



## AGENCY USER AGREEMENT between Prescription Drug Monitoring Program and

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This Agency User Agreement (Agreement) is made and entered into by and between \_\_\_\_\_ hereinafter referred to as the Agency and the Florida Department of Health, Prescription Drug Monitoring Program hereinafter referred to as the Department.

### **I. Purpose of the Agency User Agreement**

In accordance with sections 893.055 and 893.0551, Florida Statutes, local, state, and federal law enforcement, the Department or its relevant health care regulatory boards, and the Attorney General for Medicaid fraud cases may request controlled substance prescription dispensing information (Information) from the Prescription Drug Monitoring Program (PDMP). A law enforcement agency may request Information for an active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances. The Department or its relevant health care regulatory boards may request Information for the licensure, regulation or discipline of health care practitioners who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances. The Attorney General and his or her designee may request Information when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs. This Agreement sets forth the legal authority; agency head or designee, administrator and authorized user responsibilities; information safeguarding requirements; compliance and control measures and performance standards.

### **II. Legal Authority**

The PDMP collects and maintains Information in a database pursuant to sections 893.055 and 893.0551, Florida Statutes. The Information maintained in the database is confidential and exempt from public record disclosure and may only be released to an authorized user under specified circumstances.

### **III. Statement of Work**

#### **A. Agency Head or Designee Responsibilities:**

1. Designate an individual from its Agency to function as the Agency Administrator and point of contact.
2. Notify the PDMP Program Manager of changes to the Agency Administrator immediately. Authority to request and receive Information from the Program Manager shall be suspended during an Agency Administrator vacancy.
3. Ensure the Agency complies with this Agreement, the Training Guide for Law Enforcement and Investigative Agencies, and the laws and rules governing the access, use, and dissemination of information received.
4. Submit an annual attestation to the Program Manager that the Agreement is being complied with and disclose any findings of non-compliance and actions taken to regain compliance.

#### **B. Agency Administrator Responsibilities:**

1. Designate authorized users who may request Information on behalf of the Agency during the course of an active investigation regarding prescribed controlled substances.

2. Immediately update user access permissions upon separation or reassignment of users and immediately update user access permissions upon discovery of negligent, improper, or unauthorized use or dissemination of information.
  3. Conduct quarterly quality control review of user access permissions, to ensure all current users are appropriately authorized.
  4. Submit a list of authorized users to the Department annually on or before June 30.
  5. Ensure the following training is completed prior to authorized user registration:
    - a. The Training Guide for Enforcement and Investigative Agencies; and
    - b. E-FORCSE Information Security and Privacy Training Course.
  6. Ensure all authorized users have knowledge and proof of an active investigation prior to submitting a request.
  7. Immediately report any findings of noncompliance to the Program Manager.
  8. Submit an update on the disposition of the case for which the Information was requested, quarterly, in accordance with procedures established by Department rule.
- C. Authorized User Responsibilities:
1. Review the Training Guide for Enforcement and Investigative Agencies prior to registration.
  2. Complete the E-FORCSE Information Security and Privacy Training Course prior to registration.
  3. Protect and maintain the confidentiality and security of the Information received in accordance with this Agreement and applicable state and federal laws.
  4. Attest that the request for Information is predicated on and related to an active investigation.
- D. Department Responsibilities:
1. Operate and maintain the electronic database.
  2. Maintain official copy of this Agreement.
  3. Ensure/monitor compliance with this Agreement.
  4. Review and approve requests for Information timely.
  5. Notify the Agency Administrator each time a request for Information is made by an authorized user of the Agency.

#### **IV. Safeguarding Information**

The Agency will use and maintain the confidentiality of all information received under this Agreement in accordance with Section 893.0551, Florida Statutes. Information obtained under this Agreement will only be disclosed to persons to whom disclosure is authorized under Florida law. Authorized users are prohibited from requesting Information on behalf of another law enforcement agency or entity. Any person who willfully and knowingly violates any of the provisions of this section may be found guilty of a felony and is punishable as provided in Section 893.0551, Florida Statutes.

- A. Information provided will not be used for any purposes not specifically authorized by this Agreement. Unauthorized use includes, but is not limited to, requests on behalf of another law enforcement agency, requests not related to a legitimate purpose, personal use, and the dissemination, sharing, copying or passing of this information to unauthorized persons.
- B. Information provided by electronic means will be stored in a place physically secure from access by unauthorized persons.
- C. Access to the Information provided will be protected in such a way that unauthorized persons cannot review or retrieve the Information.

- D. All authorized users under the terms of this Agreement will be instructed of, and acknowledge their understanding of, the confidential nature of the Information. These acknowledgements must be maintained in a current status by the Agency.
- E. All authorized users will be instructed of, and acknowledge their understanding of, the criminal sanctions specified in state law for unauthorized use of the Information. These acknowledgements must be maintained in a current status by the Agency.
- F. All Information must be monitored on an on-going basis by the Agency. In addition, the Agency must complete an annual audit to ensure proper and authorized use and dissemination.
- G. By signing the Agreement, the representatives of the Department and Agency, on behalf of the respective Parties attest that their respective Agency procedures will ensure the confidentiality of the Information provided will be maintained.

