State of Illinois Office of the Auditor General



Performance Audit of the

Illinois Prescription Monitoring Program

September 15, 2021

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Auditor General

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OFFICE OF THE AUDITOR GENERAL FRANK J. MAUTINO

To the Legislative Audit Commission, the Speaker and Minority Leader of the House of Representatives, the President and Minority Leader of the Senate, the members of the General Assembly, and the Governor:

This is our performance audit of the Illinois Prescription Monitoring Program (ILPMP) operated by the Department of Human Services.

The audit was conducted pursuant to Legislative Audit Commission Resolution Number 154. This audit was conducted in accordance with generally accepted government auditing standards and the audit standards promulgated by the Office of the Auditor General at 74 Ill. Adm. Code 420.310.

The audit report is transmitted in conformance with Sections 3-14 and 3-15 of the Illinois State Auditing Act.

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FRANK J. MAUTINO Auditor General

Springfield, Illinois September 2021

Report Highlights

Frank J. Mautino Auditor General

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Performance Audit of the

Illinois Prescription Monitoring Program

Background:

On July 21, 2020, the Legislative Audit Commission passed Resolution
Number 154 directing the Office of the Auditor General to conduct a performance audit of the Illinois
Prescription Monitoring Program
(ILPMP) operated by the Department of Human Services (DHS) (See Appendix A).

According to DHS, the mission of the ILPMP is to provide prescribers, dispensers, and health providers with the ability to view their current or prospective patient's controlled substance prescriptions dispensed in Illinois. The ILPMP utilizes an electronic database to collect, store, and access prescription information.

A Prescription Monitoring Program (PMP) continues to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk.

Key Findings:

- Of the 50 states, 49 had a statewide PMP during this review. Most states (84%) used a single contractor to perform all four functions associated with a statewide PMP. Illinois, however, was **one of only three states that utilized multiple contractors while performing some functions in-house**.
- DHS had not fully implemented the ILPMP by the required dates. DHS was required to establish rules requiring all Electronic Health Record (EHR) systems to interface with the ILPMP and establish actions to be taken if a prescriber's EHR did not effectively interface, as required. This interfacing would ensure all providers have access to patient records. Although rules on EHRs were established late, DHS could not provide the percent of EHRs that had been interfaced by the required date of January 1, 2021. According to DHS, they have no way of knowing when all EHRs would be fully interfaced, as required.
- The Illinois Controlled Substances Act (Act) requires all licensed prescribers to register with the ILPMP as of January 1, 2018. However, as of December 2020, **only 68 percent of prescribers were registered**.
- Not all dispensers are providing data on the dispensing of controlled substances to the ILPMP, as required. **DHS is not conducting follow-up with these dispensers to ensure they provide data or to determine why they are not providing data**. The Act gives DHS the ability to impose fines for willfully failing to report the dispensing of a controlled substance. However, according to DHS, **no fines have been imposed**.
- Dispensers are required to submit information on dispensed controlled substances by the end of the next business day. Since the required dispensed date is not being submitted by dispensers or tracked by DHS,

DHS has no way of calculating if dispensers are submitting information in a timely manner.

- During a review of general IT controls, our IS auditors found the ILPMP data, as well as reporting with respect to that data, cannot be relied upon. The review found deficiencies in the areas of contractual services, business processes, change control, disaster recovery, and security. We also tested 60 prescription records for compliance with the Act and Administrative Code. Of the 60 prescription records reviewed, all (100%) contained missing or inaccurate information. Other specific issues with the data included the following:
 - Regarding license numbers, there were entries with:
 - No license number;
 - Only one letter or one number in place of the license number;
 - The word "test" in place of the license number; and
 - Alpha and numeric values which do not comprise a license number.

- Once the user's license is initially validated, it is not revalidated to ensure continued validation. Of the 48,818 user accounts, **there were 19,501 users that appear to have never logged in**. In addition, there were 3,928 accounts with a last login date of more than 12 months.
- For the last 12 months of active data provided by DHS (17,075,814 prescription records):
 - 273,923 records were for prescriptions filled prior to the time period requested;
 - 67,520 records contained an animal species code; and
 - 465 records contained a birthdate with an age over 110.
- DHS was also not ensuring all users with access rights to the ILPMP database had valid licenses. Through a comparison with Department of Financial and Professional Regulation (DFPR) licensing data, we identified 2,287 registered users without a valid license.
- DHS had not established an interagency agreement with DFPR to ensure ILPMP licensing data did not contain invalid or outdated information. DHS had also not established a process with the Department of Public Health (DPH) to conduct data reviews of sports and accident injuries, as required by the Act.
- Although the ILPMP Policies and Procedures Manual covers significant procedures such as data security and law enforcement requests, the Manual is outdated. This outdated Manual supports that DHS has not established general IT controls over the data and needs to be updated to ensure these procedures are effectively implemented.

Key Recommendations:

The audit report contains ten recommendations directed to DHS and one recommendation directed to DHS and DPH including:

- DHS should fully implement an ILPMP in accordance with State requirements by ensuring all EHRs are fully interfaced with the ILPMP, as required.
- DHS should update the Illinois Administrative Code to align with the Act related to imposing fines, and develop a formal plan to help ensure dispensing reporting requirements are being implemented as required.
- DHS should establish general information technology controls over the data and correct the significant deficiencies related to contractual services, business processes, change control, disaster recovery, and security. Until these deficiencies are corrected, the ILPMP data and reporting with respect to that data cannot be relied upon.
- DHS should establish a process to ensure the licensing data utilized by the ILPMP does not contain invalid or outdated information. DHS should consider establishing an interagency agreement with the DFPR outlining each agency's responsibilities related to licensing data.
- DHS and DPH should establish a process to conduct data reviews of sports and accident injuries as required by the Act. In addition, DHS should alert prescribers whose discharged patients were dispensed a controlled substance about the risk of addition and applicable guidelines.
- DHS should update the ILPMP Policies and Procedures Manual as it is currently outdated. The updates should include current policies related to law enforcement requests.
- DHS should ensure dispensers are submitting specific information as required by the Act and the Illinois Administrative Code. This includes addressing all of the discrepancies identified during testing.
- DHS should ensure all prescribers possessing an Illinois Controlled Substance license are registered with the ILPMP as required by the Act.
- DHS should address the identified monitoring issues and related deficiencies. DHS should also address the identified
 program assessment issues and related deficiencies by ensuring program assessment reports contain complete and
 accurate information and reinstating the exchange of data with DPH to monitor significant drug-related issues.
- DHS should address the identified ILPMP Committee weaknesses for the Prescription Monitoring Program Advisory Committee, Peer Review Committee, and long term care Advisory Committee, which has not been established to date.

This performance audit was conducted by the staff of the Office of the Auditor General.

Report Digest

On July 21, 2020, the Legislative Audit Commission passed Resolution Number 154 directing the Auditor General to conduct a performance audit of the Illinois Prescription Monitoring Program (ILPMP) operated by the Department of Human Services (DHS) (see Appendix A). The Resolution contained five audit determinations. Our assessment of these determinations is shown in **Digest Exhibit 1**. (page 1)

Digest Exhibit 1

ASSESSMENT OF AUDIT DETERMINATIONS

Determination from Audit Resolution

Whether the Department has fully implemented a Prescription Monitoring Program in accordance with State requirements including whether updated rules were adopted within one year of the effective date of the Public Act and whether all Electronic Health Records Systems were able to interface with the Prescription Monitoring Program application program on or before January 1, 2021.

Whether the Department is adequately monitoring the Program and using this information to ensure the Program is administered as required.

Whether the Program and its database are effective in helping Illinois patients by requesting program assessment information from the Department and data from the database showing changes in the number and type of drug-related issues (such as deaths, abuse, overprescribing) since the implementation of State requirements.

Whether the Department's database is accurate and up-to-date including if the information submitted by dispensers is complete and timely.

Whether the Department is utilizing its authority to impose fines when dispensing reporting requirements are not being reported as required for the Program.

Auditor Assessment

- Although the ILPMP did not adopt rules requiring all EHR systems to interface with the ILPMP as required by January 1, 2019, these rules were adopted almost 2 ½ years later. In addition, all EHRs were not fully implemented and able to interface with the ILPMP as required by January 1, 2021. According to DHS, the status on EHRs could not be provided because the total number of EHRs could not be determined. (pages 19-20)
- DHS has not sufficiently tracked monitoring reports required by the Illinois Administrative Code or ensured all monitoring reports required by intergovernmental agreements are completed. Also, DHS has not sufficiently monitored ILPMP contractors. (pages 51-57)
- DHS has not ensured reports used for program assessment contain complete and accurate information or followed up on such reports when needed. DHS has also not established an interagency agreement with DPH to reinstate the process of exchanging data in more depth and providing additional program assessment information. (pages 44-50)
- DHS has not established controls over the PIL data. Until deficiencies are corrected, the accuracy of the PIL data cannot be relied upon. In addition, auditors tested a sample of PIL data and found DHS was not ensuring dispensers were submitting all required information, not submitting problematic information, and not submitting information by the end of the next business day, as required. (pages 23-30, 35-43)
- DHS has not imposed or collected fines for the ILPMP to date and has not ensured dispensing reporting requirements are being implemented, as required. (pages 21-22)

Source: OAG assessment of the audit determinations contained in LAC Resolution Number 154.

Background

According to the Centers for Disease Control and Prevention (CDC), Prescription Monitoring Programs (PMPs) continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk. A PMP is an electronic database which collects, tracks, and stores reported data on controlled substances and select drugs in a state. PMPs provide health authorities with timely information about prescribing and patient behaviors that contribute to the epidemic and facilitate a targeted response.

The Illinois Prescription Monitoring Program (ILPMP) began in 1986 and monitored only Schedule II prescription drugs, including painkillers such as morphine and hydrocodone. The ILPMP began collecting information electronically in 2000. In 2007, the program was expanded to monitor Schedule III through V drugs, including drugs such as Vicodin, Valium, and codeine.

The ILPMP is authorized by the Illinois Controlled Substances Act (720 ILCS 570/1 et seq.) and applies to Schedule II, III, IV, and V prescription medications. Prescriptions are regulated differently based on whether they are in Schedule II or Schedules III-V:

- Schedule II A prescription for a Schedule II controlled substance shall not be issued for more than a 30-day supply. Physicians can authorize up to three sequential 30-day supplies of Schedule II controlled substances for a total of a 90-day supply.
- Schedules III-V Prescriptions cannot be filled or refilled more than six months after written or refilled more than five times unless renewed in writing by the prescriber.

Although prescriptions are regulated differently, the ILPMP is responsible for monitoring all controlled substances in Schedules II-V. (pages 4, 6, 15-16)

Other States

Of the 50 states, 49 had a statewide PMP during this review. Most of these state programs did not directly maintain their own databases and used contractors for establishing and/or maintaining them. **Appendix E** provides a more detailed overview of all other state PMP contractors.

Illinois is one of only three states that contracts with other vendors and performs some duties in-house. The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) provided information on other states with a statewide PMP during this review. Below is a summary of this information.

- 35 states contract all four database-related tasks to Appriss, Inc. (Appriss), a company providing software and technology services.
- 6 states (Maine, Maryland, Montana, Nebraska, West Virginia, and Wisconsin) contract all four functions to contractors other than Appriss.

- 3 states (Kentucky, New York, and Utah) conduct all four database-related tasks in-house.
- 3 states (California, <u>Illinois</u>, and Wyoming) contract with third-party contractors other than Appriss and perform some database-related tasks inhouse.
- 2 states (Hawaii and Massachusetts) contract with Appriss for some databaserelated tasks and some tasks are performed in-house. (pages 4-6)

Organization of the ILPMP

The Illinois Department of Human Services (DHS) is the supervising entity over the Act (720 ILCS 570/1 et seq.). Within DHS, the Bureau of Pharmacy and Clinical Support Services administers the ILPMP.

While DHS is the State entity that oversees the ILPMP, there are many contractors and other agencies involved in the process. This includes employees who provide information technology services related to the ILPMP through Eastern Illinois University (EIU). See the **text box** for an overview of the

Overview of Contractors

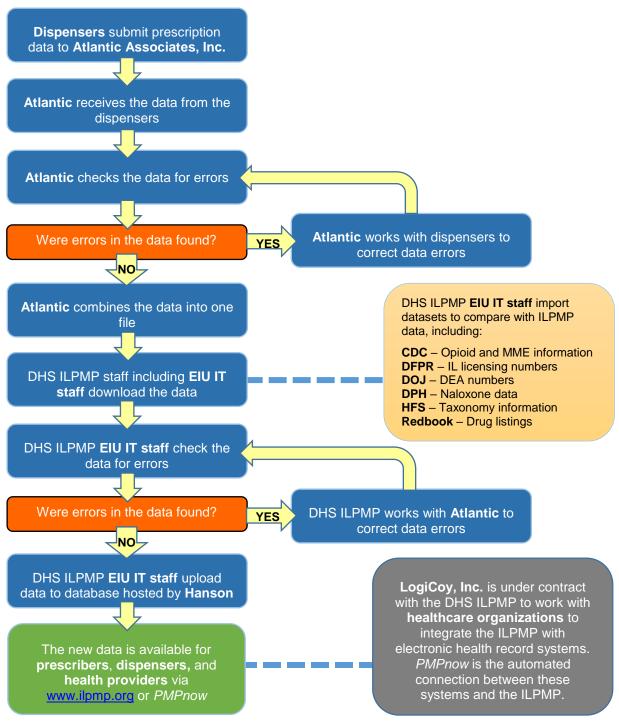
- LogiCoy, Inc. works with hospitals/centers/clinics to integrate EHR systems, maintains these connections, and supports a website and web services for EHR systems/PMPnow.
- Hanson Information Systems, Inc. provides hosting services for the PIL database and website.
- Atlantic Associates, Inc.
 obtains, reviews, and cleanses
 data on controlled substances
 from dispensers or LTC facilities.
- Eastern Illinois University
 develops and maintains the
 database by providing a Database
 Associate, Data Site Developer,
 and Web Developer.

responsibilities of the contractors utilized in the ILPMP process. Due to the number of other entities involved, the ILPMP process is complex.

Digest Exhibit 2 was created with assistance from DHS to illustrate a process flowchart of the ILPMP. According to DHS, the PIL (Prescription Information Library) data is compared with data from several agencies/entities. Data is obtained from the Illinois Department of Financial and Professional Regulation (DFPR) and the federal Department of Justice (DOJ) during the user on-boarding process. DHS also works with the Illinois Department of Public Health (DPH) through an interagency agreement for sharing data and coordinates with DPH on grants. Finally, DHS receives additional information from the Department of Healthcare and Family Services (HFS) and Redbook. More specifically, DHS imports data from the following agencies/entities for the timeframe basis noted:

- **CDC** for opioid information and MME (Morphine Milligram Equivalent) conversion factor (**annually**);
- **DFPR** for Illinois license numbers and unregistered providers (weekly);
- **DOJ** for verifying data and drug lists from the Drug Enforcement Administration (DEA) (**weekly**);
- **DPH** for Naloxone data and medical cannabis eligibility (**daily**);
- **HFS** for taxonomy data (**once to date; annually in future**); and

Digest Exhibit 2 ILPMP DATA PROCESS FLOWCHART



Note: This exhibit presents a basic framework of the ILPMP data process and agency responsibilities and is not intended to cover all iterations of the process.

Source: OAG analysis of the ILPMP data process.

• **Redbook** for all detailed drug information related to controlled substances (**monthly**).

Although DHS imports data from these agencies/entities, the data is currently not being reviewed by DHS before being imported into the PIL. (pages 8-13)

The Illinois Controlled Substances Act

The Illinois Controlled Substances Act (720 ILCS 570/1 et seq.) governs the distribution and use of a controlled substance in Illinois. The legislative intent of the Act is to curb the abuse of controlled substances by limiting access only to those with lawful and legitimate reasons to possess them by: penalizing drug trafficking and profiteering, establishing different regulation levels over types of controlled substances, and providing law enforcement with the resources to effectively enforce the Act.

Prescription Information Library

The Act establishes a PIL (or database), which must be developed to allow inquirers access to records for an individual patient or customer from the last 12 months. Access is read-only and may require technical assistance from the ILPMP through LogiCoy to establish a secure connection. The PIL shall automatically generate a login to the inquiry system when a prescriber or dispenser obtains or renews a controlled substance license.

Illinois Administrative Code for the ILPMP

The Illinois Administrative Code (77 III. Adm. Code 2080) establishes the authority held by DHS to control the abuse of Schedule II, III, IV and V retail dispensed drugs. The Administrative Code further establishes the requirements for prescribers when prescribing a controlled substance, whether written, electronic, facsimile, or verbal order. The majority of these requirements are outlined in the Act. However, some prescription requirements are only found in the Administrative Code. (pages 15-17)

Fully Implemented Program and Interfacing EHRs

DHS did not fully implement an ILPMP in accordance with State requirements, as required. All Electronic Health Records (EHRs) were not fully implemented and able to interface with the ILPMP by January 1, 2021. In addition, DHS could not provide the total universe of EHR systems or the total percentage of EHRs that had been interfaced as of January 1, 2021.

Updated Administrative Rules

Deadlines established by Public Act 100-0564 required the ILPMP to fully implement an ILPMP in accordance with State requirements including updating administrative rules within one year or January 1, 2019. Although Public Act 100-0564 contained these updated requirements, the Administrative Code was not updated by January 1, 2019, as required. However, as of June 24, 2021 (or almost 2 ½ years later), administrative rules were updated pertaining to these requirements.

EHR Systems

Deadlines established by Public Act 100-0564 also required all EHR systems to interface with the ILPMP application program by January 1, 2021. According to DHS, although the process of integrating EHR systems was in progress, all EHRs were not fully implemented and able to interface with the ILPMP by January 1, 2021, as required.

DHS was also required to establish actions to be taken if a prescriber's EHR system did not effectively interface with the PIL within the required timeline. However, DHS stated that the status on EHR integration could not be provided because the total universe of EHRs could not be determined by DHS. Therefore, DHS could not provide the total percentage of EHRs that had been interfaced by January 1, 2021, or when all EHRs would be fully interfaced, as required.

We recommended DHS should fully implement an ILPMP in accordance with State requirements by ensuring all EHRs are fully interfaced with the ILPMP, as required. (pages 19-20)

Imposing Fines

DHS has not imposed fines or ensured dispensing reporting requirements are being implemented, as required. DHS has not updated the Illinois Administrative Code to align with the Act or developed a formal plan to ensure dispensing reporting requirements are being implemented.

The Illinois Administrative Code (77 Ill. Adm. Code 2080) makes imposing fines for violating the ILPMP reporting controlled substance dispensing a requirement. According to the Act, DHS <u>may</u> impose a civil fine of up to \$100 per day for willful failure to report the dispensing of a controlled substance. However, the Administrative Code establishes DHS <u>shall</u> impose a civil fine of \$100 per day for willful violations of the ILPMP reporting requirements.

According to DHS, the ILPMP is in the process of proposing updates to the Administrative Code that would change the "shall" referenced in the current version to "may" in order to align with the Act. We reviewed the proposed updates to the Administrative Code (77 Ill. Adm. Code 2080) and found the updates propose to change this language as suggested. However, DHS has not established a formal plan to help ensure dispensing reporting requirements are being implemented as required.

We recommended DHS should update the Illinois Administrative Code to align with the Illinois Controlled Substances Act related to imposing fines and develop a formal plan to help ensure dispensing reporting requirements are being implemented as required. (pages 21-22)

Data Accuracy

DHS has not established general information technology controls over the data. Significant deficiencies related to contractual services, business processes, change control, disaster recovery, and security were also identified. Until these

deficiencies are corrected, the ILPMP data and reporting with respect to that data cannot be relied upon.

DHS has also not established a process to ensure licensing data utilized by the ILPMP does not contain invalid or outdated information. This includes not establishing an interagency agreement with DFPR. In addition, DHS has not established a process with the DPH to conduct data reviews of sports and accident injuries as required by the Act.

Review of General IT Controls

The *Review of General IT Controls* (Review) performed by our IS auditors found significant problems with the data and concluded the data cannot be relied upon. More specifically, the Review found the following:

As a result of the Department's failure to obtain, review, and fully understand the service providers' general IT controls as it related to the Prescription Monitoring Program (website, PMPnow, and PIL) and because we are unable to determine the adequacy of the service providers' general IT controls over the Prescription Monitoring Program, we are not able to rely on the data and reporting with respect to our testing of the Prescription Monitoring Program.

The Review found significant deficiencies related to the following five areas: contractual services, business processes, change control, disaster recovery, and security. Regarding the five areas identified, DHS indicated the significant deficiencies were due to a lack of resources or were the responsibility of the contractors.

We recommended that DHS should establish general information technology controls over the data and correct the significant deficiencies related to the five areas identified. Until these deficiencies are corrected, the ILPMP data and reporting with respect to that data cannot be relied upon.

DFPR Data

As discussed previously, the PIL data is compared with data from other agencies. DFPR must provide DHS with electronic access to license information of a prescriber or dispenser. According to DHS and DFPR, there is no interagency agreement between the two agencies that outlines each agency's responsibilities related to the licensing data. When asked if outdated licensees are removed by DHS, DHS officials stated no. According to DHS, there is not a process in place to check licensing data utilized by the ILPMP for invalid or outdated information.

We requested DFPR data for all individuals prescribing and dispensing controlled substances in Illinois. We compared the data to active users to determine if valid licenses were required in order to access the ILPMP. As a result of this comparison, we identified 2,287 registered users without a valid license and therefore, the ILPMP was not ensuring that all users with access rights to the PIL had valid licenses. Without an established process, the ILPMP is at risk for having individuals with invalid or outdated licenses with continued access to the ILPMP.

We recommended DHS should establish a process to ensure the licensing data utilized by the ILPMP does not contain invalid or outdated information. DHS should also consider establishing an interagency agreement with DFPR outlining each agency's responsibilities related to the licensing data.

DPH Data

According to Public Act 100-1093, effective August 26, 2018, DHS and DPH are required to coordinate continuous reviews of ILPMP and DPH data to determine if a patient may be at risk for opioid addiction. Each patient discharged from a medical facility with a specific classification related to a sport or accident injury shall be subject to data review. However, no reviews of sports and accident injury data were conducted in FY19 and FY20. In addition, DHS was not alerting prescribers whose discharged patients were dispensed a controlled substance in FY19 or FY20. The lack of reviews for sports and accident injuries and alerts to prescribers puts these patients at an increased risk for addiction.

We recommended DHS and DPH should establish a process to conduct data reviews of sports and accident injuries as required by the Act. In addition, DHS should alert prescribers whose discharged patients were dispensed a controlled substance about the risk of addiction and applicable guidelines. (pages 23-30)

Outdated ILPMP Policies and Procedures Manual

DHS has not updated the ILPMP Policies and Procedures Manual (Manual). The Manual currently contains outdated information and does not contain specific information about data security or the handling of law enforcement requests. We determined the Manual was outdated (including examples dating back to 2011 and 2013) and contained inaccurate information. Eight areas also document the Manual was outdated and requires updating.

