Memorandum of Understanding Guidance
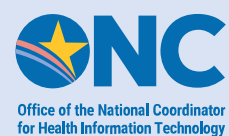
Advancing PDMP-EHR Integration Project
PDMP-EHR Integration Toolkit

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Purpose

This document translates lessons learned from the Office of the National Coordinator for Health Information Technology/Centers for Disease Control and Prevention (ONC/CDC) Advancing Prescription Drug Monitoring Program Electronic Health Record (PDMP-EHR) Integration Project into general Memorandum of Understanding (MOU) guidance. The MOU Guidance is one of several documents within the PDMP-EHR Integration Toolkit and provides key topics and points for consideration in developing PDMP-EHR data integration and sharing agreements. The intended audience for this document is State PDMP Administrators, to assist them in developing their PDMP-EHR Integration MOU document for review with health care systems in their state. This guidance is designed to be used alongside the MOU template found in the Appendix of this document.

Background

This document lists key topics often found in MOUs that require careful articulation to support streamlined data sharing between PDMPs and health care systems, institutions, or vendors. These topics are collected from conversations and work with State PDMP Administrators pursuing integration initiatives. Enhanced clarity in MOU language is often necessary because counsel for health care systems may be unfamiliar with the nuanced application of PDMP data access, use, and disclosure provisions.

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Sample MOU Areas of Consideration

Automatic versus Practitioner Initiated Queries. Some states require each query to be for an individual patient and to be practitioner initiated. Some states allow health care systems to generate automated queries to pull PDMP data for patients with appointments the following day.

Storage and Format of the PDMP data. Some states allow storage of the PDMP data in the patient's medical record within the EHR but may require the health care facility to meet state requirements regarding how and where data are stored. The permitted format of the stored PDMP data varies among states. At least one state only allows the storage of PDMP data in the medical record as a PDF attachment. Other states permit discrete PDMP data elements to be stored in the medical record, as approved by the State PDMP Administrator. Other states only allow a view of the PDMP data from within the EHR and prohibit actual storage within the EHR system.

Access/Disclosure of Stored PDMP Data. States should specify which disclosure laws and policies govern the stored PDMP data. Some states allow the access and disclosure rules that govern other data in the medical record to also govern the stored PDMP data. These states often deem the stored PDMP data to be a medical record or medical or health information. The stored PDMP data are subject to the state and federal privacy and confidentiality policies that govern other such records or information. It is also advisable for a state to clarify any PDMP disclosure restrictions that it wishes to

retain for the stored PDMP data. For example, proper retrieval of the information contained within a legal health record requires subpoenas or court orders for use in civil suits or other legal proceedings. Some states prohibit the State PDMP Administrator from disclosing PDMP data for use in certain civil proceedings. If a state wants to subject health care systems to a comparable disclosure restriction, the state should outline the circumstances in which disclosure is prohibited. Additionally, states should specify which login credentials clinicians may use to request PDMP data. Some states require clinicians to use their PDMP credentials, while others permit the use of EHR credentials.

Use of the Stored PDMP Data. Health care systems may be unaware of the numerous differences in data governance between PDMP laws and policies and other health care laws and policies. These entities sometimes assume that they and their clinicians can use PDMP data stored in the medical record as they would other information in the record. For example, Chief Medical Officers and Medical Directors sometimes ask if their institutions can include PDMP data with other patient data maintained within their EHR systems to conduct analyses of patient use and prescribing behaviors. Whether such data use is permitted varies by state. States sometimes prevent the manipulation of the PDMP data. Other states may authorize the State PDMP Administrator to permit the use of discrete PDMP data elements for clinical decision support or patient care purposes on an individual case basis.

Data Interpretations/Summaries. States generally allow health care clinicians to review and use interpretations or summaries of PDMP data, such as risk scores. At least one state permits storage in the medical record of an interpretation or summary with, but not in lieu of, PDMP data. However, some states have policies or legal opinions that a clinician's review of such an interpretation or summary does not by itself comply with a state's mandate to review a patient's PDMP data. A state should clarify whether a clinician's review of a PDMP data interpretation or summary satisfies the state's mandated PDMP use provision.

