MARYLAND DEPARTMENT OF HEALTH

Maryland's Prescription Drug Monitoring Program

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May 1, 2019

Learning Objectives

- Describe the Maryland Prescription Drug Monitoring Program (PDMP)
- Define the PDMP's role in addressing opioid misuse and diversion
- Review Maryland's PDMP Use Mandate and recent updates to the regulations
- Discuss how the PDMP can be used as a clinical tool
- Discuss how PDMP can be used as an investigative tool

Overview: Maryland's Prescription Drug Monitoring Program

Maryland's Prescription Drug Monitoring Program

- PDMP was authorized through legislation in 2011
- PDMP went live in December 2013
- PDMP is administered by Maryland's Department of Health
- PDMP is a secure, statewide, electronic database
- Contains Schedule II-V dispensed pharmaceutical controlled dangerous substances (CDS)
- Prescription data can be disclosed for clinical, investigative, and research/public education purposes as allowed by law
- The program aims to:
  - Assist healthcare providers, public health, and safety authorities with reducing the non-medical use, abuse, and diversion of prescription drugs
  - Conduct surveillance and education about the prescribing/dispensing of CDS
- The PDMP is hosted by Maryland's Health Information Exchange (HIE) system, CRISP

Overarching Goals PDMP Office

1. Enhance Clinical Utility of the PDMP
2. **Support Regulatory/Investigate Users**
3. Enable Public Health and Research Stakeholders' use of PDMP
4. Continually Improve Quality of Data and Analytic Capacity

Who can request PDMP data?

- Clinical Use:
  - Prescribers (in connection with care of patient)
  - Dispensers (in connection with dispensing prescription)
- Other state's PDMP
- Researchers (de-identified data only)
- Patient (may include parent/guardian for minors)
- Provider (self-request)

Who can request PDMP data?

- Investigative Use:
  - **Law enforcement (existing investigation & subpoena)**
  - Licensing Boards (existing investigation & subpoena)
  - Fatality Review Teams (existing case review required)
  - MDH Agencies (existing investigation required)
    - OCME, OIG, Medicaid, OCSA, OHCQ