Although the Manual describes the process of fulfilling a law enforcement request, DHS noted the current policies in the Manual are outdated. Due to the significant number of law enforcement requests and confidential data being provided in response to these requests, the lack of current policies in the Manual related to law enforcement requests is problematic and needs to be updated.

We recommended that DHS should update the ILPMP Policies and Procedures Manual as it is currently outdated. The updates should include current policies related to law enforcement requests. (pages 31-34)

Dispenser Requirements

DHS has not required dispensers to submit specific information as required by the Illinois Administrative Code and Act. In addition, DHS has not required dispensers to submit information by the end of the next business day, as required by the Act. Finally, DHS has not followed up on problematic information submitted by dispensers including prescription records with patients over 110 years old, records with an animal species code, and/or records with an invalid patient name.

As stated in the Act and the Administrative Code, dispensers must submit specific information to the ILPMP (see the **text box** for this specific information), and all

Required to be Submitted by Dispensers:

- patient ID;
- · patient location code;
- patient name and address;
- patient date of birth and gender;
- date prescription written;
- date prescription filled;
- date controlled substance dispensed;
- quantity dispensed/days supplied;
- national drug code number of the controlled substance dispensed;
- payment type used to purchase the controlled substance;
- prescriber's and dispenser's DEA numbers;
- dispenser's full name and address; and
- prescriber's full name.

Specific Testing Examples:

- "Reese Dog" was 120 years old, had an animal species code, and was in a LTC facility.
- "Sam Dog" was 120 years old, had a human species code, and had a dog's name.
- A Men's Health Center was 120 years old, had a human species code, and had a health center's name.

information must be transmitted by the end of the next business day after the date on which a controlled substance is dispensed. When asked how the ILPMP knows if required dispensing information is reported by the end of the next business day, DHS said they cannot monitor this reporting.

For required submission information, missing or incorrect information was identified in the PIL data for the 60 sample records. These areas where missing or incorrect information was found included the following:

- date controlled substance dispensed;
- dispenser DEA number;
- dispenser's full name;
- dispenser's address;
- patient ID;
- patient location code;
- patient name;
- patient date of birth;
- date sold; and
- prescriber's full name.

DHS had not followed up on problematic information submitted by dispensers (over 110 years old, animal species code, and/or missing patient name) and none of the identified issues prevented the records from being maintained in the active PIL. The lack of control is problematic and emphasizes the need for improved monitoring over the ILPMP data.

In addition, all 16 (100%) LTC prescription records were missing the information required to be submitted for LTC cases. Only the diagnosis code field was available for dispensers to submit information. All of the other required fields (ethnicity, patient weight, etc.) did not have a field where data could be submitted by dispensers.

We recommended DHS should ensure dispensers are submitting specific information as required by the Illinois Controlled Substances Act and the Illinois Administrative Code. This includes addressing the above discrepancies to meet these requirements. (pages 35-43)

Program Assessment Information

DHS has not ensured reports used for program assessment contain complete and accurate information or followed up when program assessment reports show significant changes, incorrect calculations, and/or missing information. DHS has also not established an interagency agreement with DPH to reinstate the process of exchanging data in more depth through the Opioid Data Dashboard or provided additional program assessment information to cover significant drug-related issues. Finally, DHS has not ensured all prescribers possessing an Illinois Controlled Substance license are registered with the ILPMP.

We requested DHS provide program assessment information illustrating ILPMP changes in drug-related issues (including deaths, abuse, and overprescribing) since the implementation of ILPMP State requirements. In response to this request, DHS provided the following:

- monthly statistics on the ILPMP website;
- annual indicator reports; and
- quarterly and final annual grant reports.

Quarterly and Final Annual Grant Reports

Although the Act states each prescriber possessing an Illinois Controlled Substance license shall register with the ILPMP as of January 1, 2018, DOJ grant reports support the percent of **prescribers registered to the ILPMP** was: **78%** as of June 2019, **70%** as of December 2019, **68%** as of June 2020, and **68%** as of December 2020.

We asked DHS what was done to correct the lack of registered prescribers and noncompliance with the Act. According to DHS officials, DHS reached out to DFPR to request this registration be added as a mandatory condition for license renewal. No other information was provided by DHS to address this noncompliance.

We recommended that DHS ensure all prescribers possessing an Illinois Controlled Substance license are registered with the ILPMP as required by the Illinois Controlled Substances Act.

Other Program Assessment Information

The third audit determination asks whether the ILPMP and its database are effective in helping Illinois patients by requesting DHS program assessment information and data showing changes in the number and type of drug-related issues (such as deaths, abuse, and overprescribing). It is problematic that DHS and DPH have not been linking data for the ILPMP, hospital discharges, and death certificates since 2018. According to DHS, the agencies hope to begin exchanging data more timely and efficiently in 2021 depending on DPH's resource availability.

We recommended DHS should address the identified program assessment issues and related deficiencies. (pages 44-50)

Monitoring

DHS has not performed sufficient tracking of monitoring reports required by the Illinois Administrative Code including error reports, zero reports, and personal information reports. DHS has also not ensured all monitoring reports required by intergovernmental agreements are completed as outlined in the agreements. Finally, DHS has not sufficiently monitored ILPMP contractors through System and Organization Controls reports or internal control reviews.

Intergovernmental agreements require the ILPMP to oversee additional reporting requirements. Examples of reports required by intergovernmental agreements included quarterly local level analyses and a final annual report. We reviewed intergovernmental agreements and followed up with DHS about requirements related to these reports. Although DHS completed some reporting requirements in intergovernmental agreements as required, other reporting requirements were incomplete.

Contractor Monitoring

Many of the responsibilities of the controls over IT and the data reside with contractors as delegated by DHS. We met with DHS and requested information regarding the monitoring of these contractors utilized in the ILPMP. Specifically, IS auditors asked if DHS required System and Organization Controls (SOC) reports from contractors. According to DHS, SOC reports are not required. In addition, there are no internal control reviews over the internal controls of the services provided. Without SOC reports and internal control reviews from contractors, DHS has no reliance on their internal controls of the services provided.

We recommended DHS should address the identified monitoring issues and related deficiencies. (pages 51-57)

ILPMP Committees

DHS has not updated the Illinois Administrative Code to ensure the Prescription Monitoring Program Advisory Committee (PMPAC) members for the PMPAC are the same as those required by the Act. DHS has also not ensured Peer Review Committee (PRC) members with the same profession as prescribers or dispensers were preparing preliminary reports and/or making recommendations, as required by the Act. In addition, DHS has not ensured the PRC met quarterly or fulfilled annual reporting requirements, as required by the Administrative Code. Finally, DHS has not established a long term care (LTC) Advisory Committee, as required by the Administrative Code.

The Prescription Monitoring Program Advisory Committee

The Act establishes the role of both DHS and the PMPAC in adjusting the schedule of controlled substances in the Act. PMPAC committee members play a direct role in implementing the ILPMP with DHS and provide advising on matters relevant to their field of competence. The Illinois Administrative Code (77 Ill. Adm. Code 2080) also establishes the composition and responsibilities of the PMPAC. **The Administrative Code and the Act differ in the required**

members of the PMPAC because the Administrative Code has not been updated.

Peer Review Committee

Public Act 100-1093, effective August 26, 2018, changed the makeup of the PRC. This included the addition of new members. The PRC currently consists of ten of the PMPAC members. The Act also requires a committee member whose profession is the same as the prescriber or dispenser being reviewed to prepare a preliminary report and recommendation for any non-action or action. However, we found no evidence that committee members whose profession was the same as the prescriber or dispenser being reviewed prepared any preliminary reports or made any recommendations for action or non-action, as required by the Act.

In addition, the PRC did not meet quarterly in FY19, FY20, and FY21 as required by the Administrative Code. In total, the PRC has met five times from FY19 through the end of FY21. Starting on July 1, 2017, the PRC was required to submit an annual report, delivered electronically to DHS and the General Assembly. We reviewed the FY18, FY19, and FY20 Annual Reports to determine if the required information was included. We found some required information was included such as the number of times the PRC convened; however, all three fiscal years were missing required information.

We also requested the data for the prescribers identified as being at risk in FY18 and FY19. **DHS stated these lists could not be provided. According to DHS, the lists were cleared and reloaded with each new list**. Therefore, DHS is not following up on these prescribers identified as at risk.

Long Term Care Advisory Committee

The Administrative Code defines the PMP LTC Advisory Committee. This committee is supposed to be a subunit of the PMPAC and composed of healthcare professionals associated with the care of geriatric populations. We requested a listing of members on the PMP LTC Advisory Committee. According to DHS, "this committee was never established and never met." DHS further stated the information on the LTC Advisory Committee in the Administrative Code was outdated, and DHS does not have a plan to address this outdated information at this time.

We recommended DHS should address the identified ILPMP Committee weaknesses for the PMPAC, PRC, and LTC Advisory Committee. (pages 58-65)

Audit Recommendations

The audit report contains ten recommendations directed to DHS and one recommendation directed to DHS and DPH. DHS and DPH agreed with the recommendations. The complete responses for DHS and DPH are included in this report as **Appendix F**.

This performance audit was conducted by the staff of the Office of the Auditor General.

SIGNED ORIGINAL ON FILE

JOE BUTCHER
Division Director

This report is transmitted in accordance with Sections 3-14 and 3-15 of the Illinois State Auditing Act.

SIGNED ORIGINAL ON FILE

FRANK J. MAUTINO Auditor General

FJM:SEC

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Glossary and Acronyms

Act	Illinois Controlled Substances Act (720 ILCS 570/1 et seq.) which governs the distribution and use of controlled substances in Illinois.		
Administrative Code	Illinois Administrative Code (77 III. Adm. Code 2080) establishing the authority held by DHS to control the abuse of Schedule II, III, IV and V drugs.		
CDC	Centers for Disease Control and Prevention (U.S. Department of Health and Human Services).		
COVID-19	An infectious disease caused by a newly discovered coronavirus.		
DEA	Drug Enforcement Administration (U.S. Department of Justice).		
DFPR	Illinois Department of Financial and Professional Regulation.		
DHS	Illinois Department of Human Services.		
Dispenser	Any practitioner or pharmacy that dispenses a controlled substance to an alternative user or research subject by or pursuant to the lawful order of a prescriber.		
DOJ	U.S. Department of Justice.		
DPH	Illinois Department of Public Health.		
EHR/EMR	Electronic Health Record or Electronic Medical Record. An electronic record of health-related information created, gathered, managed, and consulted by authorized clinicians and staff.		
EIU	Eastern Illinois University.		
Electronic Integration	The process by which an entity with an EHR system applies to have its EHR system integrated with the Prescription Monitoring Program.		
GRF	General Revenue Fund.		
HIPAA	Health Insurance Portability and Accountability Act.		
ILPMP	Illinois Prescription Monitoring Program. The Illinois program that collects, tracks, and stores reported data on controlled substances and drugs pursuant to Act.		
IS	Information Systems.		

Glossary and Acronyms

IT	Information Technology.
LTC	Long Term Care.
MME	Morphine Milligram Equivalents. The amount of milligrams of morphine an opioid dose is equal to when prescribed.
МуРМР	An analytical tool aggregating measures set by the CDC to assess the risk of overdose for individual patients. <i>MyPMP</i> is utilized by prescribers, but may be expanded to dispensers and health providers.
Naloxone	A drug that can reverse the effects of opioid overdose and can be life-saving.
Opioid	Natural, synthetic, or semi-synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain, and reduce the intensity of pain signals and feelings of pain. This class of drugs includes illegal drugs (such as heroin), synthetic opioids (such as fentanyl), and pain medications available legally by prescription (such as oxycodone).
Overdose	A controlled-substance-induced physiological event that results in a life-threatening emergency to the individual who ingested, inhaled, injected, or otherwise absorbed a controlled, counterfeit, or lookalike substance or a controlled substance analog.
PDMP TTAC	Prescription Drug Monitoring Program Training and Technical Assistance Center.
PDS	Pharmacy Dispensing System.
PIL	Prescription Information Library. An electronic library (or database) that contains reported controlled substance data. The PIL is the "central repository" required by the Act.
РМР	Prescription Monitoring Program or Prescription Drug Monitoring Program. An electronic database collecting, tracking, and storing reported data on controlled substances in a state.
PMPAC	Prescription Monitoring Program Advisory Committee. Committee established to aid in the implementation of the ILPMP and to advise the Clinical Director on the professional performance of prescribers and dispensers and other matters.

Glossary and Acronyms

PMPnow	Extension of the PMP that allows electronic health records, electronic medical records, and other record systems to perform automated patient queries.
PRC	Peer Review Committee. A subcommittee, formed from members of the Prescription Monitoring Program Advisory Committee, with the purpose of establishing a formal peer review of professional performance of prescribers and dispensers.
Prescriber	A healthcare professional that is authorized to prescribe medications as set forth in the various professional practices of the State of Illinois.
Redbook	Provides information on controlled substances, including National Drug Code (NDC) numbers, controlled substance types, pill shape, and more.
SAMHSA	Substance Abuse and Mental Health Services Administration (U.S. Department of Health and Human Services).

Introduction

On July 21, 2020, the Legislative Audit Commission passed Resolution Number 154 directing the Auditor General to conduct a performance audit of the Illinois Prescription Monitoring Program (ILPMP) operated by the Department of Human Services (DHS) (see Appendix A). The Resolution requires the audit include the following determinations:

- 1. Whether the Department has fully implemented a Prescription Monitoring Program in accordance with State requirements including whether updated rules were adopted within one year of the effective date of the Public Act and whether all Electronic Health Records Systems were able to interface with the Prescription Monitoring Program application program on or before January 1, 2021;
- 2. Whether the Department is adequately monitoring the Program and using this information to ensure the Program is administered as required;
- 3. Whether the Program and its database are effective in helping Illinois patients by requesting program assessment information from the Department and data from the database showing changes in the number and type of drug-related issues (such as deaths, abuse, overprescribing) since the implementation of State requirements;
- 4. Whether the Department's database is accurate and up-to-date including if the information submitted by dispensers is complete and timely; and
- 5. Whether the Department is utilizing its authority to impose fines when dispensing reporting requirements are not being reported as required for the Program.

Background

Background on Opioids

According to the Centers for Disease Control and Prevention (CDC), the overall national opioid prescribing rates declined from 2012 to 2018. In 2018, the prescribing rates had fallen to their lowest level in 13 years. However, prescribing rates continued to remain very high in certain areas across the country. While the overall opioid prescribing rate in 2018 was 51.4 prescriptions per 100 people, some counties had rates six times as high. In 11 percent of U.S. counties, enough opioid prescriptions were dispensed for every person to have one.

Opioid Prescribing Rates in Illinois

According to the National Institute on Drug Abuse, nearly 80 percent of Illinois drug overdose deaths involved opioids (or a total of 2,169 fatalities involved opioids) in 2018. In addition, in 2018, Illinois providers wrote 45.2 opioid prescriptions for every 100 persons, compared to the average U.S. rate of 51.4 prescriptions. This is the lowest rate in the State since data became available in 2006.

Although there have been improvements in prescribing rates in Illinois, the prescribing rates for opioids vary widely across different counties. The CDC website provides state maps that portray the prescribing rates per year for each of the 50 states. **Exhibit 1** displays this data in a map of the State of Illinois for 2018. As shown in this exhibit, prescribing rates range from 0 (Calhoun and Ford) to as high as 206.7 (Hardin) per 100 people in Illinois counties. Ten counties had prescribing rates with missing data or rates of 0/0.1. Five counties had prescribing rates over 112.5.

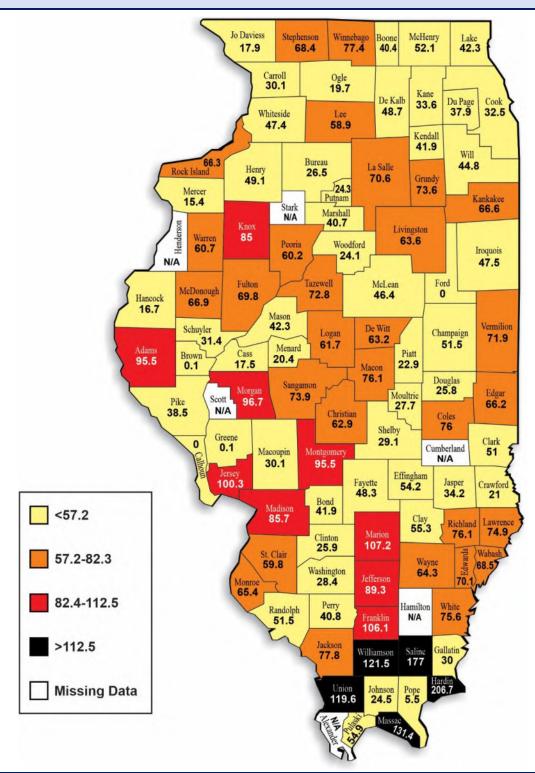
While DHS officials noted they have not done any analysis on this CDC data, they also stated they do not report data for counties with less than 10 patients and were unsure if this reporting method is what affected the data related to these counties.

Regarding the high prescribing rates in the southern Illinois counties, DHS officials noted their involvement in several projects to increase education and outreach related to opioid prescribing rates in these southern counties (the Delta region). According to DHS, the ILPMP identified and collaborated with the local health departments in the Delta region to extend outreach and educate individuals where opioid prescribing rates were above average. DHS officials provided two summary documents from July 2018 supporting their efforts to reduce opioid deaths in these counties over the following three years. Four of the five counties with prescribing rates over 112.5 (Union, Massac, Hardin, and Saline) were in this region as well as two of the counties with missing data (Alexander and Hamilton). The fifth county with prescribing rates over 112.5 (Williamson) chose not to participate in the projects.

Exhibit 1

ILLINOIS OPIOID PRESCRIBING RATES PER 100 PEOPLE

Calendar Year 2018



Source: OAG prepared from Centers for Disease Control and Prevention data.

Updated Opioid Prescribing Rates for 2019

The CDC website recently updated the state maps on prescribing rates for calendar year 2019. The map of the State of Illinois shows the 2019 prescribing rates decreased from 2018 with rates ranging from 1.1 (Stark) to 186.4 (Hardin) per 100 people in Illinois. More specifically, the number of counties with rates over 112.5 decreased from six counties in 2018 to two counties in 2019 (Hardin and Saline). Six additional counties continued to have rates in the 82.4 – 112.5 category in 2019 (Jackson, Peoria, Jefferson, Sangamon, Adams, and Williamson), which is down from nine counties in 2018. The counties with missing rates also decreased from six counties in 2018 to only one county in 2019 (Pulaski). Although prescribing rates decreased from 2018 to 2019, these rates continued to vary widely across counties and should still be monitored. For example, the same two counties continued to have the highest prescribing rates in both 2018 and 2019 (Hardin and Saline).

Prescription Monitoring Programs

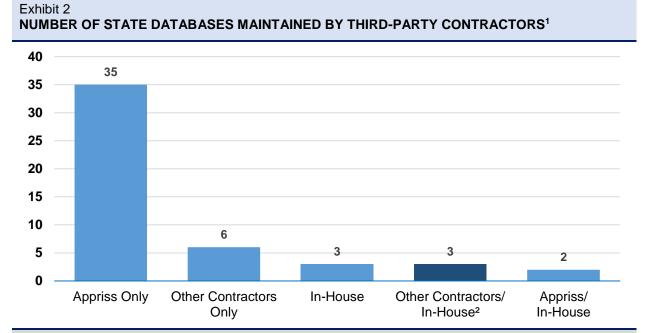
According to the CDC, Prescription Monitoring Programs (PMPs) continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk. A PMP is an electronic database which collects, tracks, and stores reported data on controlled substances and select drugs in a state. PMPs provide health authorities with timely information about prescribing and patient behaviors that contribute to the epidemic and facilitate a targeted response.

Other States

Of the 50 states, 49 had a statewide PMP during this review. Although Missouri did not have a statewide PMP, there was a PMP operated by the St. Louis County Department of Public Health. Most of these state programs did not directly maintain their own databases and used contractors for establishing and/or maintaining them.

According to the Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC), a resource for state PMPs funded by federal Department of Justice (DOJ) grants, state PMPs often contract the following four functions. The definitions for these functions were provided by DHS.

- **Data Collection** The receipt of data directly from prescribers for maintenance and the correction of errors in prescription data.
- **Data Storage** The hosting of PMP website and/or database servers.
- **Report Generation** The development of reports to answer questions about the program, such as the number of prescribers querying the system or changes in opioid dispensation.
- **Data Access** The provision of access to PMP data to those needing it, including prescribers and dispensers, law enforcement, etc.



Notes:

- ¹ PMP information is continually published and updated by the PDMP TTAC. Exhibit information is current as of October 2020.
- ² Illinois contracts with Atlantic Associates, Inc. for data collection and Hanson Information Systems, Inc. for data storage. Illinois also utilizes two other contractors. LogiCoy, Inc. works to integrate EHR systems and maintain these connections. Eastern Illinois University provides contract IT staff for information technology services.

Source: OAG prepared based on PDMP TTAC information.

As seen in **Exhibit 2**, one contractor, Appriss Inc. (Appriss), is the most commonly used outside contractor by other states for these four functions. Illinois is one of three states that contracts with other vendors and performs some duties in-house. Below is a description of the categories used in the exhibit. **Appendix E** provides a more detailed overview of all other state PMP contractors.

- **Appriss Only 35** states contract all four database-related tasks to Appriss, a company providing software and technology services.
- Other Contractors Only 6 states (Maine, Maryland, Montana, Nebraska, West Virginia, and Wisconsin) contract all four functions to contractors other than Appriss.
- **In-House 3** states (Kentucky, New York, and Utah) conduct all four database-related tasks in-house.
- Other Contractors/In-House 3 states (California, <u>Illinois</u>, and Wyoming) contract with third-party contractors other than Appriss and perform some database-related tasks in-house. See the **text box** on the following page for more information on Illinois.

 Appriss/In-House – 2 states (Hawaii and Massachusetts) contract with Appriss for some database-related tasks and some tasks are performed inhouse.

Illinois Prescription Monitoring Program

Other Contractors vs. In-House in Illinois

- Data Collection is contracted out to Atlantic Associates, Inc., which obtains, reviews, and cleanses the data from dispensers and long term care (LTC) facilities.
- Data Storage is contracted out to Hanson Information Systems, Inc., which provides hosting services for the PIL and website.
- **Report Generation** is completed in-house by ILPMP staff.
- Data Access is maintained inhouse with the assistance of contractors.
 - The database and website are maintained in-house.
 - Data collection and data storage are contracted out. LogiCoy, Inc. works to integrate EHR systems, maintain connections, and develop/support the website. Eastern Illinois University provides contract IT staff for information technology services.

The Illinois Prescription Monitoring Program (ILPMP) began in 1986 and monitored only Schedule II prescription drugs, including painkillers such as morphine and hydrocodone. The ILPMP began collecting information electronically in 2000. In 2007, the program was expanded to monitor Schedule III through V drugs, including drugs such as Vicodin, Valium, and codeine. See **Exhibit 8** for an explanation of the schedules.