Log of PDMP Data Requests. States generally specify the type of information that health care systems must maintain regarding who has requested PDMP data and when each request was made. The entities often have to provide the information upon request by the State PDMP Administrator. Sometimes states also require reporting to the State PDMP Administrator regularly, such as monthly or quarterly.

Notification of Breaches. States often outline a process by which health care systems have to notify the State PDMP Administrator of breaches that may impact the receipt and/or storage of PDMP data in the EHR system. This process usually details notification procedures and the state's authority to suspend access by an individual clinician or the EHR system's connection to the PDMP pending query. In addition, the process usually indicates that the state, if necessary, will terminate the clinician's access or the EHR system's connection.

Required Education and Monitoring. States often require health care institutions to educate their clinicians about the proper access, disclosure, and use of the PDMP data. Additionally, states require institutions to properly monitor their clinicians to ensure the clinicians' compliance with all relevant laws, regulations, and policies. States should require institutions to document that their clinicians have received the proper instruction so that documentation is readily available to the State PDMP Administrator upon request.

Required State View of Integrated PDMP Data Display. States need to confirm that the integrated PDMP data display complies with state statutes, regulations, and implementation requirements. If states have the authority to view the integration display or expect to take other reasonable compliance monitoring measures during the integration testing and approval phases, the state should include those requirements in the MOU. States should also include the authority to take

reasonable measures to investigate complaints or information received regarding the EHR system's possible noncompliance.

Appendix

Sample MOU Template

Disclaimer

A sample MOU template is provided below. Readers should consider consulting with an attorney employed by or contracted by their department or agency for assistance in crafting MOUs or other agreements to permit integration between PDMPs and health IT systems while complying with relevant legal and regulatory requirements. This sample MOU is a working draft that does not reflect any specific state or approved MOU. The sample template is a composite of multiple MOUs from different states and incorporates common themes that may be helpful to consider when drafting state and health IT integration agreements.

Template

This data sharing agreement is entered into on _____ (Effective Date) by and between the **[insert name of appropriate state agency]** (Agency) and _____, a company organized under the laws of or authorized to do business in the State of **[insert name of state]** (Participant).

SECTION 1. PURPOSE.
This agreement is intended to provide a secure and efficient method by which health care professionals may access and use PDMP data through Participant's electronic health record system (EHR).

SECTION 2. DEFINITIONS.
For the purposes of this Agreement, the following words and phrases shall have the meanings given them in this Section.

(a) "Applicable laws and standards" means all applicable state and federal laws, statutes, acts, regulations, rules, standards, policies, guidelines, conditions and judicial or administrative rulings, orders, or opinions. Such laws and standards include, but are not limited to: **[insert citations to appropriate state statutes]**; the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (Aug. 21, 1996), 45 C.F.R. parts 160 and 164 (HIPAA Privacy and Security Rules); the federal confidentiality law and regulations, 42 U.S.C. § 290dd-2, 42 C.F.R. Part 2; standards of the Centers for Medicare and Medicaid Services Conditions of Participation; and standards of accrediting agencies such as the Joint Commission on Accreditation of Health care Organizations.

(b) "Health care" means health care as defined in **[insert citation to §160.103 of HIPAA or applicable state definition].**

(c) "Health care professional" means an individual licensed by the State of **[insert name of state]** to provide health care who is employed by or under contract with Participant to provide such care on behalf of Participant.

(d) "Health record" means **[OPTION 1: the record of health care provided to a patient by all health care professionals involved in the patient's care that is designed to be accessed by all such professionals and the patient.] [OPTION 2: insert citation to applicable state definition.]**

(e) "Patient" means an individual who (1) has received or is receiving health care from a health care professional or (2) who seeks health care from a health care professional and for whom the professional affirmatively acts to provide such care, or agrees to do so.

(f) "PDMP" means the prescription drug monitoring program established and operated pursuant to **[insert citation to state PDMP statute and regulations].**

(g) "PDMP data" means data that are collected, maintained, managed and disclosed by the PDMP.

SECTION 3. GRANT OF RIGHT TO ACCESS THE PDMP.
(a) The Agency grants to Participant a nonexclusive, nontransferable, nonassignable, nonsub-licensable, and limited right to access the PDMP and make PDMP data available through Participant's EHR. Participant shall maintain a secure environment in compliance with this Agreement and applicable laws and standards to connect to the PDMP and to permit access, use and disclosure of PDMP data through Participant's EHR.

(b) Participant shall be responsible for all costs associated with the installation, modification and maintenance of hardware and software necessary to maintain a secure environment. The Agency shall not levy any service fees or charges for access, use and disclosure of PDMP data pursuant to this Agreement.

SECTION 4. ACCESS, USE, AND DISCLOSURE OF PDMP DATA IN EHR.
(a) Participant shall only make PDMP data available to its designated non-health care employees, contractors or agents and health care professionals.

(b) Designated non-health care employees, contractors, or agents:

(i) May access, use, and disclose PDMP data only as necessary to facilitate Participant's compliance with this Agreement and applicable laws and standards and

(ii) Shall comply with the terms and conditions of this Agreement and applicable laws and standards, to the same extent Participant is required to comply.

(c) Health care professionals [OPTION 1: may use EHR credentials provided by Participant to request PDMP data.][OPTION 2: shall use credentials provided by the PDMP to request PDMP data.] Health care professionals shall only request PDMP data as required or allowed by applicable laws and standards and shall submit such requests by one of the following methods:

(i) A health care practitioner may initiate a PDMP request for a single patient or

(ii) Participant may submit a single, automated request for the PDMP data of patients with appointments at Participant's location the next business day.

(d) Participant may store the PDMP data in a patient's health record in a format authorized by the Agency. PDMP data in a health record may be stored for the same duration as other patient information stored in that record. At no time during storage shall Participant alter, edit, or modify the PDMP data. As authorized by the Agency, Participant may copy or incorporate the PDMP data into a searchable computer program or database for clinical decision support or health care operations as defined by **[insert citation to §164.501 of HIPAA or appropriate state definition of "health care operations"]**. Summaries or interpretations of the PDMP data may be stored with but not in lieu of the PDMP data. Except as authorized by the Agency, health care professionals shall not use summaries or interpretations in lieu of PDMP data to comply with applicable laws and standards.

(e) PDMP data stored in a patient's health record shall be disclosed on the same terms and conditions as other patient information stored in that record. **[Insert any state requirements or restrictions on how or to whom Participant may disclose the PDMP data.]**

SECTION 5. MANAGEMENT AND MONITORING OF PDMP DATA IN EHR.
(a) Participant shall maintain, and provide to the Agency upon its request, a written policy for the management of PDMP data access, use, and disclosure. The policy shall contain a description of Participant's internal procedures for:

(i) Educating designated non-health care employees, contractors or agents and health care professionals on access, use, and disclosure of PDMP data in compliance with this Agreement and applicable laws and standards;

(ii) Imposing discipline or sanctions for non-compliant access, use or disclosure of PDMP data;

(iii) Auditing the access, use or disclosure of PDMP data by designated non-health care employees, contractors or agents and health care professionals and

(iv) Detecting access, use or disclosure by unauthorized individuals or entities.

(b) Participant shall make all reasonable changes to the policy deemed necessary by the Agency for Participant to maintain a secure environment in compliance with Section 3.

(c) Participant shall provide to the Agency all information and reports that the Agency deems necessary to monitor and investigate compliance with this Agreement and applicable laws and standards. Participant shall provide the information and reports as requested by, or on a frequency established by, the Agency.

(d) Each designated non-health care employee, contractor or agent and health care professional shall sign a statement acknowledging the responsibility of the employee, contractor, agent or professional to access, use, and disclose PDMP data in compliance with this Agreement and applicable laws and standards. Participant shall provide to the Agency upon its request a copy of the signed statement of a specified employee, contractor, agent or professional.

(e) Participant shall notify the Agency in writing if it detects any access, use or disclosure of PDMP data by a designated non-health care employee, contractor or agent or health care professional that it has reason to believe is seriously non-compliant with this Agreement or applicable laws and standards. Serious non-compliance means access, use or disclosure of PDMP data that:

(i) compromises the confidentiality of the PDMP data,

(ii) adversely affects the operation of the PDMP or

(iii) adversely affects the legal liability of the Agency.

The notice shall be without unreasonable delay and in no case later than **[insert X days]** following detection of the possibly serious non-compliance. The notice shall include:

(i) A brief description of the possibly serious non-compliance,

(ii) A description of the PDMP data elements involved in the possibly serious non-compliance and

(iii) Steps Participant is taking to investigate the possibly serious non-compliance.

Participant shall provide to the Agency investigative findings that:

(i) Indicate whether serious non-compliant access, use or disclosure occurred,

(ii) Outline steps Participant is taking to mitigate any harm, and

(iii) Identify measures being implemented to prevent further instances of serious non-compliance.

(f) Upon receipt of notice pursuant to subsection (e), the Agency shall temporarily suspend the access to PDMP data of a designated non-health care employee, contractor or agent or health care professional under investigation by Participant for possibly serious non-compliance. Upon receipt of findings pursuant to subsection (e), the Agency shall terminate the access to PDMP data of the employee, contractor, or agent or professional found to be in serious non-compliance. Participant shall take all reasonable steps to prevent access, use or disclosure of PDMP data by the employee, contractor, agent or professional whose access has been temporarily suspended or terminated.

(g) If the Agency discovers, other than by Participant's notice, serious non-compliant access, use or disclosure by a designated non-health care employee, contractor or agent or health care professional, the Agency shall terminate the access to PDMP data of that employee, contractor, agent or professional. The Agency shall notify Participant in writing of its discovery of the serious non-compliance and the termination of access to PDMP data. The notice shall be without unreasonable delay and in no case later than **[insert X days]** following the discovery of the serious non-compliance.

(h) Participant shall notify the Agency in writing if it detects access, use or disclosure by unauthorized individuals or entities. The notice shall be without unreasonable delay and in no case later than **[insert X days]** following detection of the unauthorized access, use or disclosure.

(i) Participant shall notify the Agency in writing if Participant discovers that it has failed to maintain a secure environment as required by Section 3. The notice shall be without unreasonable delay and in no case later than **[insert X days]** following discovery of the failure. Upon receipt of notice, the Agency shall temporarily suspend Participant's access to the PDMP. If the Agency discovers, other than by Participant's notice, Participant's failure to maintain a secure environment as required by Section 3, the Agency shall temporarily suspend Participant's access to the PDMP. The Agency shall notify Participant in writing of the Agency's discovery of the failure and the temporary suspension of access. Participant shall take, at Participant's expense, all reasonable steps identified by the Agency to cure the failure. Participant's inability to restore a secure environment within **[insert X days]** after sending the Agency notice or receiving notice from the Agency pursuant to this subsection may result in the Agency's termination of this Agreement pursuant to Section 7.

SECTION 6. TERM OF AGREEMENT.
This Agreement will commence on the Effective Date and will remain in effect for an initial term of **[insert X years].** Thereafter, this Agreement shall automatically renew for successive terms of one (1) year, unless either the Agency or Participant provides the other with written notice of non-renewal not less than **[insert X days]** prior to the expiration date of the then-current term.

SECTION 7. TERMINATION OF AGREEMENT AND EFFECT.
(a) Either the Agency or Participant shall have the right to immediately terminate this Agreement to comply with any change in applicable laws or standards, or interpretations thereof.

(b) Either the Agency or Participant, upon giving written notice to the other, may terminate this Agreement if the other breaches any material provision of this Agreement and fails to cure such breach, or fails to commence and continuously maintain substantial efforts to cure, within **[insert X days]** after receipt of written notice from the other.