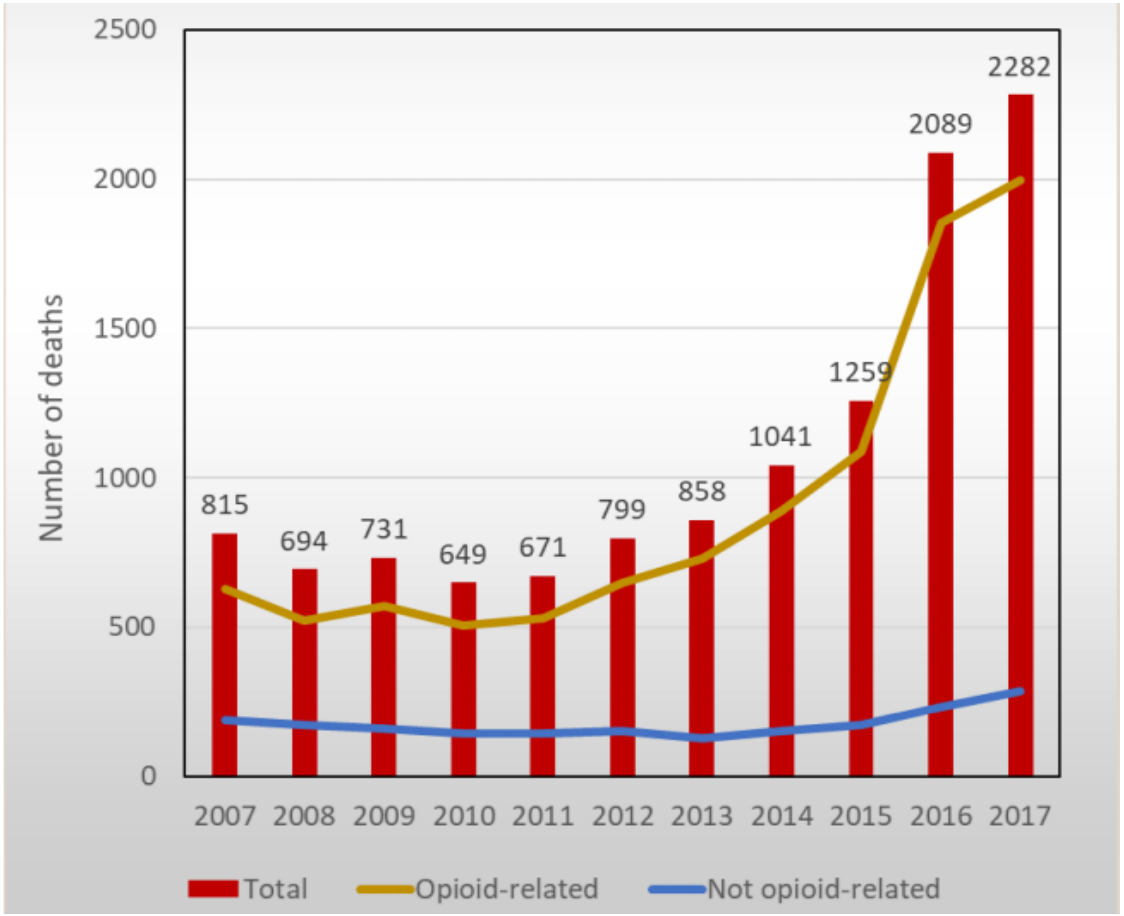
Addressing Opioid Misuse and Diversion

PDMP's Role in Addressing Opioid Misuse and Diversion

- The Centers for Disease Control and Prevention (CDC) has called opioid overdose a national epidemic
  - More than 40% of all US opioid overdose deaths in 2016 involved a prescription opioid[1]
- Increasing heroin and fentanyl use
- Health care providers are a common source of misused prescription drugs for individuals with opioid use disorder

1. Seth P, Scholl L, Rudd RA, Bacon S. Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants – United States, 2015-2016. MMWR Morb Mortal Wkly Rep. March 2018. 67(12);349–358.

Unintentional Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2017



Maryland Department of Health. *Unintentional Drug- and Alcohol-Related Intoxication Deaths in Maryland Annual Report 2017;* June 2018.

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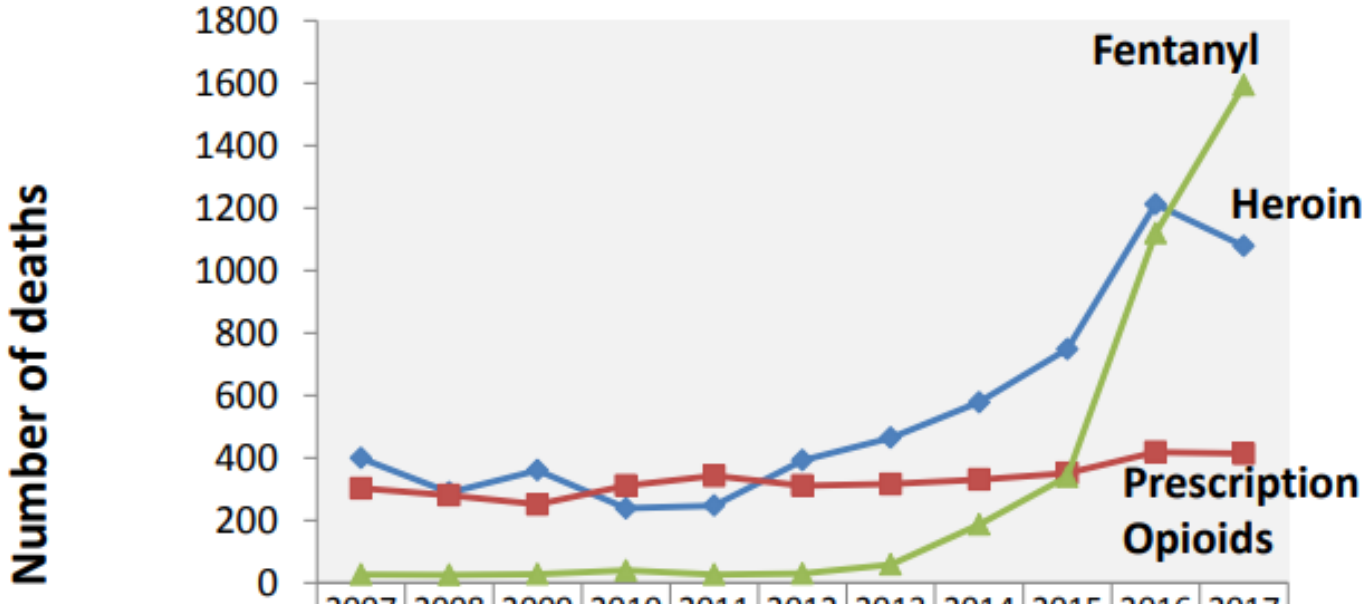
Number of Opioid-Related Deaths in Maryland by Substance, 2007-2017



