

ALLIANCE OF STATES WITH PRESCRIPTION MONITORING PROGRAMS
AND
BRANDIES UNIVERSITY'S TRAINING AND TECHNICAL ASSISTANCE CENTER

Memorandum of Understanding

Writing Guide for States with Prescription Monitoring Programs

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Introduction

This guide was created to assist states that have authorization to operate Prescription Monitoring Programs (PMP) and who wish to enter into interstate data exchange Memorandum of Understanding (MOU) with other states in developing the necessary legal framework in which to do so. As the number of unintentional deaths due to prescription drug overdoses continues to increase, there is more and more focus placed on sharing PMP data across state lines. The suggestions and example solutions contained herein are intended to provide this framework for agreements and enable interstate data exchange.

This guide was created in consultation with the Hon. Lee A. Guice¹ for the Alliance of States with Prescription Monitoring Programs and Brandies University's Training and Technical Assistance Center, and was funded by the Bureau of Justice Assistance.

MOUs must undergo review and be approved by each states' approval process. The Alliance strongly suggests that the relevant Fiscal and Legal offices be included in the review before any MOU is executed.

How to Use the Guide

As seen in the table of contents, the guide is divided into sections commonly found in Memoranda of Understanding. Although there can be variations on section names and document format, these sections outline and delineate each states' purpose and responsibilities when sharing PMP data across state borders.

Each following section contains a brief explanation as to the purpose for the section, questions that should be considered when drafting an MOU, and sample language.

The table of contents can be used as an outline to build your agency/state's MOU. As you go through each section and determine your specific needs, a narrative or listing will naturally develop. These items can be shared with your partnering state to begin discussions.

As an initial matter, it is important to determine your state's statutory/regulatory requirements and restrictions concerning both the PMP data and procurement issues. Each state may have certain restrictions on how the data is to be used and what user categories is authorized access. There should also be clear statutory authority established for sharing data across state lines (your agency's office of counsel can determine if this is in question). Your state's procurement statutes may have requirements as to the type of agreement required when entering into an agreement with a governmental agency where there is no financial obligation. You should also determine what type of agreement will be required if and when financial obligations should arise.

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MOU SECTION 1: Introduction

Usually, this portion is a narrative giving background information on the purpose of entering into an MOU. This section often contains the underlying policy statement for each state's PMP. There are a wide variety of styles and lengths for each narrative and this often depends upon the usual practice within your agency.

Questions and Responses to Consider:

What information should be included?

- Date PMP legislation became effective.
- Date of implementation.
- The controlled substance schedules that are tracked/collected
- The state agency that administers the PMP
- The public health and safety policy for each PMP and the advantages of interstate sharing.
- The intent of each state to exchange or share PMP data.

Does my agency have standard language used for PMP presentations or press releases?

If so, take advantage of that language and incorporate it into the introduction section.

Sample Language

This agreement between the state of (NAME OF STATE "A") and the state of (NAME OF STATE "B") is to establish the terms and conditions by which each party may exchange/share Prescription Monitoring Program (PMP) reports in a secure manner. Data from both State A and State B establish that citizens often cross state borders to procure prescriptions or the controlled substances themselves. Interstate data exchange gives prescribers and dispensers better clinical information with which to make health care decisions. The convenience of having the data available in a single report will encourage more prescribers to utilize PMP data and therefore be in a better position to make appropriate clinical treatment decisions and to assist in alleviating prescription drug abuse and diversion.

Recent studies show that unintentional death from prescription drug overdose is now the second highest cause of accidental deaths in State A. State A's corrections population has increased 48% over the last 5 years, with the majority of convictions involving illegal possession or diversion of drugs.

MOU SECTION 2: Purpose

This is another short section of an MOU wherein the parties have an opportunity to set out the public health, regulatory, and law enforcement policy underlying their particular PMP and the need to share data across state lines in order to achieve that purpose. There are different styles for this section of an MOU. Some utilize a short narrative set out in a section named “Recitals.” Others set out the language in a more formal manner using “Whereas” statements.

Questions and Responses to Consider:

Which style or format is used in my state for contracts or agreements?

This question can be answered by your state’s procurement personnel or legal staff as it is usually a matter of tradition or policy rather than law.

Will this document serve more than one purpose?

If you answer yes then choose which policy statements you would like to include. You may want to consult other PMP publications or press releases produced by your state.

Are there items which must be included by state or federal (grant-related) law?

SAMPLE LANGUAGE

Example of a short narrative found in a “Recitals” section with little public policy or intention added:

The purpose of a PMP is to provide health care providers and law enforcement officials with more information to assist in completing their responsibilities. Each PMP collects data on the dispensing of controlled substances. The systems collect data fields as included in the ASAP Standard for Prescription Monitoring Programs - 1997 or more recent version – as published by the American Society for Automation of Pharmacy. State A tracks Schedules II thru IV and State B tracks Schedules II thru V plus Soma. Both State A and State B recognize their citizens are not bound by state borders when visiting a doctor or a pharmacy to procure a prescription drug. In order to provide health care, regulatory and law enforcement professionals with the whole history of an individual, interstate data sharing is essential.

Example of a traditional purpose statement.

Whereas, State A and State B share many miles of state border; and,
Whereas, data collected by State B and State A prove that citizens from both State A and State B cross freely between to procure prescription drugs, and,
Whereas, State A and State B wish to do provide their citizens with the best health care while preventing abuse and diversion of prescription drug; and

Now therefore, State A and State B agree to the following:

MOU SECTION 3: Terms of Agreement

This section sets out terms which will fulfill the stated purpose of entering into the MOU. The section basically identifies items each state can provide and how they will be responsible for those items during the term of the agreement. This portion will have several subsections. Some of the items included here are usually the controlled substances schedules each state collects and reports on; whether the parties wish to exchange all data or just corresponding data; who the authorized users are and how they are authenticated and verified by each state; retention of data by each state; system breach notification requirements; and, which states' law governs use of data by an authorized user. The various subsections will be considered separately below. This section of the MOU is likely to be the longest and the most negotiated portion. It will be very helpful in your discussions with the other states to have determined as many details as possible. Knowing what "deal breakers" exist is also helpful, as you won't need to spend resources trying to negotiate a point that cannot be compromised or won.

Questions and Responses to Consider:

A. Data Reported

My state collects data on schedules II, III, and IV medications dispensed within the state. Our PMP collects data fields as listed in the ASAP version 4.0 (2007). The other state collects data on schedules II thru V plus Soma. The other PMP collects data fields as listed in the ASAP version 4.1 (2010)

What information can I provide to the other state/party?

What information can I receive from the other state/party?

Until PMPs standardize the ASAP version and the fields which are required to be reported, this will be a reoccurring concern. States must be vigilant in knowing the answers to these questions.

SAMPLE LANGUAGE

The requesting state collects data on Schedules II, III and IV only. The disclosing state collects Schedules II through V plus Soma. Each state agrees to disclose all data collected upon receiving a report request but will only show the data fields currently viewed on my state's PMP reports.

OR

Each state agrees to provide only corresponding data upon receiving a report request.

B. Data Usage

Does the other state have a different or additional category of authorized users? If so, how does each state want the differences to be recognized and addressed?

Does each state's system delineate users to the extent that some are allowed but not others?

The categories of authorized users mentioned most often in these discussions are practitioners, pharmacists, regulatory boards and law enforcement. Almost all states allow all four types of users to access the data but the circumstances under which data may be shared can vary. For example, your state allows law enforcement investigators to access the data if they have an open case, but the other state requires law enforcement investigators to have a subpoena or court order. You will need to clarify in the MOU how this difference will affect the sharing of data.

SAMPLE LANGUAGE

Authorized users include licensed medical doctors with a valid DEA number allowing for prescribing of controlled substances. The licensee must have no restrictions on their prescriptive authority. Verification of these requirements is the responsibility of the requesting state.

How do you verify authorized users?

Is it important that the other state have a similar process?

Is this a deal breaker?

For instance, the disclosing state has a three-stage verification process for all categories of authorized users. The stages are professional license/employing agency verification; drivers' license verification; and, sworn notarized statement. The requesting state has a two stage verification process for all categories of authorized users. The stages are professional license verification and sworn notarized statement.

SAMPLE LANGUAGE

Each party to this agreement recognizes the other's verification process as outlined in Attachment A and confirms acceptance of each user from the other party. Each party agrees to notify the other, in writing, within thirty (30) calendar days of the effective date of any change to their user verification process.