The ILPMP utilizes an electronic database to collect information on controlled substance prescriptions dispensed in Illinois. This data should be reported by retail pharmacies dispensing in Illinois by the end of the next business day. The program enhances the capacity of prescribers, dispensers, and health providers to review a patient's medication history for therapeutic and clinical reasons.

Major Funding Sources for the ILPMP

DHS provided an overview of the ILPMP major funding sources as well as the actual dollars spent for fiscal years 2018, 2019, and 2020. According to DHS, in 2005, the ILPMP began receiving federal funds. Since 2014, the monitoring of Schedule II controlled substances has been supported by GRF funding, while Schedule III to V controlled substances were covered

by grant funding. DHS provided the following descriptions for each of the major ILPMP funding sources:

- **General Revenue Fund (GRF)** The ILPMP uses GRF for salaries, copiers, hosting services, data collection, network scans, graduate students, office supplies, telephone lines, and membership fees.
- Centers for Disease Control and Prevention (CDC) The ILPMP has
 received CDC grants for ILPMP enhancements for project coordinators,
 ILPMP brochures, Department of Public Health (DPH) epidemiologist and
 technical assistance, academic detailing, grant evaluation, continuing
 education, Eastern Illinois University (EIU) IT staff, Electronic Health Record
 (EHR) integration, project managers, technical assistance for local health
 departments, travel, and opioid awareness campaigns.
- Substance Abuse and Mental Health Services Administration (SAMHSA)
 The ILPMP has obtained grants through collaborations with DPH and

DHS's Division of Substance Use Prevention and Recovery to provide funding for ILPMP enhancements, EIU IT staff, advertising, and hospital

integration assistance.

ILPMP Program Details

- What information is provided by the ILPMP? Schedules II-V controlled substance prescription information is provided.
- What records are available? Records are viewable for 12 months and kept on record for at least two years.
- Who submits prescription data? Dispensers in Illinois are mandated to report by the end of the next business day.
- Who can access prescription data on the website?
 - **Physicians**
 - **Pharmacists**
 - Dentists
 - Physician Assistants and Advanced Practice Nurses
 - Other Prescribers and Dispensers

Department of Justice (DOJ) – The ILPMP has received DOJ grants to enhance the ILPMP features and systems. Some enhancements include EHR integration, continuing education, website enhancements, EIU IT staff, ILPMP marketing, travel, and local health department technical assistance.

> In addition, DHS provided the actual dollars spent for each of the major ILPMP funding sources for fiscal years 2018, 2019, and 2020. **Exhibit 3** summarizes these funding sources and provides the funding amount and percent by fiscal year. Exhibit 4 provides a bar chart of these funding sources. As can be seen in these exhibits, the funding sources changed significantly over these three years:

- **CDC** funds decreased significantly from **64.6%** in FY18 to 11.1% in FY20.
- **DOJ** funds increased from 1.8% in FY18 to 6.5% in FY20.
- **GRF** funds also increased from **14.0%** in FY18 to 35.8% in FY20.
- SAMHSA funds increased significantly from **19.5%** in FY18 to **46.6%** in FY20.

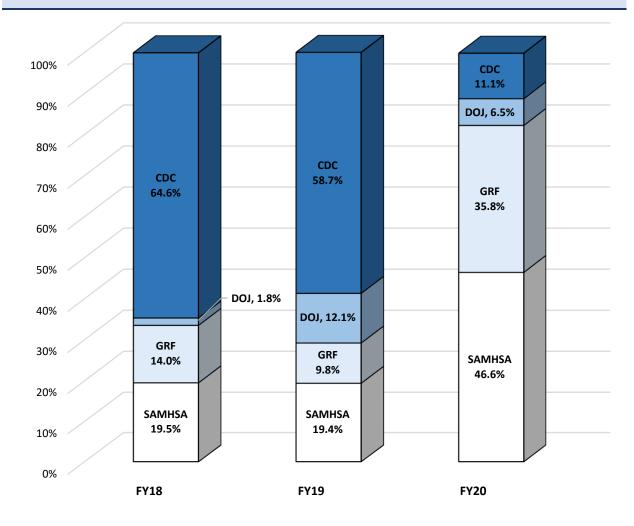
According to DHS, the CDC funding was for a grant that ended during FY20 while SAMHSA funding and GRF funding increased during that same year.

Exhibit 3 ILPMP ACTUAL SPENDING BY FUNDING SOURCE Fiscal Years 2018 through 2020

	FY18		FY1	FY19		FY20	
Funding Source	Amount	Percent of Total	Amount	Percent of Total	Amount	Percent of Total	
CDC	\$1,450,548	64.6%	\$2,467,901	58.7%	\$703,970	11.1%	
DOJ	\$40,170	1.8%	\$506,825	12.1%	\$412,107	6.5%	
GRF	\$315,201	14.0%	\$413,095	9.8%	\$2,261,360	35.8%	
SAMHSA	<u>\$438,185</u>	<u>19.5%</u>	<u>\$815,835</u>	<u>19.4%</u>	\$2,945,729	<u>46.6%</u>	
Total	\$2,244,104	100%	\$4,203,656	100%	\$6,323,167	100%	

Note: Columns may not add due to rounding. Source: OAG prepared from DHS information.

Exhibit 4 **ILPMP FUNDING SOURCE BY PERCENT OF THE TOTAL**Fiscal Years 2018 through 2020



Note: Columns may not add due to rounding. Source: OAG prepared from DHS information.

Organization of the ILPMP

The Illinois Department of Human Services (DHS) is the supervising entity over the Illinois Controlled Substances Act (Act) (720 ILCS 570/1 et seq.). Within DHS, the Bureau of Pharmacy and Clinical Support Services administers the ILPMP. The ILPMP impacts practitioners who write prescriptions and retailers that dispense Schedule II-V controlled substances in the community.

An organizational chart illustrating the reporting relationships for the ILPMP is provided in **Exhibit 5**. This includes employees who provide information technology services related to the ILPMP through Eastern Illinois University (EIU). DHS is the State entity that oversees the ILPMP; however, there are many

contractors and other agencies involved in the process. Due to the number of other entities involved, the ILPMP process is complex. As a result, **Exhibit 6** was created with assistance from DHS to illustrate a process flowchart of the ILPMP. DHS helped provide and approve the following narrative of the ILPMP process as well.

ILPMP Process by DHS

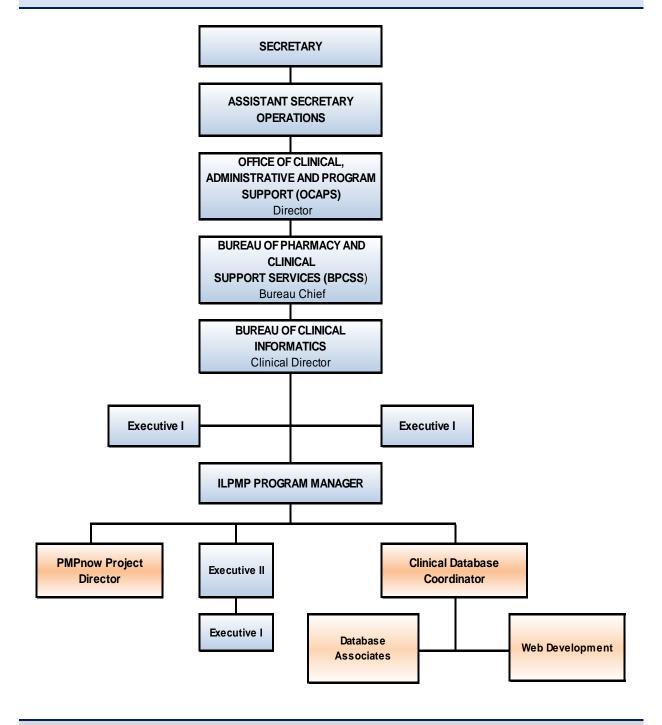
According to DHS, the mission of the ILPMP is to provide prescribers, dispensers, and health providers with the ability to view their current or prospective patient's controlled substance prescriptions for Schedules II-V as dispensed by dispensers in Illinois. DHS said this mission is accomplished through a public facing website located at www.ilpmp.org and an on-demand service available for EHR, Electronic Medical Records (EMR), and Pharmacy Dispensing Systems (PDS). This on-demand service is branded as *PMPnow*.

The *PMPnow* service is an extension of the ILPMP that allows EHR/EMR/PDS and other patient record systems the ability to perform patient queries in an automated fashion. Instead of manually logging into the website and manually entering the patient information, the EHR can make an on-demand one-to-one request to the database or Prescription Information Library (PIL) and return the pertinent information.

Prescribers, dispensers, and health providers register for an account at the www.ilpmp.org website. Once assigned credentials, users can log in and perform a search on their patients. The main benefit of the website is that users can access a patient's rolling 12-month prescription record of controlled substances.

According to DHS, the ILPMP maintains the database and website in-house with the assistance of contractors. In addition, ILPMP staff generate reports in-house. See **Exhibit 6** for a flowchart of the ILPMP data process. This process begins with the data being submitted and ends with data from the PIL being available and integrated on the website and *PMPnow*. This exhibit also illustrates the roles of the ILPMP contractors and other agencies/entities involved.

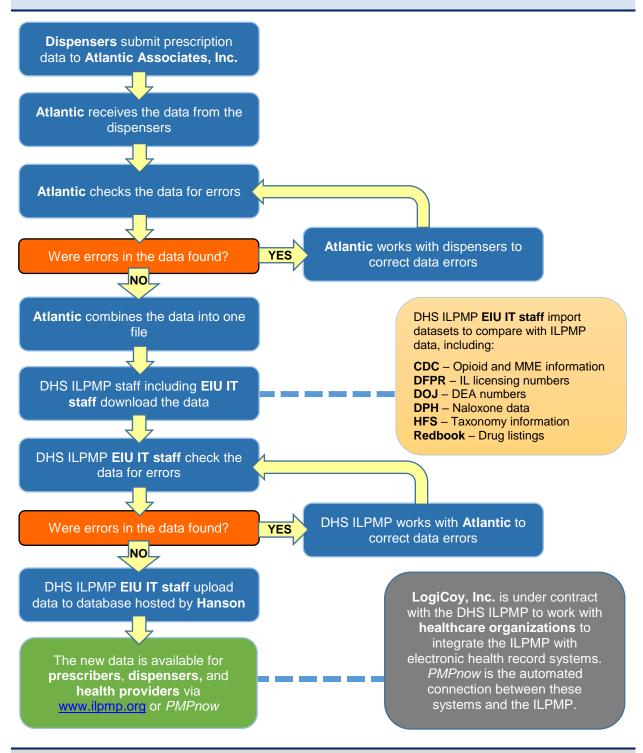
Exhibit 5 **DEPARTMENT OF HUMAN SERVICES ORGANIZATIONAL CHART**ILPMP Program



Note: Blue shading indicates DHS employees. Orange shading indicates EIU contract employees.

Source: OAG prepared from DHS information.

Exhibit 6 ILPMP DATA PROCESS FLOWCHART



Note: This exhibit presents a basic framework of the ILPMP data process and agency responsibilities and is not intended to cover all iterations of the process.

Source: OAG analysis of the ILPMP data process.

ILPMP Contractors

Overview from Contracts

- LogiCoy, Inc. works with hospitals/centers/clinics to integrate EHR systems, maintains these connections, and supports a website and web services for EHR systems/ PMPnow.
- Hanson Information Systems, Inc. provides hosting services for the PIL database and website.
- Atlantic Associates, Inc.
 obtains, reviews, and cleanses
 data on controlled substances
 from dispensers or LTC facilities.
- Eastern Illinois University
 develops and maintains the
 database by providing a Database
 Associate, Data Site Developer,
 and Web Developer.

The responsibilities of the contractors utilized in the ILPMP process are described by DHS below (see the **text box** for an overview from the contracts and **Exhibit 7** for estimated annual contract amounts):

- **LogiCoy**, **Inc.** (**LogiCoy**) assists in the connection needed to integrate EHR systems into *PMPnow*. The *PMPnow* Project Director is contracted to assist in the onboarding of these clients.
- Hanson Information Systems, Inc. (Hanson) provides hosting services for the ILPMP.
- Atlantic Associates, Inc. (Atlantic) receives and reviews pharmacy prescription data. Dispensers are mandated to send a record of their controlled substance dispensing by the "end of the next business day." Atlantic performs an integrity check on submitted files and notifies submitters of errors. Atlantic handles the on-boarding of new pharmacies and data collection. Pharmacies securely log in to the website and upload

their data. Atlantic combines data into a file, and the file is downloaded by ILPMP EIU IT staff.

• Eastern Illinois University (EIU) IT staff perform information technology services for the ILPMP. These services are split into database and web development. Database associates handle the processing of Atlantic data, query and report generation, and database table import/export. Web developers program and maintain the website. These developers aggregate the disparate datasets together to provide users with actionable information to utilize and make an informed patient assessment.

Exhibit 7 ILPMP CONTRACT AMOUNTS

Contractor	Period	Estimated Annual \$	
LogiCoy, Inc.	06/17/19 – 12/31/22	\$3,600,000	
Hanson Information Systems, Inc.	03/01/16 – 03/01/21	\$57,160	
Atlantic Associates, Inc.	07/01/19 – 06/30/21	\$106,700	
Eastern Illinois University	07/01/20 — 06/30/21	\$941,592	
Source: OAG prepared based on current contracts.			

Other Agencies/Entities

According to DHS, the PIL data is compared with data from several agencies/entities. Data is obtained from the Illinois Department of Financial and Professional Regulation (DFPR) and the federal Department of Justice (DOJ) during the user on-boarding process. DHS also works with the Illinois Department of Public Health (DPH) through an interagency agreement for sharing data and coordinates with DPH on grants. Finally, DHS receives additional information from the Department of Healthcare and Family Services (HFS) and Redbook. More specifically, DHS imports data from the following agencies/entities for the timeframe basis noted:

- **CDC** for opioid information and MME (Morphine Milligram Equivalent) conversion factor (**annually**);
- **DFPR** for Illinois license numbers and unregistered providers (weekly);
- **DOJ** for verifying data and drug lists from the Drug Enforcement Administration (DEA) (**weekly**);
- **DPH** for Naloxone data and medical cannabis eligibility (**daily**);
- **HFS** for taxonomy data (**once to date; annually in future**); and
- **Redbook** for all detailed drug information related to controlled substances (**monthly**).

Although DHS imports data from these agencies/entities, the data is currently not being reviewed by DHS before being imported into the PIL. This issue is also discussed in the *Review of General IT Controls* section of this audit.

ILPMP Website Requirements

The ILPMP website allows prescribers and dispensers to view a current or prospective patient's prescription history. The website is intended to assist medical providers to better serve their patients. The ILPMP is required to maintain a website with the requirements outlined below:

- clinical guidelines from healthcare organizations on the prescribing of opioids and controlled substances as determined by the Prescription Monitoring Program Advisory Committee (PMPAC);
- accredited continuing education programs related to prescribing controlled substances;
- programs or information from healthcare professionals that can be used to assist patients or ensure compliance with prescriptions;
- updates from the Food and Drug Administration (FDA) and the CDC relevant to prescribing;
- medical studies relevant to prescribing;
- other information regarding the prescription of controlled substances; and
- information on prescription disposal events, including take-back programs or other disposal options or events.

Although the ILPMP appeared to be maintaining an ILPMP website containing most of the identified requirements outlined in the Act, we noted two requirements that were not identified as of November 2020. We followed up with DHS, and DHS responded that links were added for these two requirements as of January 2021. As a result, we reviewed the website again and verified the two requirements had been added. Although the website requirements were not present during all fiscal years audited, the two missing requirements were added and now the website is in compliance.

MyPMP

In February 2019, ILPMP implemented a new feature called *MyPMP*. ILPMP implemented the *MyPMP* service into the website and will eventually integrate this service with EHR systems (*PMPnow*). The ILPMP, in collaboration with LogiCoy, is in the process of testing the *MyPMP* feature in *PMPnow* connections and expanding into additional EHR systems.

MyPMP is a dashboard display containing summarized patient information for a prescriber. Although dispensers and health providers can access a profile summary for a patient, MyPMP is currently only available to prescribers. According to DHS, the benefits of MyPMP include consolidated information, easy access, new and improved design, and the ability to make an informed decision. In addition, prescribers can see patients that meet potential risk thresholds.

These thresholds include the following potential risk factors among others:

- **Multiple Provider Episodes** patients who have received opioid prescriptions from five or more prescribers and filled them in five or more pharmacies within a rolling six-month period;
- **Opioid-Naïve Patients** patients who have received a new prescription for a long-acting opioid without having received an opioid in the 60 days prior to that prescription;
- Over 90 MME patients receiving, on average, a minimum of 90 MME per day over the last 30 days;
- Overlapping Opioid Prescriptions patients taking multiple opioid medications concurrently in the last 30 days;
- Overlapping Benzodiazepine and Opioid Prescriptions patients taking benzodiazepines and opioid medications concurrently in the last 30 days; and
- Medical Cannabis Card as a Part of the Opioid Alterative Program patients having an active medical cannabis card (but does not provide any information about the actual dispensing of the medical cannabis).

DHS officials stated *MyPMP* helps prescribers identify at-risk patients and track important information to follow these patients more easily. According to DHS, *MyPMP* can be selected from the homepage of a prescriber. *MyPMP* then brings up a rolling 12-month profile of all the risk factors noted above. *MyPMP* allows prescribers to click on each factor and identify the patients under each risk category. See **Appendix C** for screenshots of the *MyPMP* Home Screen and an overview of the *MyPMP* Prescriptions.

DHS officials noted the *MyPMP* functionality was added into their website in March 2019. DHS elaborated that after transitioning to *MyPMP*, the process sped up immensely and reached more prescribers. DHS hopes to expand *MyPMP* to dispensers and health providers.

The Illinois Controlled Substances Act

The Illinois Controlled Substances Act (720 ILCS 570/1 et seq.) governs the distribution and use of a controlled substance in Illinois. The legislative intent of the Act is to curb the abuse of controlled substances by limiting access only to those with lawful and legitimate reasons to possess them by:

- penalizing drug trafficking and profiteering;
- establishing different regulation levels over types of controlled substances;
 and
- providing law enforcement with the resources to effectively enforce the Act.

Illinois Controlled Substance Schedules

The ILPMP is authorized by the Act and applies to Schedule II, III, IV, and V prescription medications. The Act requires all possessing an Illinois Controlled Substance license to register with the ILPMP by January 2018. See **Exhibit 8** for a detailed description of the Illinois Controlled Substance Schedules and for examples of these controlled substances.

DHS is the supervising entity over the Act and is responsible for continually updating the schedules. Within DHS, the Bureau of Pharmacy and Clinical Support Services administers the electronic ILPMP affecting practitioners who write prescriptions and retailers that dispense Schedule II-V controlled substances in the community.

Prescriptions are regulated differently based on whether they are in Schedule II or Schedules III-V. According to the Act, requirements differ by schedule as detailed below:

- **Schedule II** A prescription for a Schedule II controlled substance shall not be issued for more than a 30-day supply. Physicians can authorize up to three sequential 30-day supplies of Schedule II controlled substances for a total of a 90-day supply.
- **Schedules III-V** Prescriptions cannot be filled or refilled more than six months after written or refilled more than five times unless renewed in writing by the prescriber.

Although prescriptions are regulated differently, the ILPMP is responsible for monitoring all controlled substances in Schedules II-V.

Exhibit 8 ILLINOIS CONTROLLED SUBSTANCE SCHEDULES

Effective January 1, 2012

Schedule	Definition	Examples			
Schedule I	 High potential for abuse; and No accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision. 	HeroinLSDPeyote			
Schedule II	 High potential for abuse; Currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions; and Abuse of the substance may lead to severe psychological or physiological dependence. 	HydrocodoneOxycodoneFentanylMethadone			
Schedule III	 Less potential for abuse than substances in Schedules I and II; Currently accepted medical use in treatment in the United States; and Abuse of the substance may lead to moderate or low physiological dependence or high psychological dependence. 	Tylenol with codeineKetamineAnabolic steroids			
Schedule IV	 Low potential for abuse relative to Schedule III substances; Currently accepted medical use in treatment in the United States; and Abuse may lead to limited to physiological dependence or psychological dependence relative to Schedule III substances. 	XanaxValiumTramadol			
Schedule V	 Low potential for abuse relative to Schedule IV substances; Currently accepted medical use in treatment in the United States; and Abuse may lead to limited physiological dependence or psychological dependence, or the substance is a targeted methamphetamine precursor as defined in the Methamphetamine Precursor Control Act. 	Robitussin ACLyrica			
Source: OAG summary of Illinois Controlled Substances Act drug schedules and DEA.					

Prescription Information Library

The Act establishes a PIL (or database), which must be developed to allow inquirers access to records for an individual patient or customer from the last 12 months. Access is read-only and may require technical assistance from the ILPMP through LogiCoy to establish a secure connection. The PIL shall automatically generate a login to the inquiry system when a prescriber or dispenser obtains or renews a controlled substances license.

According to DHS, prescribers and dispensers can access the PIL information through two methods: (1) logging into the ILPMP website or (2) utilizing the integration of the PIL with the EHR systems (*PMPnow*).

Since procedures were not conducted by DHS to ensure the completeness and accuracy of the data, we found **the data from the PIL was not complete** (see the *Review of General IT Controls* section of this audit.)

Illinois Administrative Code for the ILPMP

The Illinois Administrative Code (77 Ill. Adm. Code 2080) establishes the authority held by DHS to control the abuse of Schedule II, III, IV and V retail dispensed drugs. The Administrative Code further establishes the requirements for prescribers when prescribing a controlled substance, whether written, electronic, facsimile, or verbal order. The majority of these requirements are outlined in the Act. However, some prescription requirements are only found in the Administrative Code.

Prescription Requirements in the Administrative Code

The following prescription requirements were found only in the Administrative Code:

- The prescriber's electronic or handwritten signature, initials, thumbprint, or other biometric or electronic identification process must be affixed to the face of the prescription;
- A written prescription must be in ink with a pen, typewriter, or computer printer or with an indelible pencil;
- The prescription must specify the drug name, strength, dosage, and form;
- The prescription must contain only one Schedule II drug prescription order per prescription blank; and
- The prescription may allow more than one prescription order per prescription blank for a Schedule III, IV, or V drug.

The Administrative Code also establishes the elements for positive identification when filling a prescription, including sex, birthdate, and another verifying element that is at the discretion of the pharmacy or chain. The options for this element listed in the Administrative Code are a driver's license or equivalent, State issued ID, patient's home phone number, an internal pharmacy ID system, employer ID, student ID, or insurance ID.

Prescription Information Library Access

The Illinois Administrative Code (77 Ill. Adm. Code 2080) provides specifics about the process for eligible entities to obtain access to the PIL. The Administrative Code states the Bureau of Pharmacy and Clinical Support Services shall establish, operate, maintain, and enhance a stand-alone, one-to-one secure link that shall function as a prescriber, dispenser, and health provider inquiry system to be known as the PIL. The Bureau must additionally install a system to track each use of the PIL. In the event that an unregistered user is believed to have attempted to gain access to the PIL, staff is required to report the incident to DHS.

More specifically, the Administrative Code details the process for eligible entities to obtain PIL access.