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Heroin	399	289	360	238	247	392	464	578	748	1212	1078
Prescription opioids	302	280	251	311	342	311	316	330	351	418	413
Fentanyl	26	25	27	39	26	29	58	186	340	1119	1594

*Total opioids include heroin, prescription opioids, and illicit forms of fentanyl.

11 Maryland Department of Health. *Unintentional Drug- and Alcohol-Related Intoxication Deaths in Maryland Annual Report 2017;* June 2018.

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PDMP's Role in Addressing Opioid Misuse and Diversion

- PDMPs are important tools for preventing, identifying, and intervening with opioid misuse, overdose risk, and diversion
- PDMPs can enhance opioid prescribing and dispensing decisions, inform clinical practice, and protect patients at risk
- Maryland's PDMP program activities and recent legislative changes are aimed at ensuring the PDMP serves as an effective tool in line with best and emerging practices

Maryland's PDMP Use Mandate & Regulatory Updates

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PDMP Registration & Use Mandates

- Goal of the mandates is to promote wider adoption of the PDMP by clinicians
- The PDMP provides practitioners with available clinical resources in addition to data to assist in clinical decision-making
- The PDMP allows providers to view their own prescribing trends to guide behavior modification
- Health professional licensing Boards have the authority to enforce the PDMP use mandate

PDMP Registration Mandate

- Effective July 1, 2017:
  - Certain providers are required to be registered with the PDMP, including:
    - **CDS Prescribers:** physicians, physician assistants, nurse practitioners, nurse midwives, dentists, podiatrists and veterinarians with CDS prescriptive authority in Maryland
    - **Pharmacists**
- Providers should register now, even if missed deadline
- CDS Prescribers must be PDMP-registered when applying for new or renewal CDS Registration from Office of Controlled Substances Administration (OCSA)
- Providers only need to register once, registration and use is free, no renewal necessary
- If a provider has CRISP/PDMP access through their hospital EHR, they may still need to register for an individual account, providers should ask CRISP or their employer if they are unsure
- A Step-by-Step guide on registration is available on CRISP's PDMP webpage

PDMP Use Mandate

- Beginning July 1, 2018:
  - **Prescribers** must, with some exception, query (search) and review their patient's PDMP data prior to initially prescribing an opioid or benzodiazepine AND at least every 90 days thereafter as long as the course of treatment continues to include prescribing an opioid or benzodiazepine
  - **Prescribers** must also document their PDMP data query and review in the patient's medical record
  - **Pharmacists** must query and review patient PDMP data prior to dispensing ANY CDS drug if they have a reasonable belief that a patient is seeking the drug for any purpose other than the treatment of an existing medical condition
- Checking the PDMP is recommended for all appropriate prescribing and dispensing decisions

PDMP Use Mandate Exceptions

- A prescriber is not required to query the PDMP if the opioid or benzodiazepine is prescribed or dispensed to an individual who receives:
  - A prescription for 3 days or less
  - Treatment for cancer or cancer related pain
  - Treatment in an inpatient unit of a hospital
  - Hospice care or is diagnosed with a terminal illness
  - A prescription to treat or prevent acute pain for a period of 14 days or less following (full definitions on PDMP website):
    - A surgical procedure
    - A fracture
    - Significant trauma or
    - Childbirth
  - Treatment in an assisted living facility; a long-term care facility; a comprehensive care facility; or a developmental disabilities facility