**V. Privacy of Controlled Substance Dispensing Information**

- A. All Information disseminated from the PDMP database in any form to any entity is considered protected health information and any and all applicable federal and state laws, including the Health Insurance Portability and Accountability Act (HIPAA), govern the use of it.
- B. All information provided to an Agency, entity, or individual will be labeled “CONFIDENTIAL: This information obtained from E-FORCSE contains confidential controlled substance prescription dispensing information.”
- C. It is Agency’s duty and responsibility to maintain the confidential and exempt status of any Information received from the PDMP.
- D. Prior to an authorized user disclosing Information received from the Program Manager or support staff to a criminal justice agency, as authorized by section 893.0551(4), Florida Statutes, the authorized user should redact all Information that is not the subject of the investigation.
- E. Information received by an Agency should only be retained until the investigation or prosecution is complete and will thereafter be destroyed.

**VI. Compliance and Control Measures**

- A. Internal Control Attestation. This Agreement is contingent upon the Agency having appropriate internal controls over the Information used by the Agency to protect the Information from unauthorized access, distribution, use, modification, or disclosure. The Agency shall have an auditable, continuous chain of custody record of the transfer of confidential and exempt Information. An audit trail shall be maintained by the Agency to provide accountability for all confidential and exempt Information received by authorized users.

Upon request from the Department, the Agency Administrator must submit an attestation. The attestation must indicate that the internal controls over personal data have been evaluated and are adequate to protect the personal data from unauthorized access, distribution, use, modification, or disclosure.

- B. Annual Affirmation Statement. The Department will receive an annual affirmation from the Agency indicating compliance with the requirements of this Agreement, on or before June 30 each year.
- C. Misuse of Confidential Protected Health Information. The Agency must notify in writing the Department and the affected individual following the determination that personal information has been compromised by any unauthorized access, distribution, use, modification, or disclosure, within 30 days of such determination. The statement to the Department must provide the date and the number of records affected by any unauthorized access, distribution, use, modification, or disclosure of personal information. Further, as provided in section 501.171, Florida Statutes, the document must include: Synopsis of security breach, Policy/incident report, Number of affected persons, Security policy, Recovery steps, Services offered to individuals, and Contact information to obtain additional information.

## **VII. Performance Standards**

The Department reserves the right to impose damages upon the Agency for failure to comply with the performance standard requirements set forth below. Failure by the Agency to meet the established minimum performance standards may result in the Department finding the Agency to be out of compliance, and all remedies provided in this Agreement and under law, will become available to the Department including a corrective action plan (CAP).

- A. Corrective Action Plan
  1. If the Department determines that the Agency is out of compliance with any of the provisions of this Agreement, the Department may require the Agency to submit a CAP within a specified timeframe. The CAP will provide an opportunity for the Agency to resolve deficiencies without the Department invoking more serious remedies, up to and including Agreement termination.
  2. In the event the Department identifies a violation of this Agreement, or other non-compliance with this Agreement, the Department will notify the Agency of the occurrence in writing. The Department will provide the Agency with a timeframe for corrections.
  3. The Agency will respond by providing a CAP to the Department within the timeframe specified by the Department.
  4. The Agency will implement the CAP only after the Department's approval.
  5. The Department may require changes or a complete rewrite of the CAP and provide a specific deadline.
  6. If the Agency does not meet the standards established in the CAP within the agreed upon timeframe, the Agency will be in violation of the provisions of this Agreement and will be subject to termination.

## **VIII. Terms and Terminations**

If the Program Manager or staff becomes aware of an alleged failure to comply with this Agreement or section 893.0551(5), Florida Statutes, by authorized users of the Agency, the Program Manager, within one business day of discovery, shall suspend the access of the authorized user and notify the Agency Administrator of the suspension. The Agency Administrator shall investigate the alleged compliance failure and report the findings to the Program Manager. The Program Manager shall determine whether the authorized user's access should be reinstated. Prior to reinstatement, the authorized user must submit proof of completion of the E-FORCSE Information Security and Privacy Training Course, within 30 days.

**IX. Disclaimers of Warranty and Liability**

- A. The Department makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the contents of this report, and expressly disclaims liability for errors and omissions in the contents of information provided by the PDMP database.
- B. The PDMP database records are based on Information submitted by pharmacies and dispensing health care practitioners.
- C. Records should be verified with the entity that reported the Information before any law enforcement actions are taken.

**FORM INSTRUCTIONS:** This is an adobe fillable form. Once complete, click on the "Submit Form" button in the purple box at the top of the form. Type in your email address and full name and click send.

Agency Name	
Agency Head Name	Title
Phone Number	Email Address
Signature:  <i>(Format for electronic signature: //John F. Doe//)</i>	Date:
Florida Department of Health- Prescription Drug Monitoring Program	
Name	Title
Phone Number	Email Address
Signature:  <i>(Format for electronic signature: //John F. Doe//)</i>	Date: