

MEMORANDUM OF UNDERSTANDING

Between the

**Kentucky Cabinet for Health and Family Services
275 East Main Street
Frankfort, KY 40621**

and

**The Ohio State Board of Pharmacy
77 South High Street, Room 1702
Columbus, Ohio 43215**

PURPOSE:

The purpose of this Memorandum of Understanding is to establish the terms under which the Kentucky Cabinet for Health and Family Services (CHFS) and the Ohio State Board of Pharmacy (OSBP) agree to implement an automated process to enable sharing of data between the states' respective Prescription Monitoring Programs (PMPs). This automated PMP data exchange capability will be implemented for a selected subset of authorized prescriber and pharmacist users in each state and will utilize a Prescription Monitoring Information Exchange (PMIX) Hub server installed at the OSBP to facilitate the data exchange.

BACKGROUND:

The abuse and diversion of controlled pharmaceutical substances is a major problem impacting public health and safety. Several states have implemented PMPs to provide for monitoring and reporting controlled substances dispensed within the state. Kentucky's PMP is the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system and Ohio's PMP is the Ohio Automated Rx Reporting System (OARRS). While several states (including Kentucky and Ohio) currently allow certain authorized entities from other states to establish accounts and access their PMP data, there is currently no automated system to allow these states to provide an authorized end user with one report containing the PMP data from multiple states.

The U.S. Department of Justice, through the Bureau of Justice Assistance and in association with the IJIS Institute, is sponsoring the Prescription Monitoring Information Exchange project to facilitate interstate exchange of PMP data using a central PMIX Hub server structure that will pass requests and responses between state PMP data sharing partners. The IJIS Institute (formerly the Integrated Justice Information Systems Institute) was formed in 2001, to leverage the expertise of industry and assist justice and public safety agencies in sharing information. This PMIX Hub server structure is anticipated to be far more cost effective than each participating state establishing a point-to-point link with each exchange partner state.

As a result of Phase III of the PMIX project, the PMIX Hub server was procured and installed in a secure location at the OSBP. Implementation of the capability to exchange test PMP data between KASPER and OARRS is scheduled to be completed in September 2009. The next phase of the PMIX project is to be an Operational Level 1 implementation intended to provide the ability to utilize the PMIX HUB server to exchange actual PMP data between a subset of authorized prescriber and pharmacist users of the KASPER and OARRS systems.

AGREEMENT:

WHEREAS, pursuant to Kentucky Revised Statute (KRS) 218A.202 (6), CHFS is authorized to provide access to KASPER data, to certain authorized persons and entities; and

WHEREAS, pursuant to KRS 218A.245, CHFS is authorized to enter into reciprocal agreements, with other states, to share prescription drug monitoring information if the other state's prescription drug monitoring program is compatible with the program in Kentucky; and

WHEREAS, OSBP is authorized to provide access to OARRS data to certain authorized entities from other states; and

WHEREAS, OSBP has a prescription drug monitoring program that is compatible with the program in Kentucky; and

WHEREAS, CHFS and OSBP both maintain databases that contain data regarding prescriptions filled by pharmacies licensed by their respective states; and

WHEREAS, CHFS and OSBP desire to disclose information from their two databases to prevent the improper or illegal use of controlled substance prescriptions by people who use dispensers in both states; and

WHEREAS, CHFS and OSBP desire to define and describe the circumstances of their disclosure of information to authorized end users of their two Prescription Monitoring Programs utilizing the secure PMIX Hub server located at the OSBP;

NOW, THEREFORE, in consideration of the aforesaid premises, the parties hereby mutually agree to the following:

1. TERM and TERMINATION. This Memorandum of Understanding shall be effective upon the date of the last signatory hereto and shall terminate one year from such effective date, unless previously terminated pursuant to the terms herein. The annual term of this Memorandum of Understanding may be renewed, upon the mutual written consent of both parties. Either party may terminate this Memorandum of Understanding upon ten days written notice served on the other party or immediately for cause.
2. NOTICE. All notices or other communications required or permitted to be given under this Memorandum of Understanding shall be in writing and shall be deemed to have been duly given if delivered personally in hand, by telephonic facsimile with simultaneous regular mail, or mailed via certified mail, return receipt requested, postage prepaid on the date posted, and addressed to the parties at the addresses set forth below:

Kentucky Cabinet for Health and Family Services
Division of Audits and Investigations
275 East Main Street, 5E-D
Frankfort, KY 40621
Attention: Lee A. Guice

The Ohio State Board of Pharmacy
77 South High Street, Room 1702
Columbus, Ohio 43215
Attention: Danna Droz