PDMP Use Mandate Exceptions

- A prescriber may not be required to query the PDMP when:
  - Accessing would result in a delay in the treatment of a patient that would negatively impact the medical condition of the patient;
  - Electronic access is not operational; or
  - Data cannot be accessed due to a temporary technological or electrical failure

Written into the original regulations, the Secretary of Health has the authority to create a list of opioid or benzodiazepine drugs that have a low potential for abuse that would be exempt from the use mandate (does not currently exist)

Reporting Deadline Update

- Updates are specific to reporting deadlines:
  - (10.47.07.03.B): A dispenser shall report prescription monitoring data to the Department to **include zero report at least once every 24 hours** and in accordance with procedures developed by the Department and approved by the Advisory Board on Prescription Drug Monitoring
  - Changes reporting deadline from ‘within 3 days’ to daily
  - Requires zero-reporting

Reporting Deadline Update

- Dispensers subject to reporting requirement:
  - Hospital outpatient pharmacies
  - Community / retail pharmacies
  - Mail-order pharmacies dispensing to Maryland address
  - Dispensing practitioners
- Ensuring all dispensers are reporting data as required is a priority – we need to rely on our partners out in the field who view the original records to verify!

Implementing the PDMP into Clinical Practice

PDMP as a Clinical Tool

- Offers healthcare providers real-time, electronic access at the point of-care to their patients' complete Maryland controlled dangerous substance (CDS) prescription history in order to:
  - Enhance patient-provider communication
  - Identify aberrant drug using behavior (e.g. receiving multiple CDS prescriptions from other providers)
  - Improve providers' ability to identify possible substance use disorder and refer to or conduct appropriate assessment, treatment, and recovery services
  - Improve providers' ability to safely and effectively manage patients pain and other conditions with CDS pharmacotherapy
  - Increase confidence in prescribing decisions and patient compliance, and decrease potential for harmful drug interactions

Delegates

- Prescribers and pharmacists may delegate authority to health care staff to obtain PDMP user accounts (as “delegates”) through CRISP and query PDMP data on their behalf
- Delegates can support the integration of the PDMP into a practice workflow
- Delegates may include:
  - Licensed or non-licensed clinical staff that are employed by, or under contract with, the same professional practice or facility
- Prescribers and pharmacists may have multiple delegates
- Delegates may query the PDMP on behalf of multiple prescribers and pharmacists

DEA Self Audit

- Provides listing of prescriptions across all patients based on prescribers' DEA number
- Only accessible to an individual prescriber to view their own prescribing activity
- Opportunity to view and understand prescribing trends
- Tool to audit potential fraud concerns, for example if a prescription pad is missing

Investigative use of PDMP Data

PDMP Statute

- Data sharing within the PDMP Statute
  - §21-2A-06(b): The Program shall disclose prescription monitoring data, in accordance with regulations adopted by the Secretary, to:…(3) A federal law agency or a State or local law enforcement agency, on issuance of a subpoena, for the purpose of furthering an existing bona fide individual investigation;

PDMP Data Confidentiality

- PDMP data are confidential, privileged, not subject to discovery or subpoena in civil litigation, not public records
- Re-disclosure of PDMP data allowed only:
  - In alignment with HIPAA
  - For cross-agency collaboration on investigations

Who can be an Investigative User

- Investigative Users must be:
  - A sworn officer/agent of a federal, state, or local law enforcement agency
  - Authorized by agency leadership to submit PDMP data requests
  - Receive training in the purposes and uses of the PDMP