(c) Either the Agency or Participant, upon **[insert X days]** prior written notice to the other, may terminate this Agreement without cause.

(d) Upon termination, Participant's right to access the PDMP under Section 3 shall immediately cease. All PDMP data accessed by Participant pursuant to Section 3 shall continue to be stored, accessed, used, and disclosed pursuant to the terms and conditions of this Agreement.

SECTION 8. INDEMNIFICATION.
Participant shall defend, indemnify and hold harmless the Agency from and against any liability, claim, action, loss, damage, or expenses, including court costs and reasonable attorneys' fees, based on any third-party claims arising out of, or relating to, Participant's access, storage, use or disclosure of PDMP data in violation of this Agreement.

SECTION 9. WARRANTIES AND LIMITATION OF LIABILITY.
(a) The Agency makes no warranty that access to the PDMP pursuant to Section 3 will be error-free or uninterrupted or that all errors will be corrected. No advice or information, whether oral or written, obtained from the Agency or elsewhere will create any warranty not expressly stated in this Agreement.

(b) The Agency makes no warranty and assumes no liability related to the accuracy, currency, or completeness of the PDMP data that Participant accesses pursuant to Section 3.

(c) Participant warrants to the best of its knowledge that neither it, nor any of its designated non-health care employees, contractors or agents or health care professionals, have been convicted of or otherwise legally found in violation of applicable laws and standards. Participant shall inform the Agency if at any point during the term of this Agreement such a conviction or legal ruling occurs.

(d) Neither the Agency nor Participant shall be liable to the other or to any third party for any incidental, indirect, special, punitive, exemplary, or consequential damages arising out of or in connection with this Agreement.

SECTION 10. GENERAL.

(a) This Agreement shall be binding on the Agency and Participant, their successors and permitted assigns. Neither the Agency nor Participant shall assign or transfer this Agreement, or any part thereof, without the prior written consent of the other.

(b) This Agreement does not create in any natural person, corporation, partnership, or organization any benefits or rights and this Agreement will be effective only as to the Agency and Participant, and their successors and assigns.

(c) The Agency and Participant are independent contractors. This Agreement shall not establish a partnership, joint venture, agency or any other relationship between the Agency and Participant.

(d) This Agreement shall be governed by and construed in accordance with the laws of the State of **[insert name of state]** without reference to or application of conflict of laws rules or principles.

(e) This Agreement sets forth the entire and only Agreement between the Agency and Participant related to the subject matter herein. Any representation, promise or condition, whether oral or written, not incorporated herein shall not be binding upon the Agency or Participant.

(f) This Agreement may be modified, altered, or amended only by express written consent of the Agency and Participant.

(g) Notice required by this Agreement shall be delivered by (1) certified mail, return receipt requested; (2) first-class mail, postage prepaid; (3) email transmission; (4) facsimile transmission or (5) express or overnight carrier. Notice shall be deemed effective when the sender receives delivery confirmation of the certified mail, email or fax transmission or carrier or **[insert X days]** after the postmark of any notice placed into the U.S. mail.

(h) Neither the Agency nor Participant shall be liable for any failure or delay in performing its obligations under this Agreement beyond its reasonable control, including war, terrorism, riot, acts of God or governmental action.

(i) Nothing in this Agreement shall be construed to restrict the right of the Agency or Participant to pursue all remedies available under law for damages or other relief arising from acts or omissions of the other related to this Agreement, or to limit any rights, immunities, or defenses to which the Agency or Participant may be entitled under applicable laws and standards. No failure or delay by the Agency or Participant in exercising its rights under this Agreement shall operate as a waiver of such rights and no waiver of any right shall constitute a waiver of any prior, concurrent, or subsequent right.

(j) This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

(k) The headings in this Agreement are for the convenience of reference only and have no legal effect.

(l) If for any reason a court of competent jurisdiction finds any provision of this Agreement invalid or unenforceable, that provision of the Agreement will be enforced to the maximum extent permissible, and the other provisions of this Agreement will remain in full force and effect.