Is the user required to abide by every state's rules on use/disclosure or just the requesting state's?

What are your concerns on this issue and how do you want them addressed?

For example, if a user from STATE A requests a report from STATE B, are they constrained by STATE B law on disclosure or by STATE A law?

SAMPLE LANGUAGE

Users must adhere to the other states' restrictions

Each state agrees that at the time a request is made it will require the authorized user to certify that he or she will adhere to applicable laws and restrictions on the use and/or disclosure of data received from the disclosing state PMP.

Users must adhere to only their resident state's restrictions:

Each state agrees that at the time the request is made it will require the authorized user to certify that he or she will adhere to the requesting state's applicable laws and restriction on the use and/or disclosure of data received.

C. Data Retention:

What is the data/report retention requirement in each state?

Does any difference in retention time cause legal issues?

Does any difference in availability of the archived report create legal issues for your state?

SAMPLE LANGUAGE

Both parties acknowledge that data exchanged through the interstate exchange hub is not retained on the server nor is the data added to the requesting state's PMP. The data received from the responding state is used for the sole purpose of creating a standard format PMP report. The PMP report in State A is available on-line to the user for a period of 60 calendar days. After that time the report is archived for six (6) years and only available by appropriate grand jury subpoena. The PMP report in State B is available on-line for two years and then archived for an indefinite period.

D. Privacy and Security:

What system security standards does the interchange hub employ?

Are those standards the minimum I will accept?

Do I need further assurance from the other party as to the security of the report containing my state's data on their server?

While it is good practice to use open ended language in some contract clauses, security and privacy is not one of those areas. In this case you should be as specific as your stakeholders require.

SAMPLE LANGUAGE

All web service calls between the states and the interstate exchange hub server will use standard Secure Socket Layer (SSL) data encryption methodology for message routing and control of a request sent to the hub. Additionally, all information identifying a patient, prescriber, pharmacy or drug related information will be further encrypted using the Advanced Encryption Standard (AES) Public Key Infrastructure (PKI) data encryption methodology. The information exchange hub is only able to decrypt SSL protected data.

Each state is responsible for requiring the interstate exchange hub to implement and maintain in accordance with state requirements, industry standards, laws and all rules applicable to protected health information and personally identifiable data.

Is my agency a covered entity for HIPAA?

Is the other state's system considered a covered entity for HIPAA purposes?

Are there notification requirements I must abide by?

Does the answer impact my ability to enter into an agreement with the other state?

SAMPLE LANGUAGE

If either state is considered a covered entity for HIPAA purposes this should be stated and all notification requirements expressly set out.

Data from State A's PMP system is considered Protected Health Information as defined in Section 45 CFR 164.402 of the Health Information Portability and Accountability Act. Each party agrees to notify the other of any unauthorized use of the data within five (5) days of the discovery of said use. Further the requesting party will notify the responsive party of any security incident which may have compromised the protected health data with five (5) days of the incident.

Any breach of data as defined in Section 45 CFR 164.402 shall be reported to the responding state within five (5) business days of discovery of any such breach. Notification will include the identification of each individual whose protected health information has been or is reasonably believed to have been accessed, acquired or disclosed during the breach. Additionally, the requesting state agrees to make available, in a reasonable amount of time, any information needed to respond to individuals' inquiries regarding said breach.

If neither state is a covered entity for purposes of HIPAA, then a section should be included to cover any breach of the system containing another state's private health information.

Each party agrees to maintain the confidentiality of the responding state's data in the same manner as they protect the confidentiality of the data concerning their citizens.

E. Data Breach Responsibilities

Every state PMP houses private personal data which enjoys different levels of confidentiality depending upon said state's characterization of this information. Some states have identified the information as confidential but not covered under any section of the Health Information Portability and Protection Act (HIPPA). Others have deemed just the opposite. These various characterizations/interpretations carry very different responsibilities if the data is breached either intentionally or inadvertently.

Is my agency considered a covered entity for purposes of HIPPA?

If so, which of my state's laws may interact with HIPPA and what other requirements do they impose?

If the other party is deemed differently, do I understand the requirements of the other party?

Is my state willing and able to agree to those requirements?

Which state bears the cost of any notification requirements imposed by the non-breached state?

SAMPLE LANGUAGE

The language below may satisfy your agency unless your state imposes additional notification requirements.