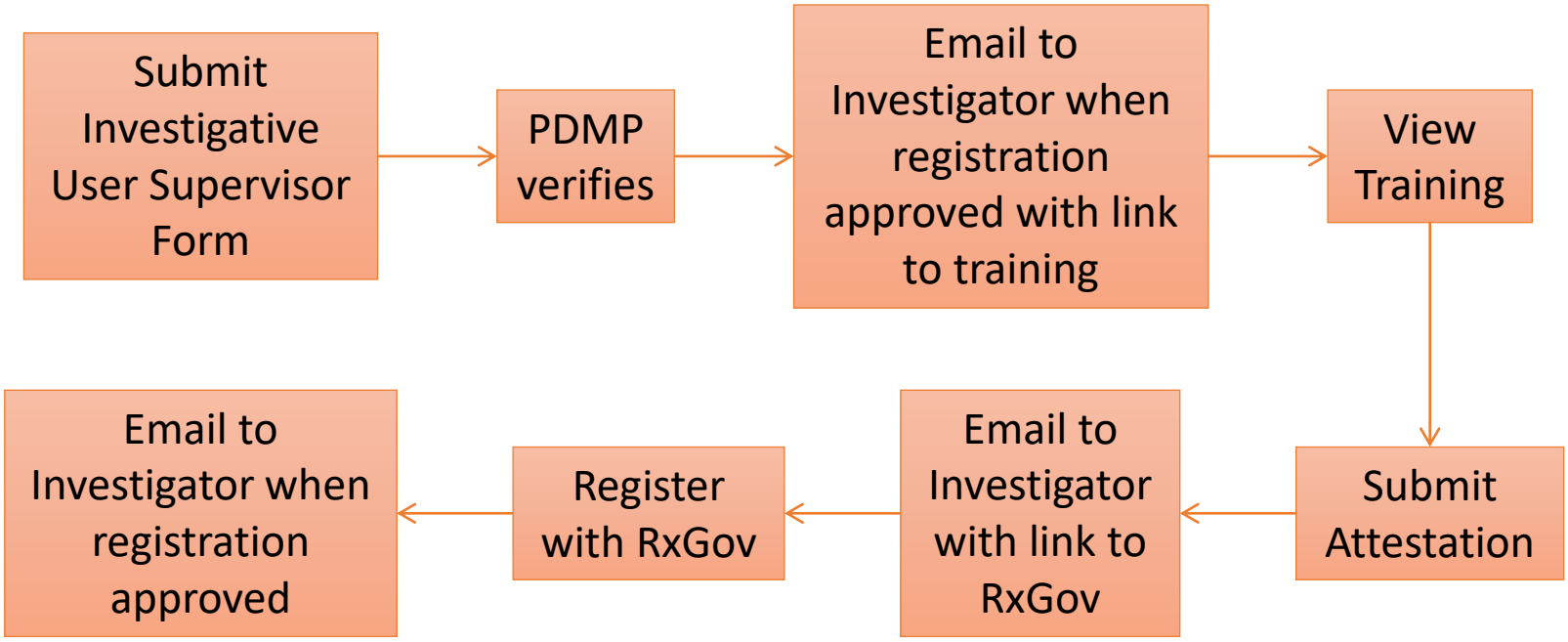
Transition to a New System

- All **New** and **Existing** Investigative Users will need to complete the following process to access PDMP by early June 2019
- Communication and instruction from the PDMP Office will be forthcoming

How to Become a new Investigative User

- Investigative Users
  - Register with the Department
  - Complete a training
  - Register with RxGov®
  - Submit subpoenas and conduct a query to retrieve reports through RxGov®

Becoming an Investigative User



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Subpoena Requirements

- ***Per Maryland rule 4-266, a subpoena must be issued:***
  1. By a clerk of a circuit court on request of the State's Attorney or the grand jury; or
  2. By the grand jury through its foreperson or deputy foreperson

  Note: Subpoenas signed by a State's Attorney are not acceptable for service on State government agencies