- First, an entity must email the ILPMP to obtain an Automated Connection Guide (ACG) and share it with its IT support team and the vendor for its EHR system to prepare for integration.
- At this point, the entity must complete a Meaningful Use Registration of Intent with DPH in order to schedule a connectivity consultation with the ILPMP.
- Finally, ILPMP staff (via LogiCoy) will establish a secure, Health Insurance
 Portability and Accountability Act (HIPAA) compliant electronic integration
 with the PIL. All entities must maintain both physical and electronic security
 of their data and report any misuse or security failures per federal HIPAA
 requirements.

The Administrative Code establishes who qualifies to be a designee with ILPMP access. The Administrative Code states a prescriber or dispenser shall only have up to three (3) designees. The ILPMP shall send notices to prescribers or dispensers to ensure those no longer employed with the entity no longer have access to the ILPMP. The Clinical Director or his/her designee shall review unusual applications to make a determination on access and shall directly monitor the development, modification, and/or expansion of the program. Finally, the PMP Assistant Administrator is tasked with reviewing the user access log for suspicious activity.

Fully Implemented Program and Interfacing EHRs

DHS has not fully implemented an ILPMP in accordance with State requirements. All EHRs were not fully implemented and able to interface with the ILPMP by January 1, 2021, as required. In addition, DHS could not provide the total universe of EHR systems or the total percentage of EHRs that had been interfaced as of January 1, 2021.

Legislative Audit Commission Resolution Number 154 asked auditors to determine whether DHS has fully implemented a Prescription Monitoring Program in accordance with State requirements including whether updated rules were adopted within one year of the effective date of Public Act 100-0564 and whether all Electronic Health Records Systems were able to interface with the Prescription Monitoring Program application program on or before January 1, 2021.

Effective January 1, 2018, all prescribers with a controlled substances license in the State of Illinois shall register with the ILPMP. Exceptions for these requirements are provided for both long term care (LTC) facilities and veterinarians. According to the Act, LTC pharmacies only need to report to the ILPMP on a monthly basis, and veterinarians are now exempt from reporting. In addition, Public Act 100-0564 implemented updated requirements for the ILPMP related to the first audit determination in this audit.

Updated Administrative Rules

Deadlines established by Public Act 100-0564 required the ILPMP to fully implement an ILPMP in accordance with State requirements including updating administrative rules within one year or by January 1, 2019. Although Public Act 100-0564 contained these updated requirements, the Administrative Code was not updated by January 1, 2019, as required. However, as of June 24, 2021 (or almost 2 ½ years later), administrative rules were updated pertaining to these requirements. According to DHS, these rules were published on July 9, 2021.

EHR Systems

Deadlines established by Public Act 100-0564 also required all EHR systems to interface with the ILPMP application program by January 1, 2021. This interfacing would ensure all providers have access to specific patient records. According to DHS, although the process of integrating EHR systems was in progress, all EHRs were not fully implemented and able to interface with the ILPMP by January 1, 2021, as required. DHS noted these delays were due to the implementation process being slowed down by COVID-19.

DHS was also required to establish actions to be taken if a prescriber's EHR system did not effectively interface with the PIL within the required timeline. However, DHS stated that the status on EHR integration could not be provided because the total universe of EHRs could not be determined by DHS. DHS stated there was no complete list of all locations that provide healthcare services in Illinois. Therefore, DHS could not provide the total percentage of EHRs that had been interfaced by January 1, 2021, as required. When asked when the total

universe of EHRs was expected to be interfaced as required, DHS could not provide an estimated date. DHS responded "to the best of our ability we will connect as many EHRs as we can."

Since all EHRs were not interfaced by January 1, 2021, as required, the timelines established by Public Act 100-0564 were not met during the audit period. As a result, the ILPMP was not fully updated or able to ensure all providers have access to specific patient records and faster transmission of this information, as required.

Fully Implemented Administrative Rules and Interfacing EHRs

RECOMMENDATION NUMBER

The Department of Human Services should fully implement an ILPMP in accordance with State requirements by ensuring all EHRs are fully interfaced with the ILPMP, as required.

1

DHS Response:

The Department accepts the recommendation. The Department took extensive steps to provide marketing and outreach for PMPnow. We currently have 203 hospitals and health systems, which is 97% of hospitals and health systems connected or actively engaged in the connection process, in addition to many other unique health care entities already connected. The Department will continue to work towards connecting all EHR Systems or their designated Health IT Module willing and able to provide a one-to-one connection between the ILPMP and providers, as required by Illinois law.

Auditor Comment:

As noted in Public Act 100-0564, DHS was required to "establish actions to be taken if a prescriber's Electronic Health Record System does not effectively interface with the Prescription Monitoring Program within the required timeline" or by January 1, 2021. During the audit, we asked DHS about the status of EHRs being interfaced, as required. DHS responded that the status on EHRs could not be provided because the total number of EHRs could not be determined by DHS. Therefore, the 97% referenced above appears to be missing additional context. In addition, it is unclear if the "actions to be taken" toward EHRs not interfaced would be effective, since the total number of EHRs could not be provided by DHS during the audit.

Imposing Fines

DHS has not imposed fines or ensured dispensing reporting requirements are being implemented, as required. DHS has not updated the Illinois Administrative Code to align with the Act or developed a formal plan to ensure dispensing reporting requirements are being implemented.

Legislative Audit Commission Resolution Number 154 asked auditors to determine whether DHS is utilizing its authority to impose fines when dispensing reporting requirements are not being reported as required for the ILPMP.

The Illinois Administrative Code (77 Ill. Adm. Code 2080) makes imposing fines for violating the ILPMP reporting controlled substance dispensing a requirement. According to the Act, DHS **may** impose a civil fine of up to \$100 per day for willful failure to report the dispensing of a controlled substance. However, the Administrative Code establishes DHS **shall** impose a civil fine of \$100 per day for willful violations of the ILPMP reporting requirements.

According to DHS officials, **fines have not been imposed or collected for the ILPMP to date**. In addition, DHS officials said there is not enough staff or a formal plan for compliance in place.

Since fines were not being imposed, we followed up regarding how DHS is ensuring dispensing reporting requirements are being followed. According to DHS, software would be needed to ensure this and identify non-compliant pharmacies. DHS currently works with Atlantic Associates, Inc. to determine if a pharmacy "is past due by more than a few days, (and) the ILPMP will notify the pharmacy to get them to report on time." Therefore, there is no formal plan in place to ensure compliance with dispensing reporting requirements. In addition, although the Act and the Administrative Code require the "date dispensed" to be submitted by dispensers, the ILPMP is not obtaining or tracking this information (see additional information under the *Dispenser Requirements* section of this audit). Therefore, the ILPMP is not ensuring dispensing reporting requirements are being implemented.

According to DHS, the ILPMP is in the process of proposing updates to the Administrative Code that would change the "shall" referenced in the current version to "may" in order to align with the Act. We reviewed the proposed updates to the Administrative Code (77 Ill. Adm. Code 2080) and found the updates propose to change this language as suggested. However, DHS was not meeting this fining requirement as outlined in the Administrative Code effective during the audit. In addition, DHS has not established a formal plan to help ensure dispensing reporting requirements are being implemented as required.

RECOMMENDATION NUMBER 2 The Department of Human Services should: • update the Illinois Administrative Code to align with the Illinois Controlled Substances Act related to imposing fines; and • develop a formal plan to help ensure dispensing reporting requirements are being implemented as required.

DHS Response:

The Department accepts the recommendation. The Administrative Code has already been drafted to align with the Illinois Controlled Substance Act related to imposing fines. Proposed rules were submitted to the Illinois General Assembly's Joint Commission on Administrative Rules on February 11, 2021. The Department will develop and implement a formal pharmacy compliance plan for dispensing reporting requirements.

Data Accuracy

DHS has not established general information technology controls over the data. Significant deficiencies related to contractual services, business processes, change control, disaster recovery, and security were also identified. Until these deficiencies are corrected, **the ILPMP data and reporting with respect to that data cannot be relied upon.** DHS has also not established a process to ensure licensing data utilized by the ILPMP does not contain invalid or outdated information. This includes not establishing an interagency agreement with DFPR. In addition, DHS has not established a process with DPH to conduct data reviews of sports and accident injuries as required by the Act.

Legislative Audit Commission Resolution Number 154 asked auditors to determine whether the Department's database is accurate and up-to-date including if information submitted by dispensers is complete and timely. Timeliness is addressed in the section on dispenser requirements.

DHS utilized two databases to operate the Prescription Monitoring Program. The production database includes prescription data obtained from dispensers. The archive database stores archived data and is used to run reports.

We worked with our IS auditors to obtain and review the data needed to address the determinations in this audit. The following two datasets were requested:

- the last 12 months of data from the production database of the PIL as well as documentation supporting the completeness and accuracy of the data; and
- a listing of all active accounts (including user name, type of user, license number, date access approved, last login date) and documentation demonstrating the listing is complete and accurate.

After numerous requests and meetings, useable data was finally obtained from DHS. However, the datasets provided by DHS were problematic, and we cannot rely on the data provided by DHS.

Review of General IT Controls

The *Review of General IT Controls* (Review) performed by IS auditors found significant problems with the data and concluded the data cannot be relied upon. More specifically, the Review found the following:

As a result of the Department's failure to obtain, review, and fully understand the service providers' general IT controls as it related to the Prescription Monitoring Program (website, PMPnow, and PIL) and because we are unable to determine the adequacy of the service providers' general IT controls over the Prescription Monitoring Program, we are not able to rely on the data and reporting with respect to our testing of the Prescription Monitoring Program.

The Review found significant deficiencies related to the following five areas: contractual services, business processes, change control, disaster recovery, and security. These significant deficiencies are discussed in more detail below.

Contractual Services

In order to develop and implement the website, *PMPnow*, and the PIL (or database), DHS contracted with four entities to provide various services. The *Review of General IT Controls* noted the following deficiencies with each of the four contracts.

- LogiCoy, Inc. (LogiCoy) The Review noted the contract and amendments did not provide for auditing or reviewing of LogiCoy's internal controls over the security and development of the connections or PMP website.
- **Hanson Information Systems, Inc.** (**Hanson**) The Review noted the contract **did not** document a review of internal controls over the hosting services.
 - In response to requests for reports reviewing/examining the internal controls of the environment, DHS provided the following: Vulnerability Assessment Reports, Information Security Policies, and Data Center Specifications. However, this information did not provide assurance that the controls had been implemented and/or were operating effectively.
- Atlantic Associates, Inc. (Atlantic) The Review noted the contract did not document the requirements for a review of the internal controls related to the security and cleansing of the data.
- Eastern Illinois University (EIU) The Review noted the contract and amendments did not require the University to provide documentation of the internal controls related to the development and maintenance of the PIL.

Business Processes

The Act requires dispensers to transmit to the central database information on controlled substances dispensed no later than the end of the next business day. The data is submitted by the dispensers to Atlantic Associates, Inc. using the American Society for Automation in Pharmacy format. Atlantic then conducts validity checks of some field values (including length, characters, etc.) and kicks back error reports to the dispensers. Atlantic consolidates the file into a single file and uploads it to a secure server. EIU IT staff then download the file to an Access database and verify the data by running various scripts for integrity. From there, it is uploaded to the webserver and archives (PIL).

When DHS receives the data from Atlantic, there **is not a reconciliation** conducted to ensure the completeness and accuracy of the data downloaded. The download does utilize a Secure File Transfer Protocol, which includes data integrity verification built into the protocol. When the data is uploaded to the servers, reconciliation is also performed by monitoring row count. However, there is no documentation maintained of the reconciliation of row counts.

According to DHS, **not all dispensers are providing data**. Additionally, they are not conducting follow-up with these dispensers to determine why they are not complying with the Act.

In addition, DHS receives data from the various sources. As discussed in the *Other Agencies/Entities* section of this audit report, these sources include: CDC, DFPR, DOJ, DPH, HFS, and Redbook. However, according to DHS, there are no procedures conducted to ensure the completeness and accuracy of the data obtained.

DHS developed the ILPMP Policies and Procedures Manual (Manual) to provide guidance related to:

- data and access;
- security;
- requests; and
- PIL design.

However, the Review noted the Manual contained:

- blank, incomplete, or missing sections;
- statements/sections not in compliance with the requirements of the Act; and
- inaccurately documented current processes or practices.

Change Control

DHS does not have a formalized internal control process to control changes to the PIL. DHS stated there is an ad-hoc process, but nothing is formalized. As such, we are unable to design suitable audit procedures to determine if changes to the PIL were properly controlled.

In addition, we noted the developers have access to the production environment, thus creating **a segregation of duties weakness**.

Disaster Recovery

DHS and Hanson developed the ILPMP IT Disaster Recovery Plan Template (Plan), which was last revised in September 2020. According to the Plan, "this document delineates our policies and procedures for technology disaster recovery, as well as our process-level plans for recovering critical technology infrastructure. The document summarizes recommended procedures. In the event of an actual emergency situation, modifications to this document may be made to ensure physical safety of our people, our systems and our data." The Review noted the Plan did not document all recovery team members or the recovery of the website.

Security

In order for a user to obtain access, a user must submit the online registration form. The information from the registration form is then validated against various other sources to ensure the identity and validity of the user's request. Specifically, DHS is to ensure:

• The user's State license is verified as valid against the DFPR professional licensing database or the licensing state's database.

• The user's DEA number is valid and not expired.

In the event the user's information is not valid or unable to be validated, DHS is to email the user stating the noted problems and deny access. In order to determine if user's information was being properly validated, we obtained the population of active users. Our Review noted significant problems.

Regarding license numbers, there were accounts with:

- no license numbers;
- only one letter or number;
- "test" as license; and
- alpha and numeric values, which do not comprise a license number.

According to the Manual, the individual's license is to be validated against the DFPR license database. Therefore, we are unable to determine how DHS is validating the user's license with the Department of Financial and Professional Regulation's licensing database.

In addition, once the user's license is validated upon initial request, **the user's license is not revalidated** to ensure continued validation. According to DHS, reviews of user access are not conducted. Furthermore, DHS does not take actions to determine if a user's license continues to be valid. In fact, DHS was unaware of how a user's access was handled if they no longer required access. Upon further review of the **48,818 total active users**, we noted:

- **Authorization Date** There were 137 accounts without an authorization date. Additionally, there were 14,692 accounts with an authorization date of February 2016 or older.
- Last Login Date There were 19,501 accounts that appear to have never logged in.

Finally, there were 3,928 accounts with a last login date of more than 12 months prior. According to the Manual, Section 1.50, if an account has been inactive for a period of more than 12 months, the ILPMP administrator will inactivate the account. According to DHS, there was an error in one of the scripts, which did not deactivate inactive accounts. DHS does log each user's activity; however, the logs are not reviewed unless an issue is brought to its attention.

Regarding the five areas identified above, DHS indicated the significant deficiencies were due to a lack of resources or were the responsibility of the contractors. Without established general IT controls over the data and continued significant deficiencies related to the six areas discussed above, the ILPMP data and reporting with respect to that data cannot be relied upon.

Lack of Controls Over the Data

RECOMMENDATION NUMBER

3

The Department of Human Services should establish general information technology controls over the data and correct the significant deficiencies related to contractual services, business processes, change control, disaster recovery, and security. Until these deficiencies are corrected, the ILPMP data and reporting with respect to that data cannot be relied upon.

DHS Response:

The Department accepts the recommendations. Although IDHS currently applies various data validation methods to the data that it receives and aggregates, we will continue to improve upon IDHS's information technology controls, including regarding contractual services, business processes, change control, disaster recovery, and security.

Auditor Comment:

Although DHS stated it applies "various data validation methods to the data that it receives and aggregates," no documentation was provided for these data validation methods during the audit. In addition, general information technology controls were not established over the data and our testing documented discrepancies within the data. If the various data validation methods had been applied as indicated in DHS's response, the number and type of discrepancies noted would not have occurred. As such, we were unable to rely on the data and reporting with respect to our testing of the Prescription Monitoring Program.

DFPR Data

As discussed previously, the PIL data is compared with data from other agencies. The Illinois Controlled Substances Act (720 ILCS 570/1 et seq.) provides key information detailing the role of DFPR. DFPR issues and maintains State licenses for prescribers, dispensers, and their designees and has the authority to issue fines. DFPR must provide DHS with electronic access to license information of a prescriber or dispenser. DFPR can also levy punitive actions, deny or refuse to renew applications, or suspend or revoke licenses as outlined in the Act.

According to DHS and DFPR, there is no interagency agreement between the two agencies that outlines each agency's responsibilities related to the licensing data. DHS explained a weekly file is provided by DFPR with licensing information. Registration information populates based on name and licensing information on the ILPMP website. If DFPR data matches, registrations are automatically validated. Any registrations not automatically validated are handled by ILPMP EIU staff. According to DHS, there are no periodic reviews of valid licenses after being added to the ILPMP. When asked if outdated licensees are removed by DHS, DHS officials stated no. According to DHS, there is not a process in place to check licensing data utilized by the ILPMP for invalid or outdated information.

Therefore, we also followed up with DFPR. DFPR does not notify DHS of orders denying, suspending, or revoking registration to distribute or dispense a controlled substance. DFPR only provides updated lists of new licenses to DHS on a weekly basis. In addition, we verified that DFPR does not impose any fines for willful

violations of the ILPMP dispensing requirements. Through communications with DHS and DFPR, we concluded there is no additional coordination between the agencies to address potential issues such as: reporting any non-compliance with the Act, investigating potential misuse of the PIL (or database), or disciplining non-compliant prescribers, pharmacies, or other ILPMP users.

DFPR Data Review

We requested DFPR data for all individuals prescribing and dispensing controlled substances in Illinois. We compared the data to active users to determine if valid licenses were required in order to access the ILPMP. This comparison is also discussed in the *Review of General IT Controls* section of this audit.

As a result of this comparison, we identified 2,287 registered users without a valid license and therefore, the ILPMP was not ensuring that all users with access rights to the PIL had valid licenses. Of the 2,287 registered users without a valid license, 8 were users that were responsible for maintenance of the PIL and would not have been required to have a license. The remaining 2,279 users without a valid license fell into the below groups:

- 7 users with the role of **Coroner**;
- 44 users with the role or **Designee**;
- **184** users with the role of **Law Enforcement**;
- 248 users with the role of **Pharmacist**; and
- 1,796 users with the role of **Prescriber**.

Without an established process, the ILPMP is at risk for having individuals with invalid or outdated licenses with continued access to the ILPMP. The lack of an interagency agreement and lack of coordination between DHS and DFPR contributes to this risk.

Accurate Licensing Data				
RECOMMENDATION NUMBER 4	The Department of Human Services should establish a process to ensure the licensing data utilized by the ILPMP does not contain invalid or outdated information. The Department of Human Services should consider establishing an interagency agreement with the Department of Financial and Professional Regulation outlining each agency's responsibilities related to the licensing data.			

DHS Response:

The Department accepts the recommendation. The Department will work with the Illinois Department of Financial and Professional Regulation (IDFPR) to establish a process to validate licensing data. Subject to IDFPR's agreement and, as necessary, the Department will establish an interagency agreement with IDFPR, outlining each agency's responsibilities related to licensing data.

DPH Data

According to DHS, DPH is supposed to share data on Naloxone administrations, medical cannabis eligibility, and hospital discharge data. DHS further explained that Naloxone data is updated as frequently as every 15 minutes and medical cannabis eligibility information is updated once a day. According to DPH, DPH receives hospital discharge data quarterly from facilities.

DHS also noted four CDC grants requiring coordination between DHS and DPH related to data sharing and/or project coordination. The four CDC grants referenced during the audit period included:

- Overdose Data to Action grant (*ongoing* 8/31/2021);
- Enhanced State Opioid Overdose Surveillance grant (*ended* 8/31/19);
- Prescription Drug Overdose Prevention for States grant (ended 8/31/19); and
- Public Health Crisis Response grant (*ended* 6/30/20).

DHS provided three associated intergovernmental agreements for these grants. According to DHS and DPH, there was no intergovernmental agreement for the Enhanced State Opioid Overdose Surveillance grant because no funds or identifiable data were exchanged between the agencies for this grant. DPH officials also noted contract work and the exchange of data between DHS and DPH was delayed during the audit period due to COVID-19.

Lack of Sports and Accident Injury Data Reviews

According to Public Act 100-1093, effective August 26, 2018, DHS and DPH are required to coordinate continuous reviews of ILPMP and DPH data to determine if a patient may be at risk for opioid addiction. Each patient discharged from a medical facility with a specific classification related to a sport or accident injury shall be subject to data review. However, **no reviews of sports and accident injury data were conducted in FY19 and FY20**.

In addition, DHS was not alerting prescribers whose discharged patients were dispensed a controlled substance. If the discharged patient is dispensed a controlled substance, the ILPMP is required to alert the patient's prescriber as to the addiction risk and urge the following of CDC guidelines and/or the respective treatment guidelines for the patient's injury. As of February 2021, DHS was in the early stages of developing a process for monitoring this and piloting the Injury and Accident Notification System with several pilot sites. Therefore, alerts were not sent to prescribers whose discharged patients were dispensed a controlled substance in FY19 and FY20.

According to DHS, the process for monitoring sport and accident injuries is still in the early stages of development. DHS and DPH are currently coordinating to exchange datasets for sports and accident injury information and creating reports. DPH and DHS are also working to define codes related to sports injuries.

As of January 2021, DHS and DPH were working to test data pull and linkage for the diagnosis code related to sports and accident injuries. According to DPH, this project was delayed due to COVID-19, but DPH was actively working to provide needed data to the ILPMP. DPH officials stated the data elements, filters, and transfer process have been defined. DPH was also testing the connection.

According to DPH, DPH plans to complete this project by December 2021 but could not commit to an implementation date with the uncertainty of COVID-19. Although DHS and DPH continue to make progress, these reviews were not being completed during our audit as required by the Act. The lack of reviews for sports and accident injuries and alerts to prescribers puts these patients at an increased risk for addiction.

Sports and Accident Injury Data Reviews

RECOMMENDATION NUMBER

5

The Department of Human Services and the Department of Public Health should establish a process to conduct data reviews of sports and accident injuries as required by the Act. In addition, the Department of Human Services should alert prescribers whose discharged patients were dispensed a controlled substance about the risk of addiction and applicable guidelines.

DHS Response:

The Department accepts the recommendation. The Department will continue efforts to work with Illinois Department of Public Health (IDPH) to establish a process to conduct data reviews of sports and accident injuries as required by the Act. IDHS will work to alert prescribers whose discharged patients were dispensed a controlled substance about the risk of addiction and applicable guidelines.

IDPH did not actively exchange hospital discharge data or syndromic surveillance data during the audit period. IDHS will work with IDPH to ensure that IDHS receives this data in a timely manner.

DPH Response:

The Department accepts the recommendation. Specifically, DPH's role is to identify sports and accident injuries through its surveillance systems and provide DHS with this data. The multi-step process to provide this data is nearly complete (approximately 80%), including working with DHS to define injury codes and data elements and testing the initial pull of injury data. DPH anticipates completing the remaining steps by December 2021, which will include the automation of data queries and data transfers, and user testing.