The parties agree to notify the other, in writing, as soon as practicable but in no case longer than five (5) days from suspecting/substantiating a system breach whereby it is reasonable to believe the responding state's data was breached. The breached state will supply all information as to what data may have been breached and when. Each party agrees to cooperate in good faith in all inquires that may arise from said breach. Each party further agrees to bear their own expense connected to any notification requirements imposed by their state law. Any notifications imposed under HIPPA, CFR 164.402, will be carried out by the agency deemed a covered entity and bear any expense in connection thereof.

F. Conflict Resolution

Conflicts can arise in any agreement. They may be due to a variety of circumstances, including factors outside either party's control; an intentional act by one of the parties' agents; a complaint filed by someone not a party to the agreement; misuse by a user; a miscommunication; or a change in state policy. Whatever the reason for a conflict, the best way to settle one is to plan for its settlement before it arises.

If State A learns of an impending change in circumstances that would materially affect the agreement, when and how should State B be notified?

An "impending change" could encompass anything from a legislative change that makes the current agreement null to anything that would require a modification in the agreement. Fairness dictates that both parties agree to some level of notification if these circumstances arise.

SAMPLE LANGUAGE

Parties agree that upon learning of any impending change in statutes or regulations which may materially affect any clause in the agreement, to notify the other party in writing of the impending change, the status of said change, agency's reasonable belief in success of said change, and any possible corrective actions which should be reviewed prior to effective date of change. Parties further agree to enter, in good faith, into discussion on possible solutions as soon as practicable after notification.

G. Possible Misuse of Data

If either state learns of data misuse, how and when does notification take place?

Which state laws will govern misuse penalties?

Who is responsible for the cost of and conducting the investigation as well as taking any action on the complaint?

What penalty will be enforced and by whom?

By far the easiest way to deal with all these misuse issues is for all states to agree that once they have sent PMP data to the exchange hub and it is received by the requesting state, that all use is governed by the requesting state's existing laws. This would alleviate any question about who investigates, who must be notified, who pays for the investigation and how any penalty may be enforced. This structure must surely already exist in every state with a functioning PMP. If this were the case the following language could be used.

SAMPLE LANGUAGE

Each party is responsible for any complaint, investigation, claim, loss, damage, lawsuit, etc relating to claims that a state's user, employee, agent or contractor failed to comply with its state or federal laws applicable to PMP data exchanged through the Hub.

Absent an agreement as stated in the paragraph above, the stakeholders should fully discuss and answer each of the questions above. Once these answers are determined they should be clearly and specifically expressed in the narrative. For example, if State A does not allow PMP data reports to be shared with the patient but State B does allow such use. State A must determine exactly how they wish to deal with this conflict in rules and state that as succinctly as possible.

SAMPLE LANGUAGE

State A restricts its prescribers from sharing PMP data with the named patient. State B does not restrict that use. The parties hereby agree to place that restriction notification on all PMP reports containing data from State A as well as any penalty associated with such misuse. The parties also agree that substantiation of any such misuse by their authorized users will result in deactivation of that user's ability to access interstate data.

MOU SECTION 4: Term and Termination

The term of the MOU defines the effective date and the life of the agreement. Termination of course defines the means by which the agreement ends. These items are particularly important in agreements between governmental entities funded by tax dollars and governed by statutes and regulations. However, as an MOU does not include a financial obligation there is no need to include an option to terminate due to lack of funding, nor is there a mandatory time limitation on the life of the agreement.

Questions and Responses to Consider:

When do you want the agreement to begin?

Usually all agreements become effective upon completion of execution by all authorized parties. There may however be reasons you need to delay implementation but wish to go ahead with obtaining a signed agreement. This is acceptable as long as you are clear as to when the agreement becomes effective.

SAMPLE LANGUAGE

Execution Language:

This agreement shall become effective upon the date of the last authorized signatory hereto.

SAMPLE LANGUAGE

Effective at a later date:

This agreement shall become effective upon the effective date of State A, Senate Bill 111, filed in State A's state legislative 2012 session.

When do you want the agreement to end?

Most agreements which include a financial obligation have statutory requirements surrounding the length of said agreement. Check with your procurement experts on this topic. If there is no requirement the agreement may stay effective until termination by either party or any other option in between.