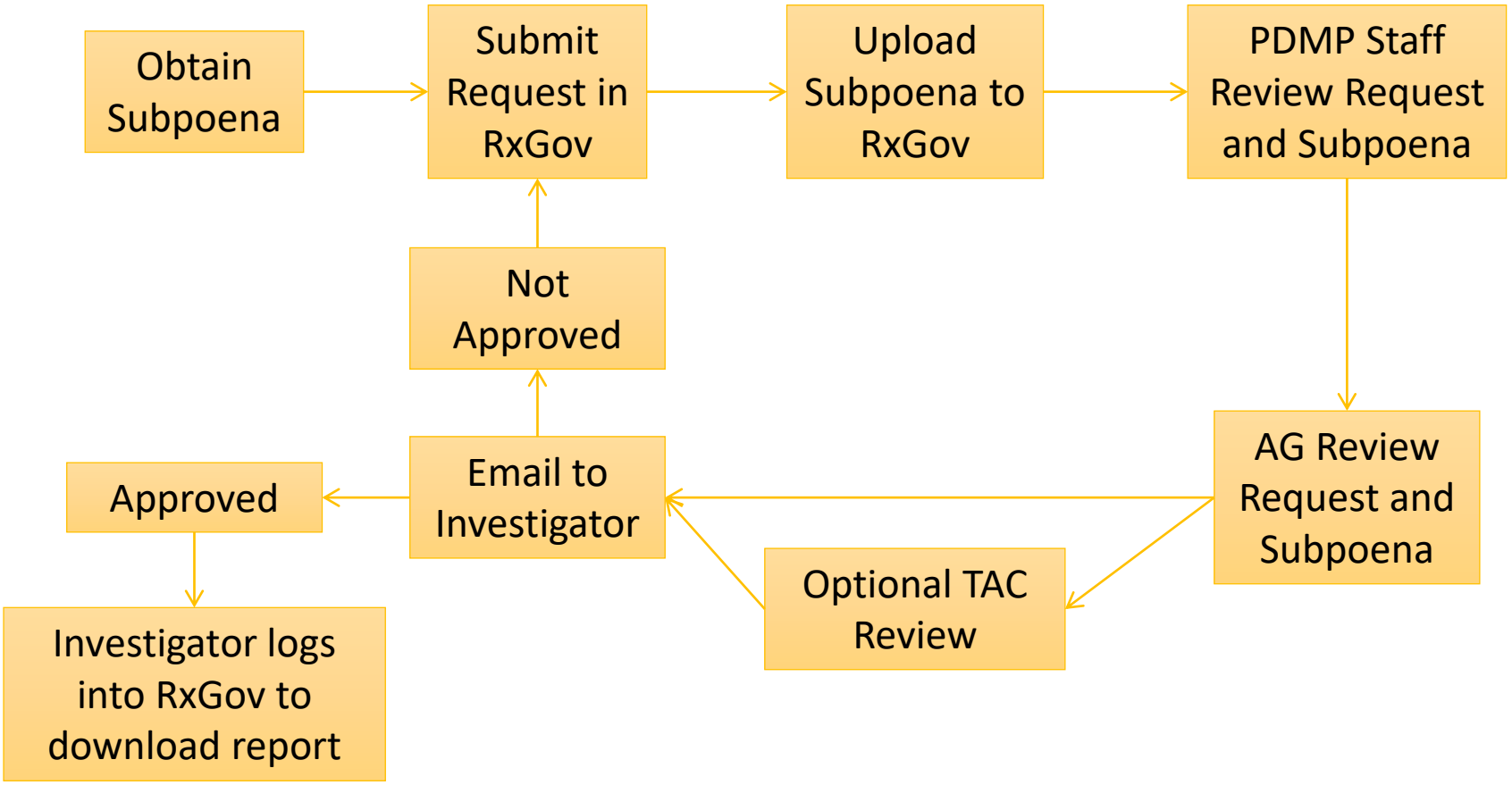
Subpoena Requirements

- Patient, prescriber, or dispenser specific reports can be requested through a subpoena
- Up to 10 names can be listed on a subpoena
- Approved subpoenas will result in data reports for all CDS prescriptions dispensed in Maryland over an indicated period of time

Using RxGov® and Accessing PDMP Data

- PDMP staff will review the request for consistency
- MDH Assistant Attorney General reviews subpoena for legal sufficiency
- Investigators will receive a notification if approved or not approved
  - If not approved a reason will be provided
- Typically turned around in a few business days (may take up to 2 weeks)
- Investigator then logs back in RxGov® to download PDMP Data Report (PDF and CSV files)

Accessing Data



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Questions?