3. TERMS OF PARTICIPATION. The parties mutually agree that their disclosure of information shall be according to the following terms:
- a. Information to be Disclosed. The information to be disclosed shall consist of PMP prescription record data that is normally provided upon request to an authorized prescriber or pharmacist under the current applicable statutes and regulations for the state PMP disclosing the data. Attachment A - Exchange Data Elements contains a list of PMP data elements that each state will send for a report request and for a report response.
 - b. Data Usage. The data will be provided only to authorized prescriber and pharmacist users of the requesting state's PMP for the purposes allowable, and with the documented restrictions that are provided under the requesting state's applicable statutes and regulations and the disclosing state's applicable statutes and regulations. The data shall not be used for any other purpose and shall not be released or disclosed to any other person or entity, except for an official representative of a state PMP party to this MOU for the purpose of validation of the accuracy of the data exchange with an official representative of the other state PMP party to this MOU. In addition, each party agrees that at the time a request is made they will require the authorized prescriber or pharmacist to certify they will adhere to applicable laws and restrictions on the use and/or disclosure of data received from the disclosing state PMP.
 - c. Privacy and Security Safeguards. All Web services calls between the state PMPs and the Hub server will utilize the standard Secure Socket Layer (SSL) data encryption methodology. In addition, all Protected Health Information will further be encrypted using the Advanced Encryption Standard (AES) Public Key Infrastructure (PKI) data encryption methodology. The PMIX Hub server will only be able to decrypt the data used for message routing and control that is encrypted using the SSL methodology. This dual encryption design is intended to provide an industry standard secure data transmission method and to ensure that there will be no visibility at the PMIX Hub server level into the PHI data including individual prescriber, dispenser or patient data.
 - d. Authorization of Users. Each party agrees that prior to granting a prescriber or pharmacist authorization to access the data in their respective PMP system, that their PMP officials will verify the identity and credentials of the user. This verification process will include a review of the applicant's driver's license data, professional license, and prescriber Drug Enforcement Administration license (if applicable). Authorized users will include only selected physicians and pharmacists.
 - e. Retention of Data. Each party agrees that all PMP prescription record data exchanged through the PMIX Hub server will be used only to prepare the standard patient report in the current format utilized by the state requesting the

data. The prescription record data will not be stored in the requesting state's PMP data base or any other database, except that the requesting state may retain the resulting PMP patient report image based upon the following report image data retention guidelines.

Kentucky retains patient report images for a period of two calendar years plus the current calendar year in online storage where the report images remain available to the original report requestor. After removal from online storage the report images are retained indefinitely in a restricted database that is available only to KASPER staff.

Ohio retains patient report images for a period of 30 days in online storage where the report images remain available to the original report requestor. After removal from online storage, the report images are retained indefinitely in a restricted database that is available only to OARRS staff.

- f. The parties agree to notify the other party, in writing, of any use and/or disclosure of the Protected Health Information that involves the other party's Protected Health Information that is not permitted or required by this Memorandum of Understanding of which the requesting party becomes aware within five (5) business days of the requesting party's discovery of such unauthorized use and/or disclosure.
 - g. The requesting party agrees to notify the other party within five (5) business days of any security incident involving the successful unauthorized access, use, disclosure, modification, or destruction of the other party's electronic Protected Health Information due to interference with electronic systems operations.
 - h. The requesting party agrees to notify the other party with five (5) business days of discovery of any breach of unsecured Protected Health Information that involves the other party's Protected Health Information as the terms "breach" and "unsecured Protected Health Information" are defined in 45 CFR 164.402 and any subsequent regulations and/or guidance from the Secretary of DHHS. Notice of such a breach shall include the identification of each individual whose unsecured protected health information has been, or is reasonably believed by the requesting party to have been, accessed, acquired, or disclosed during such breach. The requesting party further agrees to make available in a reasonable time and manner any information needed by the other party to respond to individuals' inquiries regarding said breach.
 - i. The parties agree that OSBP is not a covered entity nor a business associate under the Health Insurance Portability and Accountability Act and that OARRS operates pursuant to the exemption of 45 CFR 164.512(a). Therefore, OARRS is not bound by the notifications required by the American Recovery and Reinvestment Act of 2009.
4. LIMITED LIABILITY. The parties will not waive the intent to assert available limitations and immunities pursuant to that state's applicable law in all cases.