SAMPLE LANGUAGE

Until termination:

This agreement remains effective until such time as either party terminates by sending thirty (30) days written notice to the appropriate party in State A.

A specified length:

This agreement remains effective for one (1) calendar year from the effective date as set out above. The agreement may be renewed for additional one (1) year periods by written agreement between the parties.

How long between notice and termination?

Given the fact that termination of a data sharing agreement will impact your PMP's users you should consider/plan for the possible termination of the agreement and how you will notify your users. By taking the plan into account, you will be able to determine how much time you need between notice and actual end of data sharing.

SAMPLE LANGUAGE

Either party may terminate this agreement for no cause with thirty (30) days notice upon serving written notice upon the other or immediately for cause.

How may the notice be delivered?

This question is one better answered by your legal or procurement experts. State requirements may differ and you will need to come to the negotiating table with a clear understanding of your limitations. Usually, a party can enter into an agreement with more restrictive/limiting clauses without running afoul of their state's requirements.

SAMPLE LANGUAGE

All written notices served under this agreement must be sent via certified mail, return receipt requested and sent to the parties listed below. Receipt of the notice is effective on the date of receipt noted upon United States Postal Service return receipt.

MOU SECTION 5: Miscellaneous Boilerplate

Questions and Responses to Consider:

Boilerplate is a term used to describe language and/or terms that are always found in contracts. The language used can be slightly different depending upon each jurisdiction but the overall intent is the same. You may have experienced legal services wrangling over language in these sections that seems to mean the same thing. These negotiations often arise because court decisions in each jurisdiction have specifically recognized certain phrases as being the legally correct language to use in similar circumstances. This hurdle may initially seem insurmountable, but patience and persistence often eases both parties into agreement.

The boilerplate language for each state should be obtained from your procurement subject matter experts and reviewed by PMP subject matter experts. Once the review is complete, all stakeholders can come together to discuss whether changes are needed to address your specific topic. (See Force Majeure below for an example).

SAMPLE LANGUAGE

The following list includes several examples of boilerplate language required/found in all MOU's.

A. Liability Limitations:

The parties shall not/do not waive the intent to assert available defenses and immunities pursuant to that state's applicable law in all cases.

B. Indemnification :(to guard against anticipated loss)

No party waives any right or defense to indemnification that may exist in law or equity. Each party shall be responsible for the negligent acts and/or omissions of its officers, agents, employees, and contractors.

C. Force Majeure:

Neither party shall be responsible for delay or failure to perform any part of this MOU when caused by events or circumstances outside the control of each party, including but not limited to acts of God, fire, flood, war, sabotage, terrorism, embargo, civil commotion, acts or omissions by a government entity, power or communication failures not caused by the parties, equipment or software failure not cause by the parties or contractors.

No party shall be deemed in violation of this MOU 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 enemies, accidents, fires, explosions, acts of God including, without limitation, earthquakes, floods, winds, or storms. In such an event the intervening cause must no be through the fault of the party asserting such an excuse, and the excused party is obligated to perform in accordance with the terms of the MOU after the intervening cause ceases.

D. Amendments and Assignments:

The terms and conditions of the MOU shall not be amended without mutual written consent of both parties. No duties or obligations may be assigned without prior written agreement by the other party.

The Parties shall not assign or subcontract the whole or any part of the MOU without the other Party's written consent.

E. Material Change in Circumstance:

This allows for immediate termination if funding is not authorized or some other action is taken by the legislature, over which the party has no control, which makes it impossible to fulfill the agreement. It is a good place to include a notification requirement: the party shall notify the other as soon as practicable once the action has been taken.

Either party may terminate the agreement contract if funds are not appropriated to the contracting agency or are not otherwise available for the purpose of making payments without incurring any obligation for payment after the date of termination, regardless of the terms of the contract. The terminating party shall provide thirty (30) calendar days written notice of termination of the contract.

Either party may terminate the agreement for convenience if deemed in the best interest of the contracting state. The terminating party shall provide thirty (30) calendar days written notice of termination of the contract. The terminating party shall remain responsible for any financial obligations reasonably incurred by the other party in expectation of fulfilling the agreement's full term.

F. Severability:

A finding of invalidity of any section, subsection, or clause in this MOU shall not affect the validity of the remaining sections, subsections or clauses in this MOU.