Outdated ILPMP Policies and Procedures Manual

DHS has not updated the ILPMP Policies and Procedures Manual (Manual). The Manual currently contains outdated information and does not contain specific information about data security or the handling of law enforcement requests.

In addition to the review performed of the Manual as part of the *Review of General IT Controls*, we reviewed the Manual in more detail during this audit. The following additional information can be noted about the Manual.

- DHS provided the Manual to document many of the needed elements to support the database.
- DHS confirmed that although the Manual states "draft," the July 2019 version is final.
- The Manual covers important topics such as ILPMP Data and Access, ILPMP Security and Safeguards, ILPMP Requests, and PIL Design.

According to DHS, the Manual was noted as current and final. However, through requirements identified in the Act, meetings with DHS, and follow-up questions, we determined the Manual was outdated (including examples dating back to 2011 and 2013) and contained inaccurate information. The following eight areas document the Manual was outdated and requires updating.

- Timeframes for Prescription Records In the Manual, DHS stated dispensers and retail pharmacies submit prescription information on a weekly basis to the ILPMP. However, the Act requires dispensers to transmit information not later than the end of the next business day. When we followed up with DHS, officials stated the Manual needed to be updated. The Manual also included information on a biweekly file from Atlantic Associates, Inc. being imported into the ILPMP server. However, we determined Atlantic submits prescription data to the ILPMP by the end of the next business day, and then the ILPMP staff upload the data the same day it is received in most cases.
- Error Screening The Manual stated the ILPMP database is <u>screened</u> for erroneous prescription entries before being uploaded to ensure data is accurate. When asked for documentation supporting these screenings, DHS said reviews are conducted daily and issues are fixed on the spot. **DHS stated there is no documentation or support for these reviews or screenings**.
- **Dispenser Timeliness** According to the Manual, pharmacies <u>not reporting</u> their controlled substances dispensed, as required by the Act, are contacted to ensure compliance and completeness of the PMP database. However, when asked how this contacting is being monitored and how the ILPMP knows if dispensing information is not reported, DHS said not all pharmacies submit data daily. Since all pharmacies do not report every day, **DHS officials stated this reporting cannot be monitored**.

- **Reporting Requirements** According to the Manual, the ILPMP prepares a monthly abstract report to determine if any patient is obtaining controlled substances from six prescribers and six dispensers (or more) within a month (6-6-1 reports). If a patient meets the criteria, an advisory report is sent to the prescribers and dispensers. A sample of the letters sent by the ILPMP is included in the Manual as an attachment. However, according to DHS, the ILPMP identifies patients obtaining controlled substances from five providers and five prescribers within a six-month period (5-5-6 reports). In addition, according to DHS, the ILPMP stopped sending letters through the mail to prescribers as of September 2018. In January 2019, a new *MyPMP* feature was implemented. Although the ILPMP does not provide letters when patients meet these criteria, users can initiate and utilize unsolicited reports through this new feature for this information.
- User Authorization The Manual states prospective PIL users complete registration forms through the ILPMP website. The Manual also states DHS verifies the authenticity and validity of the registration request by checking the license status of the applicant on the DFPR website, looking up the registrant DEA number, and verifying the contact information and place of employment through internet searches. However, according to DHS, the user authorization process includes automatic validation based on DFPR controlled substance license data.
- **PIL Data Format** The Manual references <u>47</u> fields in the PIL; however, according to DHS, the number of fields in the PIL changed several times in 2020. As of June 2020, the PIL contained <u>55</u> fields. Further, the Manual states the format for prescription data is the ASAP 2007v.4.1 format, while the current standard used by the ILPMP is version 4.2A from 2016.
- Former Employees Former employees are referenced throughout the Manual. Two employees are mentioned for their roles in the process of accessing, modifying, and loading data into the database. However, these individuals were not ILPMP employees as of September 2020.
- Law Enforcement Requests The Manual states law enforcement requests can come by mail, fax, or email. According to DHS, the ILPMP still processed fax/email requests but was transitioning users over to the Law Enforcement Online Request (LEOR) process, whereby law enforcement request a website account through the ILPMP website. See below for additional information on law enforcement requests.

Law Enforcement Requests

Although the Manual describes the process of fulfilling a law enforcement request, DHS noted the current policies in the Manual are outdated. According to DHS, there are no formal agreements with law enforcement officials. Law enforcement can make requests via mail, fax, email, or through an <a href="https://linear.com/linear.co

According to the Manual, the requestor is required to be informed of possible problems with the data as well as to only use the data as an aid in an investigation, not to use the data as the main basis for conviction, and such information is not to be made public. We followed up on what happens to the data after being provided to law enforcement. DHS noted that the requested prescription information is sent using the State's secure service. Because some requested information is provided to law enforcement officials pursuant to a subpoena, DHS could not attest to how the data is handled after being provided.

According to DHS, the ILPMP is transitioning to using the Law Enforcement Online Request (LEOR) system. The system does not allow any search capabilities for law enforcement. These users log in and answer various questions. Requests are then reviewed by staff. Once approved, staff use the State's secure service to send the requested data to law enforcement.

We reviewed the law enforcement data on the ILPMP website and the grant report totals to determine the total number of law enforcement requests made in CY19 and CY20. Although DHS officials estimated around 500 law enforcement requests a year, the totals from the ILPMP website and the DOJ grant reports supported a more significant number of law enforcement requests in CY19 and CY20. The data from the ILPMP website displayed 1,912 requests in CY19 and 1,043 requests in CY20. Meanwhile, the DOJ grant reports showed 1,665 requests in CY19 and 833 requests in CY20. Therefore, as seen in **Exhibit 9**, the totals represented a difference of 247 requests in CY19 and 210 requests in CY20.

Exhibit 9 **DIFFERENCE IN REPORTED NUMBER OF LAW ENFORCEMENT REQUESTS**Calendar Years 2019 through 2020

Year ¹	ILPMP Website	DOJ Grant Reports	Difference ²
2019	1,912	1,665	247
2020	1,043	833	210

Notes

- ¹ The annual numbers were totaled by auditors from monthly data.
- ² According to DHS, the law enforcement data from the ILPMP website is more accurate due to other states being entered incorrectly or filtered out of the DOJ grant reports.

Source: OAG prepared from DHS data.

We followed up with DHS about the difference in the number of requests from the ILPMP website compared to the DOJ grant reports. According to DHS, although all law enforcement requests are included on the ILPMP website, sometimes other states are not counted in the DOJ grant reports due to the name being entered incorrectly or filtered out. Therefore, according to DHS, the ILPMP website data is more accurate while the DOJ grant reports do not include all requests. DHS further stated that the problem with these discrepancies has been resolved but only when using the online form for law enforcement requests. According to DHS, a pre-filled form is now used for online requests allowing the

user to choose their state from a drop-down menu. Therefore, the updated online form would not affect the law enforcement requests made by mail, fax, or email.

Due to the significant number of law enforcement requests and confidential data being provided in response to these requests, the lack of current policies in the Manual related to law enforcement requests is problematic and needs to be updated.

Conclusion

According to DHS, although the copy of the Manual provided was the most current available, the Manual is under revision. The ILPMP policies, procedures, and website have all changed considerably since the Manual was fully revised. DHS is reviewing the current policies, amending them as needed, and prioritizing the inclusion of new ones. After necessary consultations, DHS plans to implement new procedures and monitor, review, and revise as necessary.

The Manual covers important topics, including ILPMP Data and Access, ILPMP Security and Safeguards, ILPMP Requests, and PIL Design. As stated previously, the Manual being outdated supports that DHS has not established general IT controls over the data. In addition, the ILPMP's significant procedures cannot be effectively implemented under an outdated Manual.

Update the ILPMP Policies and Procedures Manual

RECOMMENDATION NUMBER

6

The Department of Human Services should update the ILPMP Policies and Procedures Manual as it is currently outdated. The updates should include current policies related to law enforcement requests.

DHS Response:

The Department accepts the recommendation. The Department will update the ILPMP Policies and Procedures Manual.

Dispenser Requirements

DHS has not required dispensers to submit specific information as required by the Illinois Administrative Code and Act. In addition, DHS has not required dispensers to submit information by the end of the next business day, as required by the Act. Finally, DHS has not followed up on problematic information submitted by dispensers including prescription records with patients over 110 years old, records with an animal species code, and/or records with an invalid patient name.

As stated in the Act and the Administrative Code, dispensers must submit specific information to the ILPMP (see the **text box** for this specific information), and all information must be transmitted by the end of the next business day after the date on which a controlled substance is dispensed. When asked how the ILPMP knows if required dispensing information is reported by the end of the next business day, DHS said not all pharmacies submit data daily so DHS cannot monitor this reporting. Regardless, once the information is collected, the data is held in the PIL, and all entries must be searchable by field.

Date Filled, Date Dispensed, and Date Sold

Required to be Submitted by Dispensers:

- patient ID;
- patient location code;
- patient name and address;
- patient date of birth and gender;
- date prescription written;
- date prescription filled;
- date controlled substance dispensed;
- quantity dispensed/days supplied;
- national drug code number of the controlled substance dispensed;
- payment type used to purchase the controlled substance;
- prescriber's and dispenser's DEA numbers;
- dispenser's full name and address; and
- prescriber's full name.

According to the Act, the <u>date filled</u> for a controlled substance and the <u>date dispensed</u> for a controlled substance **are both required to be submitted to the ILPMP.** According to DHS, date filled and date dispensed are defined as follows:

- **Date filled** refers to when a prescription is dosed out, labeled, and prepared but not picked up from the pharmacy; and
- **Date dispensed** refers to when the medicine is distributed to the person named on the prescription or their Agent.

We reviewed the Submitter's Guide (Guide) prepared by Atlantic for additional information. The Guide is the electronic reporting manual for controlled substance schedules and provides guidance for reporting prescription data and data submission options. Although the Guide lists many of the dispenser requirements separately (patient first name, patient last name, patient address, patient zip code), the Guide lists the date a controlled substance was

filled/dispensed together as one item. Even though the date filled and date dispensed are listed as one item in the Guide, both dates are required by law and have distinct definitions.

In addition, the Manual addresses the structure of the database and lists the fields that are included in the data table. Although the Manual included the **date filled**

in the list of fields in the data table, the Manual did not include the **date dispensed** in the list of fields in the data table. The Manual should list both fields in the structure of the database, since they are both required. According to DHS officials, the **date dispensed** is not being submitted by dispensers or tracked by DHS.

The American Society for Automation in Pharmacy Standards defined date filled and date sold as follows:

- **Date filled** is the date the prescription was prepared rather than dispensed. The Standards note this field as **required**. This definition is comparable to DHS's definition of date filled.
- **Date sold** is used to determine the date the prescription was dispensed (the date the prescription was picked up/left the pharmacy), not the date prepared.

Exhibit 10
PRESCRIPTION RECORDS BY MONTH AND
YEAR FILLED

March 2020 through February 2021

Month and Year Filled	Number of Prescriptions
Prescriptions Filled Prior to March 2020	273,923
March 2020	1,439,662
April 2020	1,261,375
May 2020	1,258,896
June 2020	1,344,063
July 2020	1,385,135
August 2020	1,354,229
September 2020	1,371,017
October 2020	1,433,408
November 2020	1,348,566
December 2020	2,042,889
January 2021	1,407,984
February 2021	<u>1,154,667</u>
Total:	17,075,814
Source: DHS PIL data.	

This definition is comparable to DHS's definition of **date dispensed**.

During testing, we noted DHS collected the date sold for some records. DHS stated the date sold field was not used to run any monitoring reports, as this field did not always have a value and/or was submitted as blank. Without collecting the date dispensed or date sold, DHS cannot calculate if dispensers are transmitting prescriptions by the end of the next business day, as required.

Dispenser Requirement Testing

Since procedures were not conducted by DHS to ensure the completeness and accuracy of the data, we found **the ILPMP data and reporting with respect to that data cannot be relied upon.** However, in order to review dispenser requirements during Fieldwork testing, we requested the last 12 months of active data from the PIL. After numerous requests and meetings with DHS officials, we eventually obtained the requested active data from the PIL for March 2020 through February 2021.

The data for these months included a total of **17,075,814** prescription records. See **Exhibit 10** for a breakdown of the prescription records

by month in the PIL data provided. We shared this information with DHS, and DHS confirmed both the total number of prescriptions and monthly breakdown provided. We asked DHS why prescriptions in this data were filled prior to

March 2020. According to DHS, the ILPMP, "tries to mitigate issues with data received from external pharmacies...and could include human entry induced errors. Some of these entries could also be pharmacy corrections of previously submitted or scripts that were previously rejected upon initial submission."

Although we confirmed the total and monthly breakdown of prescription records with DHS, we could not ensure the records provided for this data were reliable due to the significant problems with the data identified in the *Review of General IT Controls* (see the *Review of General IT Controls* section of this audit).

Even though the data was determined to not be reliable, the fourth audit determination asks if information submitted by dispensers was complete and timely. In order to address this audit determination, the data needed to be utilized to test the information required to be submitted by dispensers. See **Appendix B** for a description of the testing and sampling methods. In addition to the problems identified in the *Review of General IT Controls*, we found the following issues while reviewing the PIL data provided:

- 67,520 records contained an animal species code;
- 465 prescription records contained a birthdate with an age over 110; and
- **0** LTC records contained LTC submission requirements.

As a result, we sampled **60 total prescription records** to review dispenser requirements including the following:

- 45 randomly selected prescription records;
- 5 records with an animal species code;
- 5 records with a birthdate over 110 years old; and
- 5 LTC prescription records.

Testing Results

We found the following specific information required to be submitted by dispensers was included in the 60 sample records. This information was not missing in any of the following fields reviewed:

- patient address;
- patient gender;
- date prescription written;
- date prescription filled;
- quantity dispensed/days supplied;
- national drug code number of the controlled substance dispensed;
- payment type used to purchase the controlled substance; and
- prescriber's DEA number.

For other required information, some missing or incorrect information was identified in the PIL data for the 60 sample records (see **Exhibit 11**). These areas where some missing or incorrect information was found included the following:

- patient ID;
- patient location code;
- patient name;
- patient date of birth;
- date sold; and
- prescriber's full name.

Exhibit 11
TESTING RESULTS FOR DISPENSER REQUIREMENTS

PIL Data Field	Number Tested	Records with Missing or Incorrect Information	Percent with Missing or Incorrect Information
Patient ID	60	6	10%
Patient Location Code	60	29 ¹	48%
Patient Name	60	2 ²	3%
Patient Birthdate	60	5 ³	8%
Date Dispensed	60	60	100%
Date Sold	60	26	43%
Prescriber's Full Name	60	14	2%
Dispenser DEA Number	60	60	100%
Dispenser's Full Name	60	60	100%
Dispenser's Address	60	60	100%

Notes

Source: OAG prepared from DHS testing results.

In addition, there were four areas where missing or incorrect information was identified in the PIL data for all the 60 sample records. These areas where all the records contained missing or incorrect information included the following:

- date controlled substance dispensed;
- dispenser DEA number;
- dispenser's full name; and

¹²² records with erroneous input, and 7 records with an LTC patient location code but were not LTC.

² Patient name was a name of a location (not a person) for these 2 records.

³ Birthdate was 12/30/1899 for these 5 records.

⁴ Prescriber's full name was a medical facility name, not a person.

• dispenser's address.

Date Controlled Substance Dispensed

Of the 60 prescription records tested, all 60 (100%) were missing a date dispensed. According to the Act, date dispensed, or the date the medicine is distributed to the person named on the prescription or their Agent, is required to be transmitted by dispensers. According to DHS, the date a controlled substance is dispensed is not being submitted by dispensers or tracked by DHS.

Of the 60 prescription records tested, 26 (43%) were missing a date sold. According to the American Society for Automation in Pharmacy Standards, date sold is used to determine the date the prescription was dispensed. DHS stated the date sold field often does not have values in it and/or is submitted as blank. DHS also stated that the date sold field is not used for any monitoring purposes.

Dispenser's DEA Number, Full Name, and Address

The Act establishes separate definitions for dispensers and pharmacies. The Act defines a dispenser as one who dispenses and a pharmacy as any store, ship, or other place in which pharmacy is authorized to be practiced under the Pharmacy Practice Act. DHS officials stated they believe the intent of these requirements is for pharmacy information, citing the conflicting definitions of dispenser between the Act and the Administrative Code. The Administrative Code defines a dispenser as any practitioner or pharmacy that dispenses a controlled substance or an alternative user or research subject by or pursuant to the lawful order of a prescriber. DHS should work toward changing the definition of dispenser in the Act to align with the Administrative Code and/or current practices.

Exhibit 12 BIRTHDATES IN PIL DATA					
Birthdate / (Age)	Number of Prescriptions				
12/30/1899 / (121 years old)	263				
1/1/1900 / (121 years old)	135				
1/1/1901 / (120 years old)	39				
Other / (over 110 years old)	28				
Total: 465					
Source: OAG prepared from DHS testing results.					

- Of the 60 prescription records tested, all 60 (100%) were missing a dispenser DEA number. The Act requires dispensers to transmit the dispenser's DEA registration number and defines dispenser as a practitioner who dispenses. However, according to DHS officials, pharmacies only send the pharmacy location DEA number to the ILPMP.
- Of the 60 prescription records tested, all 60 (100%) were missing a dispenser name and address. The Administrative Code requires dispensers to transmit the dispenser name and address. DHS stated the dispenser full name and address are derived from the pharmacy DEA number.

Over 110 Years Old

For the population of PIL data between March 2020 and February 2021, 465 prescriptions had birthdates over 110 years old. **Of these 465 records, 437 records shared three birthdates** (see **Exhibit 12**).

Records Tested:

Of the **5** prescription records tested with ages over 110 years old:

- 3 records (60%) had an animal species code and included "Dog" in the patient name field.
- 2 records (40%) had location names in the patient name fields (an animal hospital and a men's health center).
 - According to DHS, animal hospitals are not required to report, and the first record should be removed from the data. DHS also stated the second record from a men's health center was bad input.

Specific Examples:

- "Reese Dog" was 120 years old, had an animal species code, and was in a LTC facility.
- "Sam Dog" was 120 years old, had a human species code, and had a dog's name.
- A Men's Health Center was 120 years old, had a human species code, and had a health center's name.

We followed up with DHS regarding records with problematic birthdates indicating ages over 110 years old. According to DHS, the ILPMP had not established a control over the verification of birthdates. DHS officials discussed working toward developing a "kick back" with Atlantic, so data would be kicked back to a pharmacy when a birthdate indicating an age over 116 is entered. When asked why the age of 116, DHS responded that 116 was used due to "using the age of the oldest person in the United States."

Species Code

Of the 465 records with problematic birthdates, 265 (57%) also contained a species code of "2," indicating an animal species. A significant number of records also had blank species codes in the data. We followed up with DHS about these non-human and blank species codes. According to DHS, although the species codes were blank and did not contain a code of "1" for human species, the blank codes indicate the species was a human for these records.

Since non-human and blank species codes were included for monitoring purposes, we followed up with DHS regarding the purpose of the species code. DHS stated the species code is included in monitoring reports because "animal 'parents' have the potential for medication shopping and abuse."

Although DHS included these species codes for monitoring purposes, 265 records ended up in the

active PIL data containing both a birthdate over 110 years old and a species code of "2" for an animal. In addition, of the 465 records with problematic birthdates, 132 records did not have a patient name. For example, these records had a facility name, such as an animal hospital or medical center.

None of these issues (over 110 years old, animal species code, and/or missing patient name) prevented the records from being maintained in the active PIL. The lack of control is problematic and emphasizes the need for improved monitoring over the ILPMP data.

Long Term Care (LTC) Cases

The Administrative Code requires additional submission requirements for prescriptions dispensed to LTC patients. The following information must be included in the ILPMP patient profiles for LTC entries only:

- name of medication;
- patient information should be kept up to date at all times:

- patient ethnicity (if available);
- patient location code including LTC facility State provider number and corresponding location at the facility;
- pre-existing conditions;
- patient weight, when available electronically; and
- patient height, when available electronically.
- diagnosis information;
- additional information for patient admissions to acute care facilities:
 - date admitted, if known to the dispenser;
 - date discharged, if discharged at time of transmission, if known to dispenser;
 - reason for admission, if known to the dispenser; and
 - any changes to medication therapy, if known to the dispenser.

Therefore, auditors included <u>five</u> prescription records for patients in LTC to determine whether DHS was collecting these additional fields. In addition, <u>two</u> LTC prescription records appeared in our random sample of 45 records.

When discussing exceptions from fieldwork testing, DHS officials noted a patient location code of 99 meant it was a prescription for a patient in LTC. Using this additional information, there were <u>nine</u> additional LTC records included <u>for a total of 16 LTC prescription records reviewed</u> in the sample of 60 total prescription records.

Although additional controls were established for the benefit of LTC patients, these controls were not being implemented as required. As seen in **Exhibit 13**, all 16 (100%) LTC prescription records were missing the information required to be submitted for LTC cases. In addition, only the diagnosis code field was available for dispensers to submit information. All of the other required fields (ethnicity, patient weight, etc.), did not have a field where data could be submitted by dispensers. In the sample of 60 total prescription records, only one included a diagnosis code, but it was not an LTC prescription. According to DHS, "the LTC program has not been funded for years, but they do accept the records if a pharmacy sends them."

In addition to not including the LTC submission requirements, **7 of the 16** records had other issues. Examples of these other issues included: animal species codes, animal names with a human species code, and places as patient names. According to the Administrative Code, LTC pharmacies shall transmit patient profiles to the PIL **weekly** (versus daily for non-LTC patients). However, LTC pharmacies are not reporting to the ILPMP, so these requirements are not being met on a weekly basis.

Exhibit 13
TESTING RESULTS FOR LTC REQUIREMENTS

PIL Data Field	Number Tested ²	Records with Missing Information	Percent with Missing Information
Name of Medication ¹	16	16	100%
Patient Ethnicity ¹	16	16	100%
Patient Location Code ³	16	16	100%
Pre-existing Conditions ¹	16	16	100%
Patient Weight ¹	16	16	100%
Patient Height ¹	16	16	100%
Diagnosis Code	16	16	100%
Date Admitted ¹	16	16	100%
Date Discharged ¹	16	16	100%
Reason for Admission ¹	16	16	100%
Changes to Medicine ¹	16	16	100%

Notes:

Source: OAG prepared from DHS testing results.

Conclusion

As noted above, we found additional discrepancies while reviewing dispenser reporting requirements during fieldwork testing. Specifically, we found dispensers were not submitting all information as required by the Illinois Controlled Substances Act and the Illinois Administrative Code. These discrepancies and/or lack of information being submitted as required enforces the ILPMP data is not complete and cannot be relied upon.

¹ No field was available for dispensers to submit the information.

Includes all records indicated as LTC. Five records indicated as LTC had a birthdate of 12/30/1899. Two additional records indicated as LTC had an animal species code.

³ 10 of 16 records had a patient location code of 99 indicating LTC; however, all 16 were missing the LTC facility State provider number and location of the facility. No field was available for dispensers to submit the information.

