discretion, require The Organization to comply with the requirements of the above Ownership and Destruction of Information paragraph, in the same manner as though the agreement had been terminated. This paragraph shall in no way alter, amend, limit or change the terms and conditions in this Agreement as they relate to performance of this Agreement, and shall solely relate to violation of the terms of this Agreement.
 - 11.3. **Effect of Termination.** Upon termination or expiration of this Agreement, (a) use of the Application will immediately cease; and (b) all obligations concerning such Application will cease.
12. **Survivorship.** The obligations to safeguard the confidentiality, privacy and security of PHI imposed herein shall survive the termination of this Agreement.
13. **Injunctive Relief.** Notwithstanding any rights or remedies under this Agreement or provided by law, PDMP retains all rights to seek injunctive relief to prevent or stop the unauthorized use or disclosure of PHI by the Organization, any of its subcontractors or agents, or any third party who has received PHI from the Organization.
14. **Binding Effect.** Subject to the limitations on assignment provided elsewhere in this Agreement, the Agreement shall be binding on the parties and their successors, but neither party may assign the Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld. This Agreement will be binding upon and inure to the benefit of the respective successors and assigns of the PDMP and The Organization.

15. **Ambiguities, Strict Performance and Priorities.** Any ambiguities in this Agreement shall be resolved in favor of an interpretation that promotes compliance with Pennsylvania Act 191 of 2014, HIPAA, regulations promulgated thereunder and HITECH. Any conflicts in the security and privacy terms and conditions of this agreement with those in this Agreement shall be interpreted to favor of the terms and conditions that promote greater degree of security and privacy. The parties agree that any modifications to those laws shall modify the obligations of the parties hereunder without the need for formal amendment of the Agreement. This Agreement will be construed in accordance with the plain meaning of its language and neither for nor against the drafting party. The headings in this Agreement are for convenience only and will not affect the interpretation of any of the Agreement terms and conditions. If at any time either party fails to demand strict performance by the other party of any of the terms of this Agreement, such failure will not be construed as a waiver of any such term, and either party may at any time demand strict and complete performance by the other party.
16. **Notice.** For any notice under this Agreement to be effective the notice must be made in writing and sent to the address of the appropriate contact provided in the Agreement.
17. Notwithstanding section 5 of this Agreement, any notice to the other party pursuant to this Agreement shall be deemed provided if sent by first class United States mail, postage prepaid, as follows:

To PDMP:

Pennsylvania Prescription Drug Monitoring Program
Room 604, Health & Welfare Building
625 Forster Street
Harrisburg PA 17120-0701
Phone: 844-377-7367 Fax: 717-265-8222
Email: ra-dh-pdmp@pa.gov

To The Organization:

The Organization: _____
Attn: _____
Address: _____
City, State, Zip: _____
Phone: _____ **Fax:** _____
Email: _____

IN WITNESS WHEREOF, the parties hereto agree to the foregoing and have caused this Agreement to be executed as of the day and year last written below.

Subscribing Organization

Pennsylvania Prescription Drug Monitoring Program

Representative (Print name)

Representative (Print name)

Signature

Signature

Title

Title

Date

Date