5. LIABILITY. Each agency shall assume the responsibility and liability for acts and omissions of its own officers, agents, or employees in connection with the performance of their official duties. For tort liability purposes, no participating agency shall be considered the agent of the other participating agencies. Each participating agency shall be liable (if at all) only for the torts of its own officers, agents, or employees that occur within the scope of their official duties. The parties expressly agree that no provision of this agreement is in any way intended to constitute a waiver, by either party, of any immunity from suit that either party may have by operation of law.
6. FORCE MAJEURE. No party shall be deemed to be in violation of this Memorandum of Understanding if it is prevented from performing any of its obligations hereunder due to strikes, failure of public transportation, civil or military authority, act of public enemy, accidents, fires, explosions, or acts of God including, without limitation, earthquakes, floods, winds, or storms. In such an event the intervening cause must not be through the fault of the party asserting such an excuse, and the excused party is obligated to promptly perform in accordance with the terms of the Memorandum of Understanding after the intervening cause ceases.
7. INDEMNIFICATION. No party waives any right or defense to indemnification that may exist in law or equity.
8. INDEPENDENT PUBLIC AGENCIES. The parties are associated with each other only for the purpose and to the extent set forth in this Memorandum of Understanding, and in respect to performance of services pursuant to this Memorandum of Understanding, each party is and shall be a public agency separate and distinct from the other parties and, subject only to the terms of this Memorandum of Understanding, shall have the sole right to supervise, manage, operate, control, and direct performance of the details incident to its duties under this Memorandum of Understanding. Nothing contained in this Memorandum of Understanding shall be deemed or construed to create a partnership or joint venture, to create relationships of an employer-employee or principal-agent, or to otherwise create any liability of one agency whatsoever with respect to the indebtedness, liabilities, and obligations of the other agencies or any other parties.
9. CONFIDENTIALITY. Each party shall keep confidential all information, in whatever form, produced, prepared, observed, or received by that party to the extent that such information is confidential by law or otherwise required by this Memorandum of Understanding; except that the information may be provided to the authorized requestor (end user) of the PMP for the purposes allowable, and with the documented restrictions that are provided under each state's applicable statutes and regulations.
10. COSTS. Each party shall bear responsibility for its own costs or expenses incurred in the performance of their obligations herein.
11. AMENDMENTS AND ASSIGNMENT. The terms and conditions of this Memorandum of Understanding may only be amended by mutual written consent of both parties and no party shall assign its respective rights or obligations under this Memorandum of Understanding without prior written consent of the other party.

12. PROPER AUTHORITY. The parties hereto represent and warrant that the person executing this Memorandum of Understanding on behalf of each party has full power and authority to enter into this Memorandum of Understanding and that the parties are authorized by law to perform the services set forth in paragraph (3).

IN WITNESS WHEREOF, the parties hereto have caused this Memorandum of Understanding to be signed and intend to be legally bound thereby.

By: Janie Miller

Date: 9/28/09

Janie Miller, Secretary
Kentucky Cabinet for Health and Family Services

By: Brian Judy

Date: 9/14/09

Brian Judy, Office of Legal Services
Kentucky Cabinet for Health and Family Services

By: William T. Winsley

Date: 9-4-2009

William T. Winsley, Executive Director
The Ohio State Board of Pharmacy

Attachment A – PMP Exchange Data Elements

PMP Data Elements for an Exchange Request

Data Element	Provided by KY	Provided by Ohio
Patient first name	Yes	Yes
Patient last name	Yes	Yes
Patient identifier (Social Security #, Driver's License #, or other identifier provided by report requestor)	Yes	No
Patient date of birth	Yes	Yes
Patient street address	Yes	If available
Patient city	Yes	If available
Patient state	Yes	If available
Patient zip code	Yes	Yes
Report request start date	Yes	Yes
Report request end date	Yes	Yes
Requestor Name	Yes	Yes
Requestor ID #	Yes	Yes
Requestor Profession (Prescriber or Pharmacist)	Yes	Yes
Request Date	Yes	Yes

PMP Data Elements for an Exchange Response

Data Element	Provided by KY	Provided by Ohio
Patient first name	Yes	Yes
Patient last name	Yes	Yes
<i>The following data elements are provided for each prescription record based on the data reported by the dispenser.</i>		
Patient date of birth	Yes	Yes
Patient street address	No	Yes
Drug name	Yes	Yes
Drug quantity	Yes	Yes
Drug strength	Yes	Yes
Drug days supply	Yes	Yes
Date written	No	Yes
Date dispensed	Yes	Yes
Prescriber name	Yes	Yes
Prescriber city	Yes	Yes
Dispenser name	Yes	Yes
Dispenser city	Yes	Yes