Ensure Dispenser Requirements are Completed as Required

RECOMMENDATION NUMBER

7

The Department of Human Services should ensure dispensers are submitting specific information as required by the Illinois Controlled Substances Act and the Illinois Administrative Code. This includes addressing the following discrepancies with meeting these requirements:

- ensuring dispensers are submitting specific information to the ILPMP by the end of the next business day after a controlled substance is dispensed;
- ensuring the following required information is submitted by dispensers: Patient ID, Patient Location Code, Patient Name, Birthdate, Date Sold, and Prescriber's Full Name;
- beginning to collect and ensure the following additional required information is submitted by dispensers: Date Dispensed, Dispenser's DEA Number, Dispenser's Full Name, and Dispenser's Address;
- following up on problematic information submitted by dispensers so such information does not end up in the active PIL data including: records with patients over 110 years old, records with an animal species code, and/or records with an invalid patient name; and
- ensuring the following required information for LTC cases is submitted by dispensers on a weekly basis and the fields needed for their submission are created including: Diagnosis Code, Name of Medication, Date Discharged, Changes to Medicine, Reason for Admission, Date Admitted, Pre-existing Conditions, Patient Ethnicity, Patient Height, and Patient Weight.

DHS Response:

The Department accepts the recommendation. The Illinois Prescription Monitoring Program (ILPMP) will ensure that dispensers are submitting specific information as required by the Illinois Controlled Substance Act and the Illinois Administrative Code and will work with the Department's Office of Legislative Affairs where legislation may be required.

Program Assessment Information

DHS has not ensured reports used for program assessment contain complete and accurate information or followed up when program assessment reports show significant changes, incorrect calculations, and/or missing information. DHS has also not established an interagency agreement with DPH to reinstate the process of exchanging data in more depth through the Opioid Data Dashboard or provided additional program assessment information to cover significant drug-related issues. Finally, DHS has not ensured all prescribers possessing an Illinois Controlled Substance license are registered with the ILPMP as required by the Act.

Legislative Audit Commission Resolution Number 154 asked auditors to determine whether the ILPMP and its database are effective in helping Illinois patients by requesting DHS program assessment information and data showing changes in the number and type of drug-related issues. According to DHS, ILPMP program assessment information supports that State requirements have had a positive effect on drug-related issues. By increasing the use of the ILPMP website and *PMPnow* connections, DHS states these increases have led to lower prescribing and lower abuse rates.

DHS Program Assessment Information

We requested DHS provide program assessment information illustrating ILPMP changes in drug-related issues (including deaths, abuse, and overprescribing) since the implementation of ILPMP State requirements. In response to this request, DHS provided the following:

- monthly statistics on the ILPMP website;
- annual indicator reports; and
- quarterly and final annual grant reports.

Monthly Statistics

According to DHS, this program assessment information utilized for illustrating ILPMP changes in drug-related issues can be found on the ILPMP website under the monthly statistics. The ILPMP website contains monthly statistics for users, various requests, and *PMPnow*. There is limited data beginning in January 2008 and more detailed data in recent years through May 2021. The definitions for the data fields were provided by DHS. The data contained in the more recent years included the following fields:

- New Registered Users any person registering for an ILPMP account in the current month;
- **Total Users (Active and Inactive)** any person registered for an ILPMP account including non-active accounts;
- **Total PMP Website Requests** any search made by a person to view patient data:

- Total *PMPnow* Connections a web application provided from LogiCoy that utilizes a unique location code and is set up when an EHR/EMR connection is established;
- **Total** *PMPnow* **Requests** a web application provided from LogiCoy that utilizes a unique location code and is set up when an EHR/EMR connection is established and counts the queries requested through it; and
- **Total Law Enforcement Requests** a request made by law enforcement via website, mail, or fax.

As seen in **Exhibit 14** and **Appendix D**, there appears to have been a significant increase in new registered users and total *PMPnow* requests in FY18. Approximately 200-300 new registered users were typically added per month in FY17. However, the number of new registered users increased significantly when 14,170 new registered users were added in December 2017 and 10,649 new registered users were added in January 2018. In addition, the number of *PMPnow* requests almost doubled in December 2017 and tripled in January 2018 when compared to November 2017.

According to DHS, these increases correlate with the implementation of Public Act 100-0564, which was signed in November 2017 and became effective January 1, 2018. Therefore, the updated ILPMP statutory requirements had a positive impact on the ILPMP by increasing the number of new registered users and total *PMPnow* requests. However, since there is a lack of general IT controls over the data, the data presented cannot be relied upon (see additional information in the *Data Accuracy* section of the audit).

We followed up with DHS regarding the "expected total" differing from the "reported total" in the monthly statistics. According to DHS, a security option was enabled to allow for safe updates to the database and this caused an anomaly

Exhibit 14 ILPMP STATISTICS

Fiscal Years 2017 through 2020

Fiscal Year	New Registered Users	Total Users (Active and Inactive) ¹	Total PMP Website Requests	Total <i>PMPnow</i> Connections ²	Total <i>PMPnow</i> Requests	Total Law Enforcement Requests
FY17	3,939	35,108	2,987,589	14	4,944,013	867
FY18	30,900	65,670	3,381,365	35	29,802,795	973
FY19	4,724	70,570	4,628,796	226	54,846,060	1,516
FY20 ³	3,566	71,473	4,180,342	713	73,750,804	1,504

Notes:

- ¹ Total users (active and inactive) indicate total users at the end of each fiscal year. According to DHS, total users may not be equal to the sum of new registered users and total users from the previous year due to an anomaly in certain circumstances for automated tasks.
- ² PMPnow connections indicate total connections at the end of each fiscal year.
- ³ Duplicates and veterinarian accounts were removed in FY20.

Source: OAG prepared from DHS ILPMP website information.

in certain circumstances. DHS did not elaborate further, but we concluded **the monthly statistics did contain some incorrect calculations** as a result.

Indicator Reports

DHS also provided indicator reports related to program assessment information for the ILPMP. These reports included totals by month for January 2015 through December 2020 for the following indicators. None of the indicator reports included information on deaths.

- **5-5-6 Patients** patients who received opioid prescriptions from five or more prescribers at five or more pharmacies in a rolling six-month period;
- **Benzodiazepine/Opioid Overlap Patients** patients with co-prescriptions of benzodiazepines and opioid medications concurrently within a 30-day period;
- **Number of Opioid Prescriptions** the total number of opioid prescriptions each month;
- Number of Patients Over 90 MME patients who received, on average, a minimum of 90 MME (Morphine Milligram Equivalent) per day over the last 30 days; and
- Number of Opioid Patients the total number of opioid patients each month.

As seen in **Exhibit 15**, the indicator reports showed a downward trend in opioid-related issues between December 2015 and December 2020. More specifically, there were only three instances in which the indicators did not decrease compared to the previous calendar year (see bolded numbers in this exhibit).

We asked DHS about the purpose of the indicator reports. DHS confirmed the indicators were used in presentations to the PMPAC and in reports with local health departments. In addition, the 5-5-6 Patients, Benzodiazepine/Opioid Overlap Patients, and Patients Over 90 MME indicators were available on *MyPMP* for prescribers to directly access these indicators.

Although DHS uses these reports for program assessment, DHS confirmed these reports are not audited. In addition, according to DHS, the data for these reports was obtained from the PIL. As stated previously, DHS has not established general IT controls over the data from the PIL so we cannot rely on this data or these reports.

Exhibit 15 ILPMP INDICATOR REPORTS Calendar Years 2015 through 2020¹

Indicator	2015	2016	2017	2018	2019	2020
5-5-6 Patients	6,735	4,512	3,604	2,872	2,252	1,444
Benzodiazepine/ Opioid Overlap Patients	102,388	77,440	67,323	55,973	47,460	43,843
Opioid Patients	522,159	410,549	361,042	378,577 ²	337,532	340,541 ²
Opioid Prescriptions	639,091	598,313	568,933	512,961	475,390	409,179
Patients Over 90 MME	36,656	31,732	27,707	30,411²	16,824	16,428

Notes

Source: OAG prepared from DHS indicator reports.

Quarterly and Final Annual Grant Reports

According to DHS, the ILPMP also tracks programmatic progress through quarterly and annual grant reports. Through these reports, the ILPMP is able to assess progress in each proposed project detailing if successful or unsuccessful. However, when we reviewed these reports that DHS listed as being used for program assessment, we found the following:

• Quarterly Grant Reports – Although the Act states each prescriber possessing an Illinois Controlled Substance license shall register with the ILPMP as of January 1, 2018, DOJ grant reports support the percent of prescribers registered to the ILPMP was: 78% as of June 2019, 70% as of December 2019, 68% as of June 2020, and 68% as of December 2020 (see Exhibit 16). We asked DHS what was done to correct the lack of registered prescribers and noncompliance with the Act. According to DHS officials, DHS reached out to DFPR to request this registration be added as a mandatory condition for license renewal. No other information was provided by DHS to address this noncompliance.

¹ Totals are for the month of December from each calendar year.

² Bolded numbers show when indicators did not decrease compared to the previous December.

Exhibit 16

LICENSED PRESCRIBERS REGISTERED WITH ILPMP

June 2019 through December 2020

Date ¹	Total Illinois Licensed Prescribers	ILPMP Registered Prescribers	Percent of Prescribers Registered with ILPMP
June 30, 2019	75,331	58,511	78%
December 31, 2019	81,872	57,224	70%
June 30, 2020	85,309	58,199	68%
December 31, 2020	87,947	59,502	68%

Note:

Source: OAG prepared from DOJ grant reports.

The lack of registered prescribers violates the Act and does not allow the ILPMP to fully assess or monitor the program as all prescribers are not registered under the program.

Ensure Prescribers are Registered with the ILPMP as Required

RECOMMENDATION NUMBER

8

The Illinois Department of Human Services should ensure all prescribers possessing an Illinois Controlled Substance license are registered with the ILPMP as required by the Illinois Controlled Substances Act.

DHS Response:

The Department accepts the recommendation. The Department will work with the Illinois Department of Financial and Professional Regulation to make ILPMP registration a required condition for Controlled Substance license approval and renewal.

In addition, DOJ grant reports track the number of unsolicited reports to prescribers. According to DHS, unsolicited reports are reports proactively created and forwarded to an end user. Auditors reviewed quarterly DOJ grant reports and noted a dramatic decrease in the number of unsolicited reports. As seen in **Exhibit 17**, the total number of unsolicited reports sent to prescribers between January 2019 and June 2019 was significantly higher than the number of unsolicited reports to prescribers in the three following six month periods. We asked DHS about this significant decrease in unsolicited reports to prescribers in the State. According to DHS, "this MyPMP feature was implemented in the first week of January, 2019. When users logged into their accounts, they were notified of the new feature. The feature became popular the first few months of

¹ Number of licensed or registered prescribers as of the date listed.

implementation then cooled off as users had already seen the feature a few times."

• **Final Annual Grant Reports** – According to DHS, the ILPMP created an annual performance review for each year of the CDC Prescription Drug Overdose Prevention for States grant, including one final report created for the last year of the grant (September 2018 – August 2019). In the final annual report, we noted **approximately 90 instances** where indicators appeared to be missing data. We asked DHS about the limited or missing data for these indicators. According to DHS officials, the final annual report was approved as complete by the CDC. DHS added there were no missing indicators during this period, but the CDC went through changes in their reporting and information may not show up on the final annual report. Regardless, a

Exhibit 17 UNSOLICITED REPORTS TO PRESCRIBERS		
Months and Year	Prescribers	
January - June 2019	4,295	
July - December 2019	447	
January - June 2020	374	
July - December 2020 344		
Source: OAG prepared from DOJ grant reports.		

significant number of indicators appeared as blank on the final annual report provided. Examples of these missing indicators included:

- opioid naïve patients (patients who have not been prescribed opioid analgesics in the past 60 days) prescribed long-acting/extended release opioids;
- prescription days with overlapping opioid prescriptions; and
- prescription days with overlapping opioid and benzodiazepine prescriptions.

In the final annual report, the report stated DHS was unable to execute relevant queries to extract data for the above indicators from 2017 through 2019. The lack of indicators does not allow the ILPMP to use these reports to fully monitor or track the ILPMP's programmatic progress as noted by DHS.

Other Program Assessment Information

DHS stated the ILPMP is still working on an interagency agreement with DPH to exchange data in more depth as well as include additional data assessments through the Opioid Data Dashboard. According to DHS, data was posted annually from 2013 to 2018. According to DPH, staff linked data for the ILPMP, hospital discharges, and death certificates. Although DHS and DPH have been discussing expanding the Opioid Data Dashboard and revisiting this data sharing process, DHS noted the exchange of data has been delayed due to COVID-19. The two agencies should work together to ensure this data covering significant drug-related issues is still available through the DHS and DPH websites.

The third audit determination asks whether the ILPMP and its database are effective in helping Illinois patients by requesting DHS program assessment information and data showing changes in the number and type of drug-related issues (such as deaths, abuse, and overprescribing). It is problematic that DHS

and DPH have not been linking data for the ILPMP, hospital discharges, and death certificates since 2018. The lack of this information indicates the ILPMP and its database are not effective in monitoring these drug-related issues. According to DHS, the agencies hope to begin exchanging data more timely and efficiently in 2021 depending on DPH's resource availability.

Program Assessment Issues			
RECOMMENDATION NUMBER	The Department of Human Services should address the identified program assessment issues and related deficiencies by:		
9	 ensuring reports used for program assessment contain complete and accurate information and following up when such reports show significant changes, incorrect calculations, and/or missing information; and 		
	 establishing an interagency agreement with the Department of Public Health to reinstate the process of exchanging data in more depth through the Opioid Data Dashboard and providing additional program assessment information to cover significant drug-related issues such as deaths, abuse, and overprescribing. 		

DHS Response:

The Department accepts the recommendation. The Department will address the identified program assessment issues and related issues by working to ensure that reports contain complete and accurate information, and work with the Illinois Department of Public Health to reinstate the process of exchanging data.

Monitoring

DHS has not performed sufficient tracking of monitoring reports required by the Illinois Administrative Code including error reports, zero reports, and personal information reports. DHS has also not ensured all monitoring reports required by intergovernmental agreements are completed as outlined in the agreements. Finally, DHS has not sufficiently monitored ILPMP contractors through System and Organization Controls reports or internal control reviews.

Legislative Audit Commission Resolution Number 154 asked auditors to determine whether DHS is adequately monitoring the program and using this information to ensure the Program is administered as required. To gain a better understanding of monitoring being performed by DHS, we requested a listing of all monitoring reports utilized by DHS. This request included the purpose of the report, what the report monitors, how often the report is run, and who uses the reports.

Monitoring Reports

DHS said there are monthly, quarterly, and on-demand monitoring reports utilized for the PIL. Although most of these reports are utilized by DHS's Clinical Director of the Bureau of Clinical Informatics, a few reports are also utilized by the ILPMP Peer Review Committee (PRC), the DOJ Bureau of Justice Assistance, the DHS Division of Substance Use Prevention and Recovery, and the University of Illinois at Chicago.

According to DHS, the following reports are run. All reports are run only for DHS's Clinical Director of the Bureau of Clinical Informatics and for program purposes unless otherwise noted in parentheses.

Monthly Reports

- Trends in Prescriptions and Patients for Opioids and Benzodiazepines
- Patients with Overlapping Opioid Prescriptions
- Patients with Prescriptions Greater than 90 MME in Opioids
- Patients meeting Specific Opioid Thresholds
- Number of Patients Receiving Long-acting Opioids
- Number of Patients on Medical Marijuana
- Naloxone Dispenses
- Buprenorphine Dispenses
- Data Waiver Reports
- Peer Review Data (ILPMP Peer Review Committee)

Quarterly Reports

Performance Measure Tool Reports (DOJ Bureau of Justice Assistance)

- Prescribers Registered in the ILPMP before/after Senate Bill 772 on Drug Abuse
- ILPMP use before/after Senate Bill 772 on Drug Abuse
- Number of ILPMP Integrated Systems Currently/Previously
- Data Needed for PowerPoint Presentations

On-Demand Reports

- FOIA Requests (Upon Request)
- Academic Detailing (University of Illinois at Chicago)

Overseeing Additional Reporting Requirements in the Administrative Code

The Illinois Administrative Code requires the ILPMP to oversee additional reporting requirements. Examples of reporting requirements outlined in the Administrative Code included error reporting, zero reporting, and personal information reports. We found DHS was not performing sufficient tracking of these three reports as required. See **Exhibit 18** for more information on examples of required monitoring for the ILPMP.

Error Reporting

The Administrative Code states how prescribers and dispensers report errors, as required by the Act. Prescribers shall report errors within 7 days of the discovery of the error using a built-in error reporting system. Dispensers shall retract the incorrect prescription and retransmit the prescription correctly to the ILPMP within 7 days of noticing an error.

We asked DHS how error reporting is tracked, and if DHS has a system for monitoring the quantity of errors submitted by dispensers. According to DHS, the ILPMP follows the American Society for Automation in Pharmacy's protocol on error reporting. If a pharmacist notices an error, the pharmacist can submit a new prescription entry into the PIL and note in a specific column that a previous entry was made in error. DHS elaborated that some smaller pharmacies call the ILPMP directly and manually report prescription errors. In addition, Atlantic Associates, Inc. verifies the validity of some field values and kicks back error reports to pharmacies.

We requested the number of error reports tracked by DHS during FY19. DHS responded this is not a physical report but an obligation for prescribers to report to pharmacies and for pharmacies to resubmit to the ILPMP. DHS further stated the ILPMP "does not track the number of error reports PMP users submit" and could not provide the total number of errors resubmitted by dispensers to the ILPMP in FY19. Therefore, we noted **DHS was not performing sufficient tracking of error reporting by dispensers**. By tracking such error reporting information, DHS would help ensure the ILPMP is adequately monitoring errors according to required timelines and ensuring the ILPMP is being administered with accurate prescription information as required.

DHS officials stated DHS is beginning to track errors through a webpage where dispensers submit updates for their prescription records, and ILPMP staff review the updates. According to DHS, this webpage has an expected implementation date of October 2021.

Zero Reporting

According to the Administrative Code, dispensers must submit a zero report to the ILPMP when they do not dispense a Schedule II-V drug on a given day as set forth by the American Society of Automation in Pharmacy's protocol. DHS stated pharmacies should submit zero reports when they would normally submit prescription information to the PIL, but DHS does not track these zero reports.

We requested the total number of zero reports submitted to DHS during FY19. DHS responded that **249** zero reports were received from Atlantic in FY19. DHS explained each of these 249 reports contained numerous entries. For example, DHS shared an example file with **3,982** zero reports submitted on a given day. According to DHS, Atlantic collects the data on zero reports for the PIL and provides a zero report file to DHS with a spreadsheet containing the pharmacy IDs, start and end periods, pharmacy names, and addresses. DHS officials stated DHS does not track the number of zero reports received from dispensers or compare these reports to the Schedule II-V submissions from dispensers on a given day. Therefore, we noted **DHS did not perform sufficient tracking of zero reporting by dispensers**. By tracking zero reporting information, DHS would help ensure all dispensers are reporting daily to the ILPMP (either through a zero report or a prescription submission) as required.

In addition, when DHS provided the 12 months of active data from the PIL for March 2020 through February 2021, the data included zero reports submitted for two dates. DHS confirmed the zero report data should not have been included in the PIL data provided. DHS noted an internal check would be instituted to monitor for this.

DHS officials also noted they are currently developing a pharmacy compliance tool to deduce which pharmacies submitted records based on prescription date and zero reporting for a given day but provided no estimated date for implementation.

Personal Information Reports

The Administrative Code allows for a personal information report of a patient's prescription profile to be obtained if the patient, parent, or guardian completes and submits a notarized request to the ILPMP. According to DHS, these reports include patient profiles with patient and prescription information.

We requested the total number of personal information reports provided by DHS in FY19 but DHS could not provide that information. According to DHS, the number of personal information reports provided was not tracked by DHS. Therefore, we noted **DHS did not perform sufficient tracking of personal information reports provided** to patients, parents, or guardians. DHS should track these reports provided due to the confidentiality of the data contained in them and monitor how many requests are made and responded to by DHS. By

tracking personal information reports, DHS would help ensure these reports remain confidential and are only provided to those allowed to request them.

DHS further stated personal information reports were now currently being tracked with a spreadsheet. In addition, DHS is planning to transition from a spreadsheet to a web tool. According to DHS, the tracking of personal information requests began at the end of April 2021. DHS also noted the ILPMP only receives approximately two or three personal information requests annually.

Overseeing Additional Reporting Requirements in Intergovernmental Agreements

Intergovernmental agreements require the ILPMP to oversee additional reporting requirements. Examples of reports required by intergovernmental agreements included quarterly local level analyses and a final annual report. We reviewed intergovernmental agreements and followed up with DHS about requirements related to these reports. Although DHS completed some reporting requirements in intergovernmental agreements as required, other reporting requirements were incomplete.

Quarterly Local Level Analyses

DHS and DPH entered an interagency agreement for the CDC Prescription Drug Overdose Prevention for States grant. As part of the agreement, DHS was to address the prescription drug and heroin abuse epidemic by implementing strategies related to enhancing and maximizing the ILPMP and by focusing on implementing community or insurer/health system interventions in high-burden communities.

According to DHS, this was a joint effort between DHS and DPH. The ILPMP provides DPH with the data. DHS was required to use county, community, and zip code level ILPMP data to conduct public health surveillance and publicly disseminated analyses on a **quarterly basis**.

We requested the total number of quarterly local level analyses completed during FY19. According to DHS, only two of the four required quarterly reports were completed in FY19 as seen in Exhibit 18. Therefore, this reporting requirement was only 50% implemented as required by the intergovernmental agreement.

Exhibit 18
EXAMPLES OF REQUIRED MONITORING
Fiscal Year 2019

Reports Received by DHS	Submitted by	Requirement	Reports Received ¹	Reports Required
Error Reports	Dispensers	77 III. Adm. Code 2080	*	As needed
Zero Reports	Dispensers ²	77 III. Adm. Code 2080	249	As required

Reports Submitted by DHS	Received by	Requirement	Reports Submitted	Reports Required
Personal Information Reports	Patients, Parents, or Guardians	77 III. Adm. Code 2080	*	As requested
Quarterly Local Level Analyses	Publicly Disseminated	Intergovernmental Agreement with DPH (CDC Prescription Drug Overdose Prevention for States Grant)	2	4
Final Annual Report	CDC and DPH	Intergovernmental Agreement with DPH (CDC Prescription Drug Overdose Prevention for States Grant)	1	1

Notes:

Source: OAG prepared based on DHS information.

Final Annual Report

As part of the same intergovernmental agreement, DHS was required to provide a final report to the CDC and DPH documenting work carried out under the grant at the end of the agreement term. According to DHS, the ILPMP created an annual performance review for each year of the CDC Prescription Drug Overdose Prevention for States grant, including one final report created for the last year of the grant (September 2018 – August 2019).

We requested the total number of final annual reports completed in FY19. According to DHS, one final annual report was completed for the grant period as required. DHS also provided this report during the audit. Therefore, DHS did complete this final annual report as required by the intergovernmental agreement.

¹ DHS could not provide the number of reports run in FY19 for reports with an asterisk.

² Dispensers submit zero reports to Atlantic. Atlantic combines the zero reports into a single file for a given day and provides the file to the ILPMP.

Contractor Monitoring

Many of the responsibilities of the controls over IT and the data reside with contractors as delegated by DHS. We met with DHS and requested information regarding the monitoring of these contractors utilized in the ILPMP. Specifically, IS auditors asked if DHS required System and Organization Controls (SOC) reports from contractors. According to DHS, SOC reports are not required from contractors. In addition, there are no internal control reviews over the internal controls of the services provided. Without SOC reports and internal control reviews from contractors, DHS has no reliance on their internal controls of the services provided. The contracts received for these services do not require SOC Examinations or Review of Internal Controls Reports.

As discussed previously in the *Review of General IT Controls* section, **DHS is not sufficiently monitoring ILPMP contractors.** The contractors have significant responsibilities; therefore, internal control reviews ensure the accuracy and validity of the PIL, data, and website. Without adequate internal controls, DHS cannot determine the accuracy and validity of the PIL data.

FY19 LogiCoy Contract Example

The LogiCoy FY19 contract was amended several times over a short period and significantly increased the total amount of the contract by \$1,395,550. The contract was started at \$436,500 with a completion date of **October 2018**. Then, the following amendments were made to the contract:

- The contract **increased \$800,000** (totaling \$1,236,500) on 10/30/18 with a revised completion date of **December 2018**.
- The contract **increased \$1,200,000** (totaling \$2,436,500 total) on 12/31/18 with a revised completion date of **June 2019**. However, the funding was not sufficient to support this increase.
- As a result, an updated amendment was proposed and the contract was increased \$595,550 on 1/1/19 (totaling \$1,832,050) with the completion date of **June 2019**.

We followed up with DHS regarding the significant increases in the FY19 LogiCoy contract. According to DHS, the PMP was seeing an exponential increase of facilities wanting to connect to *PMPnow* due to statutory mandates. Although the contract amounts were increasing significantly, the contracts did not provide for auditing or reviewing the security of the data or web services or change controls. In addition, DHS could not provide the total percentage of connections that had been fully interfaced as of January 1, 2021. Therefore, this contract increased from \$436,500 to \$1,832,050 in a single fiscal year and yet did not have proper security controls or monitoring of the completion requirements established.

RECOMMENDATION NUMBER 10 The Department of Human Services should address the identified monitoring issues and related deficiencies by: • performing sufficient tracking of monitoring reports required by the Illinois Administrative Code including error reports, zero reports, and personal information reports; • ensuring all monitoring reports required by intergovernmental agreements are completed as outlined in the agreements; and • sufficiently monitoring ILPMP contractors through System

and Organization Controls reports or internal control

DHS Response:

The Department accepts the recommendation. The Department will work to incorporate report tracking measures. The Department will work with its Office of the Agency Procurement Officer to incorporate contract language, requiring auditing and review of internal controls for contracted vendors, requested reporting, such as System and Organization Controls (commonly referred to as SOC reports), and that such tracking measures are implemented and operating efficiency.

reviews.

ILPMP Committees

DHS has not updated the Illinois Administrative Code to ensure the Prescription Monitoring Program Advisory Committee (PMPAC) members for the PMPAC are the same as those required by the Act. DHS has also not ensured Peer Review Committee (PRC) members with the same profession as prescribers or dispensers were preparing preliminary reports and/or making recommendations, as required by the Act. In addition, DHS has not ensured the PRC met quarterly or fulfilled annual reporting requirements, as required by the Administrative Code. Finally, DHS has not established a long term care (LTC) Advisory Committee, as required by the Administrative Code.

According to DHS, the ILPMP coordinates with the ILPMP committee members

Comparison of PMPAC Membership Requirements

PMPAC Members Required by the Act:

- 1 family care/primary care physician;
- 1 pain specialist physician;
- 4 other physicians (1 may be an ophthalmologist);
- 2 advanced practice registered nurses;
- 1 physician's assistant;
- 1 optometrist;
- 1 dentist:
- 1 clinical representative from a statewide hospital organization;
- 3 pharmacists: and
- Clinical Director as Secretary.

PMPAC Members Required by the Administrative Code:

- 1 Clinical Director (Chairperson);
- 4 physicians licensed to practice medicine in all branches;
- 3 pharmacists;
- 1 dentist;
- 1 podiatric physician;
- 1 optometrist;
- 1 advanced practice nurse; and
- 1 physician assistant.

to determine the data and monitoring reports that would be useful to them. DHS noted that committees have undergone changes recently including increasing the size and changing the composition of the committees. The Illinois Controlled Substances Act and the Illinois Administrative Code include three ILPMP committees: PMPAC; PRC; and the LTC Advisory Committee.

The Prescription Monitoring Program Advisory Committee

The Act establishes the role of both DHS and the PMPAC in adjusting the schedule of controlled substances in the Act. While the ultimate decision to add, remove, or reschedule a drug from its classification lies with DHS, the PMPAC plays an advisory role in the decision for all drugs mentioned in the Act.

PMPAC committee members also play a direct role in implementing the ILPMP with DHS and provide advising on matters relevant to their field of competence. According to the Act, the PMPAC consists of 15 members and the Clinical Director serves as the Secretary. The **text box** provides the details for PMPAC membership requirements. In 2019, PMPAC members were

required to be selected from nominations submitted by their respective professional associations. DHS noted committee membership requirements were also updated and put on staggered terms for 1-year, 2-year, and 3-year required terms.

The Act states the PMPAC shall:

 provide a uniform approach to reviewing the Act to determine whether changes should be recommended;

- review drug schedules to manage changes to the Administrative Code;
- review current guidelines on prescribing, training, patient assessment, updates from the FDA and CDC, and relevant medical studies and publications involving controlled substances;
- make recommendations for inclusion of these materials on the ILPMP website:
- semi-annually review the website content;
- semi-annually review funding opportunities; and
- semi-annually review communications to be sent to all registered users of the ILPMP.

The Illinois Administrative Code (77 Ill. Adm. Code 2080) also establishes the composition and responsibilities of the PMPAC. **The Administrative Code and the Act differ in the required members of the PMPAC because the Administrative Code has not been updated.** See the **text box** for a listing of the updated members as well as a listing of the outdated members of the PMPAC. Although the subsections of the Administrative Code were effective as of September 2017, the Act has a more recent effective date as of August 2019.

In addition, the Administrative Code states the PMPAC's review of the ILPMP website, funding opportunities, and communications to system users are to be conducted on a quarterly basis. The Act states these activities must be conducted on a semi-annual basis (see items #5-7 in **Exhibit 19**).

While the Administrative Code is not up-to-date with the Act in terms of required membership, the ILPMP has submitted draft administrative rules to the Joint Committee on Administrative Rules (JCAR) for review, which include updates to the PMPAC and PRC membership. Based on the PRC and PMPAC membership requirements in the draft administrative rules, all vacancies will have been addressed for both committees once these draft rules have been approved.

PMPAC Meetings

According to the Act, the Prescription Monitoring Program Advisory Committee is tasked with the following charges to be completed. These charges include:

- 1. Provide a uniform approach to reviewing the Act in order to determine whether changes should be made to the General Assembly.
- 2. Review current drug schedules in order to manage changes to the administrative rules pertaining to the utilization of this Act.
- 3. Review the following:
 - a. current clinical guidelines developed by healthcare professional organizations on the prescribing of opioids or other controlled substances;
 - accredited continuing education programs related to prescribing and dispensing;

- programs or information developed by healthcare professional organizations that may be used to assess patients or help ensure compliance with prescriptions;
- d. updates from the FDA, CDC, and other public and private organizations which are relevant to prescribing and dispensing;
- e. relevant medical studies; and
- f. other publications which involve the prescription of controlled substances.
- 4. Make recommendations for the inclusion of these materials or other studies which may be effective resources for prescribers and dispensers on the ILPMP website established under Section 318.

In addition, according to Public Act 100-1093, the following charges must be reviewed semi-annually (as of August 26, 2018). Previously, the requirement for review of these charges was quarterly.

- 5. Semi-annually review the content of the ILPMP website established pursuant to Section 318 to ensure this internet website has the most current available information.
- 6. Semi-annually review opportunities for federal grants and other forms of funding to support projects which will increase the number of pilot programs which integrate the inquiry system with electronic health records.
- 7. Semi-annually review communication to be sent to all registered users of the inquiry system, including recommendations for relevant accredited continuing education and information regarding prescribing and dispensing.

We reviewed the PMPAC meetings for these charges and followed up with DHS. Since the first charges #1-4 were required to be completed but without a defined timeframe, we reviewed these charges to see if they were reviewed at least once a year for FY18, FY19, and FY20. The second charges #5-7 were required quarterly during FY18 and semi-annually during FY19 and FY20. Therefore, we reviewed these charges accordingly. **Exhibit 19** provides an overview of the results. As can be seen in this exhibit, none of the committee charges required on a quarterly and semi-annual basis were completed for all three fiscal years reviewed (see charges #5-7). In addition, for all 12 charges reviewed, only 4 (33%) were completed at least once a year during FY18, FY19, and FY20 (whether required by a defined timeframe or not).

Exhibit 19 REVIEW OF PMPAC CHARGES BY FISCAL YEAR Fiscal Years 2018 through 2020

#	Charge	FY18	FY19	FY20
1	Provide a uniform approach to reviewing the Act in order to determine whether changes should be made to the General Assembly	Yes	Yes	Yes
2	Review current drug schedules in order to manage changes to the administrative rules pertaining to the utilization of this Act	No	Yes	No
3a	Review current clinical guidelines developed by healthcare professional organizations on the prescribing of opioids or other controlled substances	Yes	Yes	No
3b	Review accredited continuing education programs related to prescribing and dispensing	Yes	Yes	Yes
3c	Review programs or information developed by healthcare professional organizations that may be used to assess patients or help ensure compliance with prescriptions	Yes	No	Yes
3d	Review updates from the FDA, CDC, and other public and private organizations which are relevant to prescribing and dispensing	Yes	No	Yes
3e	Review relevant medical studies	Yes	No	Yes
3f	Review other publications which involve the prescription of controlled substances	Yes	No	Yes
4	Make recommendations for the inclusion of these materials or other studies which may be effective resources for prescribers and dispensers on the ILPMP website established under Section 318	No	No	No
5	Semi-annually review the content of the ILPMP website established pursuant to Section 318 to ensure this internet website has the most current available information	No 1 of 4	Yes 2 of 2	No 1 of 2
6	Semi-annually review opportunities for federal grants and other forms of funding to support projects which will increase the number of pilot programs which integrate the inquiry system with electronic health records	No 1 of 4	No 1 of 2	Yes 2 of 2
7	Semi-annually review communication to be sent to all registered users of the inquiry system, including recommendations for relevant accredited continuing education and information regarding prescribing and dispensing	No 3 of 4	No 1 of 2	No 0 of 2

Notes:

Source: OAG prepared based on requirements in the Act.

¹ Charges #1 through #4 are required by the Act but without a defined timeframe. Auditors reviewed these charges to see if they were reviewed at least once a year for FY18, FY19, and FY20.

² Charges #5 through #7 are required to be reviewed semi-annually as of August 26, 2018 (FY19 and FY20). Previously, such reviews were required quarterly (FY18).

Peer Review Committee

Public Act 100-1093, effective August 26, 2018, changed the makeup of the PRC. This included the addition of new members. The PRC currently consists of ten of the PMPAC members. The Administrative Code establishes the composition and responsibilities of the PRC.

The purpose of the PRC is to establish a formal peer review of professional performance of prescribers and dispensers. The PRC is required to periodically review the PIL data to determine whether prescribers or dispensers may be acting outside of their profession's current standard and practice. When prescribers or dispensers are identified through this review process, the PRC is required by the Administrative Code to request information regarding their prescribing or dispensing practices. After this information is requested, prescribers or dispensers have **30 days** to respond.

In addition, the PRC is required to refer a prescriber or dispenser to DFPR in the following situations:

- the prescriber or dispenser does not respond to three consecutive requests for information;
- the prescriber or dispenser does not have a satisfactory explanation for the practices identified; or
- the prescriber or dispenser does not sufficiently rectify the practices identified.

The Act also requires a committee member whose profession is the same as the prescriber or dispenser being reviewed to prepare a preliminary report and recommendation for any non-action or action. However, we found no evidence that committee members whose profession was the same as the prescriber or dispenser being reviewed prepared any preliminary reports or made any recommendations for action or non-action, as required by the Act.

DHS officials stated the metrics for each member have been requested and will be incorporated into review. DHS also stated that members were to be compiling these reports for the February 2021 meeting. We reviewed the February 2021 meeting minutes and found that the guidelines for these reports were discussed, but no reports or recommendations were completed. We also reviewed the June 2021 meeting minutes and found the PRC was planning to send letters to prescribers who were prescribing outside of the guidelines. According to the minutes, the PRC was in the process of drafting the letters and planning to send them prior to June 30, 2021.

The Administrative Code establishes the PRC is to meet quarterly and follow annual reporting requirements. In addition, the PRC is to review the data in the PIL to identify prescribing or dispensing outside of professional standards. According to DHS, there is a rule change in progress changing the PRC meeting requirements from quarterly to semi-annually. Although these drafted rules were sent to JCAR in November 2019, the current Administrative Code still requires the PRC to meet quarterly.

PRC Meetings

The PRC did not meet quarterly in FY19, FY20, and FY21 as required by

Exhibit 20 PRC MEETINGS SUMMARY Fiscal Years 2019 through 2021				
Meeting Date			Met Quarterly as Required?	
		FY19		
	2 of 4 Require	ed Meetings (50	0%)	
09/18/18	3	5	NIa	
12/10/18	4	5	No	
FY20				
1 of 4 Required Meetings (25%)				
07/31/19	8	10	No	
	FY21			
2 of 4 Required Meetings (50%)				
02/02/21	8	10	Nie	
06/02/21	6	10	No	
Source: OAG prepared based on PRC meeting minutes.				

the Administrative Code. In total, the PRC has met five times from FY19 through the end of FY21. Exhibit 20 details the number of meetings by fiscal year. The committee met twice in FY19, once in FY20, and twice in FY21. The exhibit also shows the number of PRC members attending.

Although the PRC is required to meet quarterly according to the Administrative Code, DHS stated the PRC only met once during FY20 and twice in FY21. Although DHS referenced COVID-19 as a reason for not meeting, the majority of their meetings were previously held remotely. According to DHS, before COVID-19, members had the option to attend in person, but the majority of the members called in for the meetings. Therefore, it is unclear why the meetings could not have continued remotely during COVID-19.

Annual Reports

Starting on July 1, 2017, the PRC was required to submit an annual report, delivered electronically to DHS and the General Assembly. The following information must be included in each report:

- the number of times the PRC convened;
- the number of prescribers and dispensers reviewed;
- the number of information requests made by the committee; and
- the number of referrals made to DFPR.

We reviewed the FY18, FY19, and FY20 Annual Reports to determine if the required information was included. We found some required information was included such as the number of times the PRC convened; however, all three fiscal years were missing required information. In addition, DHS made no referrals to DFPR during the three years, which indicates a lack of review over the process with DFPR. Moreover, we noted the following:

• In FY18, 32,749 prescribers were reviewed, 1,239 prescribers were identified and notified as being at potential risk, and 0 referrals were made to DFPR. The number of dispensers reviewed was not disclosed, and no additional information was requested.

- In FY19, **32,992** prescribers were reviewed, **1,313** prescribers were identified and notified of potentially prescribing outside of recommended guidelines, and **0 referrals were made to DFPR**. The number of dispensers reviewed was not disclosed, and no additional information was requested.
- In FY20, the required information related to peer review was not included. There was no documentation of reviewing prescribers or dispensers, identifying and notifying those outside of guidelines, or the number of referrals made to DFPR.

We also requested the data for the 1,239 prescribers identified as being at risk in FY18 and the 1,313 prescribers identified as being at risk in FY19. **DHS stated these lists could not be provided. According to DHS, the lists were cleared and reloaded with each new list**. Therefore, DHS is not following up on these prescribers identified as at risk. Further, DHS noted the lists were stopped when new committee members were added, so a new process could be developed. We requested supporting documentation for this new process, but no such information was provided.

Long Term Care Advisory Committee

The Administrative Code defines the PMP LTC Advisory Committee. This committee is supposed to be a subunit of the PMPAC and composed of healthcare professionals associated with the care of geriatric populations. It also includes university partners who perform research and longitudinal outcome evaluations.

We requested a listing of members on the PMP LTC Advisory Committee. **According to DHS,** "this committee was never established and never met." DHS further stated the information on the LTC Advisory Committee in the Administrative Code was outdated, and DHS does not have a plan to address this outdated information at this time.

ILPMP Committee Weaknesses

RECOMMENDATION NUMBER

11

The Department of Human Services should address the identified ILPMP Committee weaknesses by:

- ensuring the Illinois Controlled Substances Act and the Illinois Administrative Code have the same <u>Prescription</u> <u>Monitoring Program Advisory Committee (PMPAC)</u> members listed for the PMPAC. In addition, the PMPAC charges outlined by the Act should be completed, as required.
- ensuring Peer Review Committee (PRC) members with the same profession as the prescribers or dispensers being reviewed are preparing preliminary reports and/or making recommendations, as required by the Act. In addition, PRC meetings should be held quarterly and fulfill annual reporting requirements with the required information, as required by the Illinois Administrative Code. Finally, the lists of at-risk prescribers should not be cleared and should be followed up on.
- establishing an <u>LTC Advisory Committee</u> as required by the Illinois Administrative Code. This committee should be composed of healthcare professionals associated with the care of geriatric populations and include university partners performing research and longitudinal outcome evaluations.

DHS Response:

The Department accepts the recommendation.

The Administrative Code has been drafted and updates member composition to align with the statute. The proposed Code changes were presented to Illinois General Assembly's Joint Commission on Administrative Rules (JCAR) most recently on February 11, 2021.

The Department will develop a mechanism for the Peer Review Committee (PRC) members with the same profession as the prescribers or dispensers being reviewed to prepare preliminary reports and/or make recommendations, as required by the Act. The Administrative Code updating the meetings from quarterly to at least semi-annually has been submitted to JCAR. The Department will fulfill annual reporting requirements with the required information, as required by the Illinois Administrative Code. ILPMP will track all communications with at-risk prescribers for appropriate follow-up or referral to IDFPR.

The Department will analyze the need for establishing an LTC Advisory Committee as required by the Illinois Administrative Code. If the Department determines a committee is not needed, the Department will work to remove the committee from the Illinois Administrative Code.

Appendix A

Legislative Audit Commission Resolution Number 154

Legislative Audit Commission

Resolution No. 154
Presented by Senator Ellman

WHEREAS, opioid abuse and related overdoses are a national epidemic; and

WHEREAS, according to the Centers for Disease Control and Prevention, more than 46,000 people died in 2018 from overdoses involving opioids including prescriptions, which increased from previous years; and

WHEREAS, from 2015 through 2017, the rate of overdose deaths in Illinois increased by more than 75 percent and in 2017, there were 2,202 drug overdose deaths involving opioids in Illinois - a rate which was higher than the national rate; and

WHEREAS, prescription drug monitoring programs include electronic databases that track controlled substance prescriptions and are among the most promising state-level interventions to help prevent the abuse of opioid prescribing, inform clinical practice, and protect patients at risk while providing health authorities with information about patient behaviors including prescribing histories, timely data, and proactive reports; and

WHEREAS, the Prescription Monitoring Program (Program) was originally established effective April 1, 2000 under the Illinois Controlled Substances Act (720 ILCS 570/) which is under the jurisdiction of the Illinois Department of Human Services (Department); and

WHEREAS, dispensers are required to submit information to the central repository on certain controlled substances prescribed; and

WHEREAS, the Department is required to ensure all providers have access to specific patient records during the treatment of their patients and adopt rules requiring all electronic health records to interface with the program by January 1, 2021; and

WHEREAS, the Department was also given the authority to impose a civil fine of up to \$100 per day for willful failure to report controlled substance dispensing to the Prescription Monitoring Program; and

WHEREAS, the Bureau of Pharmacy and Clinical Support Services, within the Department, administers the Prescription Monitoring Program in Illinois for practitioners who write prescriptions and retailers that dispense controlled substances; and

WHEREAS, in 2018, Illinois had 62,353 prescribers and 2,283 registered dispensers under the responsibility of the Department; and

WHEREAS, the Department is also the supervising entity over the Illinois Controlled Substance Act; therefore, be it

RESOLVED, BY THE LEGISLATIVE AUDIT COMMISSION, that the Auditor General is directed to conduct a performance audit of the Prescription Monitoring Program operated by the Department of Human Services; and be it further

RESOLVED, that the performance audit include, but not be limited to, the following determinations:

- Whether the Department has fully implemented a Prescription Monitoring Program (Program) in accordance with State requirements including whether updated rules were adopted within one year of the effective date of the Public Act and whether all Electronic Health Records Systems were able to interface with the Prescription Monitoring Program application program on or before January 1, 2021;
- Whether the Department is adequately monitoring the Program and using this information to ensure the Program is administered as required;
- 3) Whether the Program and its database are effective in helping Illinois patients by requesting program assessment information from the Department and data from the database showing changes in the number and type of drug-related issues (such as deaths, abuse, overprescribing) since the implementation of State requirements;
- 4) Whether the Department's database is accurate and up-to-date including if the information submitted by dispensers is complete and timely; and
- 5) Whether the Department is utilizing its authority to impose fines when dispensing reporting requirements are not being reported as required for the Program; and be it further

RESOLVED, that the Illinois Department of Human Services as well as any other entity that may have information pertaining to this audit cooperate fully and promptly with the Auditor General's Office in the conduct of this audit; and be it further

RESOLVED, that the Auditor General commence this audit as soon as possible and report his findings and recommendations, upon completion in accordance with the provisions of Section 3-14 of the Illinois State Auditing Act; and be it further

RESOLVED, that a copy of this resolution be delivered to the Auditor General and the Illinois Department of Human Services.

Adopted this 21 day of July, 2020.

SIGNED ORIGINAL ON FILE

Senator Jason Barickman
Co-Chair, Legislative Audit Commission

SIGNED ORIGINAL ON FILE

Representative Robert Rita Co-Chair, Legislative Audit Commission

Appendix B

Audit Scope and Methodology

This performance audit was conducted in accordance with generally accepted government auditing standards and the audit standards promulgated by the Office of the Auditor General at 74 Ill. Adm. Code 420.310. Audit standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The audit objectives are contained in Legislative Audit Commission Resolution Number 154, which directed the Office of the Auditor General to conduct a performance audit of the Illinois Prescription Monitoring Program (See **Appendix A**). We reviewed the Illinois Controlled Substances Act (720 ILCS 570) and the Illinois Administrative Code (77 Ill. Adm. Code 2080, 2081), which regulate the Illinois Prescription Monitoring Program (ILPMP), as well as Public Act 100-0564, which established requirements for the integration of Electronic Health Records with the ILPMP.

In conducting this audit, we reviewed statutes, administrative rules, and agency procedures for the Department of Human Services (DHS) related to the audit objectives. Any instances of noncompliance are included in the audit report as recommendations. We requested and reviewed specific documents related to the ILPMP, including policies and procedures, overviews and flowcharts for the program, budget and funding source information, organizational charts, as well as any applicable contracts, grants, and interagency agreements.

Auditors reviewed management controls and assessed risk related to the audit's objectives. A risk assessment was conducted to identify areas that needed closer examination. We examined the five components of internal control – control environment, risk assessment, control activities, information and communication, and monitoring – along with the underlying principles. We considered all five components to be significant to the audit objectives. Any deficiencies in internal control that were significant within the context of the audit objectives are discussed in the body of the report. We assessed the risk of fraud occurring as related to the audit objectives and discussed these risks in an audit team meeting.

During the audit, we conducted teleconferences and phone interviews with officials from DHS. We met with the Clinical Director for the Bureau of Informatics and the Program Manager for the ILPMP to obtain an overview of the program, including monitoring and required reporting, program oversight, and changes in requirements to the Act and Administrative Code. We also met with Eastern Illinois University's ILPMP Clinical Database Coordinator to understand how data was submitted to the ILPMP, how data was reviewed, controls for program databases, and the role of contractors. Auditors continued to meet with DHS officials throughout the audit to collect documentation, discuss preliminary

testing results, potential audit findings, and follow-up on questions relating to the ILPMP.

During program meetings, we were informed of ILPMP coordination between the ILPMP and the Illinois Department of Public Health (DPH) and the Department of Financial and Professional Regulation (DFPR). We communicated with DPH officials to discuss interagency data sharing and coordination for activities with the ILPMP. We also communicated with DFPR officials to discuss the fining process for non-compliance with the Act and the sharing of controlled substance licensing data. Auditors continued to stay in contact with both agencies for follow-up on questions relating to the program.

PIL and Active User Data

We worked with our Information Systems auditors to obtain and review the data needed to address the determinations in this audit. The following two datasets were requested in order to do this:

- the last 12 months of data from the Prescription Information Library (or database) as well as documentation supporting the completeness and accuracy of the data; and
- a listing of all active accounts (including user name, type of user, license number, date access approved, last login date) and documentation demonstrating the listing was complete and accurate.

After numerous requests and meetings, useable data was finally obtained from DHS. DHS provided PIL data from March 2020 through February 2021. We analyzed the prescription data provided and determined that for the twelve-month period there were 17,075,814 total prescription records as transmitted by dispensers to the PIL.

During the audit, DHS could not provide necessary information to determine if prescriptions were submitted by the end of the next business day as required by the Act. Necessary information includes the date a controlled substance was dispensed and the identification of pharmacies closed on weekends. Therefore, we were unable to test the ILPMP data for the timeliness of dispenser reporting.

Testing and Sampling

Our IS auditors conducted a *Review of General IT Controls*. As part of the Review, a listing of all active accounts was compared to all individuals prescribing and dispensing controlled substances from DFPR. In addition to reviewing licensing information, the review included reviewing internal controls and identified significant deficiencies in the areas of contractual services, business processes, change control, disaster recovery, and security. The Review concluded that DHS had not established general or IT controls over the data. More specifically, the Review found the following:

As a result of the Department's failure to obtain, review, and fully understand the service providers' general IT controls as it related to the Prescription Monitoring Program (website, PMPnow, and PIL) and because we are unable to determine

the adequacy of the service providers' general IT controls over the Prescription Monitoring Program, we are not able to rely on the data and reporting with respect to our testing of the Prescription Monitoring Program.

Even though the data was determined to not be reliable, the fourth audit determination asks if information submitted by dispensers was complete and timely. In order to address this audit determination, the data needed to be utilized to test the information required to be submitted by dispensers. Therefore, for testing purposes, we selected a sample of 60 prescription records entered between March 2020 and December 2020. We decided to leave January 2021 and February 2021 out for testing because we did not have the raw data for those files and would have to follow up with DHS for additional information related to them. More specifically, we reviewed:

- 45 randomly selected records stratified over the 10 months of data including: 4-5 records selected for every month of the 10 months sampled (March 2020 through December 2020); and
- 15 additional records over three areas determined to need additional review including: 5 long term care (LTC) records, 5 species code "2" or animal records, and 5 records with a birthdate over 110 years old. Records were randomly selected within the three areas.

This resulted in **60 total records** reviewed for Fieldwork testing. The sample should not be projected to the population. The testing conducted for each record included compliance with submission requirements, including prescriber, dispenser, patient, and controlled substance information. Out of the 60 records tested, we found all of them had some missing or incorrect information.

Exit Conferences

Exit conferences were held with DHS and DPH. DHS was provided a copy of the draft report and DPH was provided relevant sections of the draft report. The dates of the exit conferences, along with the principal attendees are noted below:

Exit Conference	August 5, 2021
Agency	Name and Title
DHS	 Grace Hou, Secretary Dulce Quintero, Assistant Secretary of Operations Francisco DuPrey, Chief Operating Officer Daniel Dyslin, Senior Deputy General Counsel Jennifer Aring, Director of the Office of Clinical, Administrative and Program Support Meta Jo Floyd, Bureau Chief of Pharmacy and Clinical Support Services Sarah Pointer, Clinical Director of Clinical Informatics

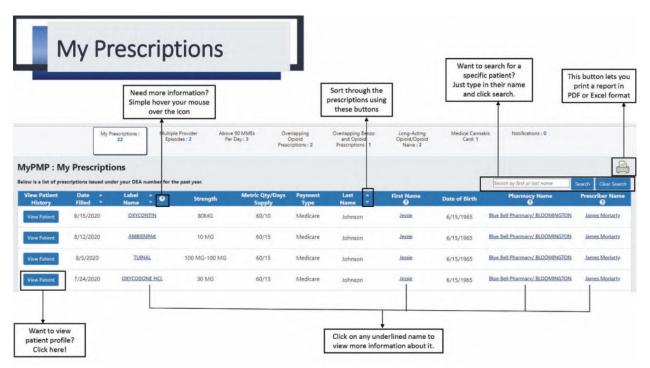
	 Craig Berberet, ILPMP Program Manager Ed Dowllar, EIU Clinical Database Coordinator Amy Macklin, Chief Internal Auditor Albert Okwuegbunam, Audit Liaison
Illinois Office of the Auditor General	 Sarah Cors, Senior Audit Manager Alison Storm, Audit Supervisor Kathy Lovejoy, Principal of IS Audits Miranda Karger, IS Audit Manager Dylan Cain, Audit Staff James Kanter, Audit Staff

Exit Conference	August 6, 2021
Agency	Name and Title
DPH	 Justin DeWitt, Chief of Staff Ellen Bruce, Deputy General Counsel, Ethics Officer Candice Long, Chief Internal Auditor Jennifer Epstein, Assistant Deputy Director of Office of Policy, Planning, and Statistics Chinyere Alu, Division Chief of Patient Safety and Quality, Office of Policy, Planning, and Statistics Dejan Jovanov, Discharge Data Manager, Office of Policy, Planning, and Statistics Karen Mancera-Cuevas, Deputy Director, Office of Health Promotion Myles Willingham, Division Chief of Medical Cannabis, Office of Health Promotion
Illinois Office of the Auditor General	 Sarah Cors, Senior Audit Manager Dylan Cain, Audit Staff James Kanter, Audit Staff

Appendix C MyPMP Screenshots MyPMP Home Screen



By Default, this page displays total prescriptions within the last 12 months attributed to your DEA number(s)



Source: OAG Prepared from DHS fictitious examples illustrating the MyPMP. No confidential information included.

Appendix D

ILPMP Monthly Statistics

Appendix D

ILPMP MONTHLY STATISTICS¹

Fiscal Years 2017 through 2020

			FY17			
Month	New Registered Users	Total Users (Active and Inactive) ²	Total PMP Website Requests	Total PMPnow Connections	Total <i>PMPnow</i> Requests	Total Law Enforcement Requests
July	353	31,522	224,294	8	237,648	60
August	424	31,946	251,094	8	280,094	57
September	378	32,324	258,745	8	265,793	75
October	311	32,635	251,937	9	265,902	70
November	271	32,906	252,785	10	237,694	41
December	229	33,135	239,273	10	199,410	85
January	244	33,379	265,374	10	221,288	67
February	212	33,591	227,988	11	353,545	96
March	257	33,848	234,465	11	596,846	85
April	341	34,189	262,881	11	544,557	79
May	379	34,568	259,262	14	841,245	75
June	540	35,108	259,491	14	899,991	77
Total	3,939	N/A	2,987,589	N/A	4,944,013	867
			FY18			
July	359	35,467	239,232	16	867,630	68
August	393	35,860	264,932	17	991,201	70
September	375	36,235	231,234	18	717,479	110
October	352	36,587	251,711	19	1,038,869	91
November	353	36,940	242,425	19	1,103,635	123
December	14,170	51,110	239,193	25	2,222,739	22
January	10,649	61,759	308,117	25	3,621,173	168
February	2,023	63,782	299,068	27	3,477,917	29
March	868	64,651	326,590	28	3,163,399	121
April	506	65,181	315,862	29	3,877,812	52
May	390	65,543	333,479	32	4,349,166	87
June	462	65,670	329,522	35	4,371,775	32
Total	30,900	N/A	3,381,365	N/A	29,802,795	973

Notes:

Source: OAG prepared from DHS information.

¹ As stated in the report, the data cannot be relied upon since there is a lack of general IT controls over the data.

² According to DHS, total users may be not equal to the sum of new registered users and total users from the previous month due to an anomaly in certain circumstances for automated tasks.

The total number of users decreased for July 2019 because the ILPMP removed duplicates.

⁴ The total number of users decreased for November 2019 because the ILPMP removed all veterinarian accounts.

Appendix D ILPMP MONTHLY STATISTICS¹ Fiscal Years 2017 through 2020

			FY19			
Month	New Registered Users	Total Users (Active and Inactive) ¹	Total PMP Website Requests	Total <i>PMPnow</i> Connections	Total <i>PMPnow</i> Requests	Total Law Enforcement Requests
July	716	66,253	369,939	37	4,275,825	62
August	606	66,720	444,020	44	4,995,576	84
September	516	67,326	350,521	50	4,014,643	67
October	394	67,821	420,326	54	4,593,632	109
November	301	68,215	407,091	58	4,248,013	102
December	257	68,516	342,716	74	4,393,964	78
January	349	68,805	400,724	87	4,406,654	111
February	243	69,122	369,650	94	4,393,163	80
March	344	69,365	379,599	103	4,499,799	170
April	289	69,709	395,446	107	4,897,906	86
May	290	69,998	391,067	166	5,079,343	367
June	419	70,570	357,697	226	5,047,542	200
Total	4,724	N/A	4,628,796	N/A	54,846,060	1,516
			FY20			
July ³	555	70,507	386,325	231	5,387,371	123
August	376	70,876	387,554	250	6,402,475	459
September	324	71,252	355,990	456	5,284,833	89
October	340	71,574	377,547	622	6,912,385	90
November ⁴	230	69,646	332,593	661	6,286,300	70
December	220	69,876	350,805	674	6,663,118	67
January	298	70,096	379,174	681	7,092,551	117
February	303	70,394	339,670	682	5,956,729	86
March	307	70,697	344,242	691	6,381,266	57
April	242	70,996	301,479	691	6,070,776	105
May	234	71,238	296,080	696	5,461,406	133
June	137	71,473	328,883	713	5,851,594	108
Total	3,566	N/A	4,180,342	N/A	73,750,804	1,504

Notes:

Source: OAG prepared from DHS information.

¹ As stated in the report, the data cannot be relied upon since there is a lack of general IT controls over the data.

² According to DHS, total users may not be equal to the sum of new registered users and total users from the previous month due to an anomaly in certain circumstances for automated tasks.

The total number of users decreased for July 2019 because the ILPMP removed duplicates.

⁴ The total number of users decreased for November 2019 because the ILPMP removed all veterinarian accounts.

Appendix E

Other State PMP Contractor Comparison

Appendix E

OTHER STATE PMP CONTRACTOR COMPARISON¹

State ²	Data Collection	Data Storage	Report Generation	Data Access
Alabama	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Alaska	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Arizona	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Arkansas	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
California	Atlantic Associates, Inc.	In-House	In-House	In-House
Colorado	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Connecticut	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Delaware	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Florida	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Georgia	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Hawaii	Appriss Inc.	In-House	Appriss Inc.	Appriss Inc.
ldaho	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Illinois	Atlantic Associates, Inc.	Hanson Information Systems, Inc.	In-House	In-House
Indiana	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
lowa	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Kansas	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Kentucky	In-House	In-House	In-House	In-House
Louisiana	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Maine	NIC	NIC	NIC	NIC

Notes:

Black indicates Appriss Only states (35). **Orange** indicates Appriss/In-House states (2). **Red** indicates In-House states (3). **Green** indicates Other Contractors/In-House states (3). **Blue** indicates Other Contractors Only states (6).

Source: OAG prepared from PDMP TTAC information.

¹ PMP information is continually published and updated by the PDMP TTAC. Exhibit information is current as of October 2020

² Missouri has been omitted as there was no statewide PMP. During this review, the PMP operated by the St. Louis County Department of Public Health was Appriss Only.

Appendix E OTHER STATE PMP CONTRACTOR COMPARISON¹

State	Data Collection	Data Storage	Report Generation	Data Access
Maryland	NIC	NIC	NIC	NIC
Massachusetts	Appriss Inc.	In-House	In-House	In-House
Michigan	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Minnesota	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Mississippi	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Montana	Montana Interactive	Montana Interactive	Montana Interactive	Montana Interactive
Nebraska	NIC	NIC	NIC	NIC
Nevada	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
New Hampshire	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
New Jersey	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
New Mexico	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
New York	In-House	In-House	In-House	In-House
North Carolina	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
North Dakota	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Ohio	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Oklahoma	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Oregon	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Pennsylvania	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Rhode Island	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
South Carolina	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
South Dakota	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Tennessee	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Texas	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Utah	In-House	In-House	In-House	In-House

Notes:

Black indicates Appriss Only states (35). Orange indicates Appriss/In-House states (2). Red indicates In-House states (3). Green indicates Other Contractors/In-House states (3). Blue indicates Other Contractors Only states (6).

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² Missouri has been omitted as there was no statewide PMP. During this review, the PMP operated by the St. Louis County Department of Public Health was Appriss Only.

Appendix E OTHER STATE PMP CONTRACTOR COMPARISON¹

State	Data Collection	Data Storage	Report Generation	Data Access
Vermont	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Virginia	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
Washington	Appriss Inc.	Appriss Inc.	Appriss Inc.	Appriss Inc.
West Virginia	Mahantech Corporation	Mahantech Corporation	Mahantech Corporation	Mahantech Corporation
Wisconsin	NIC Wisconsin	NIC Wisconsin	NIC Wisconsin	NIC Wisconsin
Wyoming	Atlantic Associates, Inc.	In-House	In-House	Atlantic Associates, Inc.

Notes:

Black indicates Appriss Only states (35). Orange indicates Appriss/In-House states (2). Red indicates In-House states (3). Green indicates Other Contractors/In-House states (3). Blue indicates Other Contractors Only states (6).

Source: OAG prepared from PDMP TTAC information.

¹ PMP information is continually published and updated by the PDMP TTAC. Exhibit information is current as of October 2020.

² Missouri has been omitted as there was no statewide PMP. During this review, the PMP operated by the St. Louis County Department of Public Health was Appriss Only.

Appendix F

Agency Responses



JBPritzker, Governor

Grace B. Hou, Secretary

100 South Grand Avenue, East • Springfield, Illinois 62762 401 South Clinton Street • Chicago, Illinois 60607

August 11, 2021

Sarah Cors Senior Audit Manager Office of the Auditor General Iles Park Plaza 740 East Ash Street Spring field, IL62703-3254

Dear Ms. Cors:

Attached, please find the Department's official responses to the findings identified in the Illinois Department of Human Services performance audit of the Illinois Prescription Monitoring Program (ILPMP).

Please review the attached Departmental responses and let me know if you have any questions or concerns.

You can reach me at amy.macklin@illinois.gov or (217) 558-6931.

Sincerely,

SIGNED ORIGINAL ON FILE

Amy Macklin, CPA Chief Internal Auditor

The Illinois Department of Human Services responses to PMP Audit Recommendations

Recommendation #1: The Department of Human Services should fully implement an ILPMP in accordance with State requirements by ensuring all EHRs are fully interfaced with the ILPMP, as required.

IDHS Response: The Department accepts the recommendation. The Department took extensive steps to provide marketing and outreach for PMPnow. We currently have 203 hospitals and health systems, which is 97% of hospitals and health systems connected or actively engaged in the connection process, in addition to many other unique health care entities already connected. The Department will continue to work towards connecting all EHR Systems or their designated Health IT Module willing and able to provide a one-to-one connection between the ILPMP and providers, as required by Illinois law.

Auditor Comment #1

As noted in Public Act 100-0564, DHS was required to "establish actions to be taken if a prescriber's Electronic Health Record System does not effectively interface with the Prescription Monitoring Program within the required timeline" or by January 1, 2021. During the audit, we asked DHS about the status of EHRs being interfaced, as required. DHS responded that the status on EHRs could not be provided because the total number of EHRs could not be determined by DHS. Therefore, the 97% referenced above appears to be missing additional context. In addition, it is unclear if the "actions to be taken" toward EHRs not interfaced would be effective, since the total number of EHRs could not be provided by DHS during the audit.

Recommendation #2: The Department of Human Services should: update the Administrative Code to align with the Illinois Controlled Substance Act related to imposing fines; and develop a formal plan to help ensure dispensing reporting requirements are being implemented as required.

IDHS Response: The Department accepts the recommendation. The Administrative Code has already been drafted to align with the Illinois Controlled Substance Act related to imposing fines. Proposed rules were submitted to the Illinois General Assembly's Joint Commission on Administrative Rules on February 11, 2021. The Department will develop and implement a formal pharmacy compliance plan for dispensing reporting requirements.

Recommendation #3: The Department of Human Services should establish general information technology controls over the data and correct the significant deficiencies related to contractual services, business processes, change control, disaster recovery, and security. Until these deficiencies are corrected, the ILPMP data and processes, change control, disaster recovery, and security reporting with respect to that data cannot be relied upon.

IDHS Response:

The Department accepts the recommendations. Although IDHS currently applies various data validation methods to the data that it receives and aggregates, we will continue to improve upon IDHS's

information technology controls, including regarding contractual services, business processes, change control, disaster recovery, and security.

Auditor Comment #2

Although DHS stated it applies "various data validation methods to the data that it receives and aggregates," no documentation was provided for these data validation methods during the audit. In addition, general information technology controls were not established over the data and our testing documented discrepancies within the data. If the various data validation methods had been applied as indicated in DHS's response, the number and type of discrepancies noted would not have occurred. As such, we were unable to rely on the data and reporting with respect to our testing of the Prescription Monitoring Program.

Recommendation #4: The Department of Human Services should establish a process to ensure the licensing data utilized by the ILPMP does not contain invalid or outdated information. The Department of Human Services should consider establishing an interagency agreement with the Department of Financial and Professional Regulation outlining each agency's responsibilities related to licensing data.

IDHS Response: The Department accepts the recommendation. The Department will work with the Illinois Department of Financial and Professional Regulation (IDFPR) to establish a process to validate licensing data. Subject to IDFPR's agreement and, as necessary, the Department will establish an interagency agreement with IDFPR, outlining each agency's responsibilities related to licensing data.

Recommendation #5: The Department of Human Services and the Department of Public Health should establish a process to conduct data reviews of sports and accident injuries as required by the Act. In addition, the Department of Human Services should alert prescribers whose discharged patients were dispensed a controlled substance about the risk of addiction and applicable guidelines.

IDHS Response: The Department accepts the recommendation. The Department will continue efforts to work with Illinois Department of Public Health (IDPH) to establish a process to conduct data reviews of sports and accident injuries as required by the Act. IDHS will work to alert prescribers whose discharged patients were dispensed a controlled substance about the risk of addiction and applicable guidelines.

IDPH did not actively exchange hospital discharge data or syndromic surveillance data during the audit period. IDHS will work with IDPH to ensure that IDHS receives this data in a timely manner.

Recommendation #6: The Department of Human Services should update the ILPMP Policies and Procedures Manual as it is currently outdated. The updates should include current policies related to law enforcement requests.

IDHS Response: The Department accepts the recommendation. The Department will update the ILPMP Policies and Procedures Manual. **Recommendation #7:** The Department of Human Services should ensure dispensers are submitting specific information as required by the Illinois Controlled Substance Act and the Illinois Administrative Code. This includes addressing the following discrepancies with meeting these requirements:

Ensuring dispensers are submitting specific information to the ILPMP by the end of the next business day after a controlled substance is dispensed;

Ensuring the following required information is submitted by dispensers: Patient ID, Patient Location Code, Patient Name, Birthdate, Date Sold, and Prescriber's Full Name;

Beginning to collect and ensure the following additional required information is submitted by dispensers: Date Dispensed, Dispenser's DEA Number, Dispenser's Full Name, and Dispenser's Address;

Following-up on problematic information submitted by dispensers so such information does not end up in the active PIL data including: records with patients over 110 years old, records with an animal species code, and/or records with an invalid patient name; and

Ensuring the following required information for LTC cases is submitted by dispensers on a weekly basis and the fields needed for their submission are created including: Diagnosis Code, Name of Medication, Date Discharged, Changes to Medicine, Reason for Admission, Date Admitted, Pre-existing Conditions, Patient Ethnicity, Patient Height, and Patient Weight.

IDHS Response:

The Department accepts the recommendation. The Illinois Prescription Monitoring Program (ILPMP) will ensure that dispensers are submitting specific information as required by the Illinois Controlled Substance Act and the Illinois Administrative Code and will work with the Department's Office of Legislative Affairs where legislation may be required.

Recommendation #8: The Department of Human Services should ensure all prescribers possessing an Illinois Controlled Substance license are registered with the ILPMP as required by the Illinois Controlled Substance Act.

IDHS Response: The Department accepts the recommendation. The Department will work with the Illinois Department of Financial and Professional Regulation to make ILPMP registration a required condition for Controlled Substance license approval and renewal.

Recommendation #9: The Department of Human Services should address the identified program assessment issues and related deficiencies by:

Ensuring reports used for program assessment contain complete and accurate information and following-up when such reports show significant changes, incorrect calculations, and/or missing information; and

Establishing an interagency agreement with the Department of Public Health to reinstate the process of exchanging data in more depth through the Opioid Data Dashboard and providing additional program assessment information to cover significant drug-related issues such as deaths, abuse, and overprescribing.

IDHS Response: The Department accepts the recommendation. The Department will address the identified program assessment issues and related issues by working to ensure that reports contain complete and accurate information, and work with the Illinois Department of Public Health to reinstate the process of exchanging data.

Recommendation #10: The Department of Human Services should address the identified monitoring issues and related deficiencies by:

Performing sufficient tracking of monitoring reports required by the Illinois Administrative Code including error reports, zero reports, and personal information reports;

Ensuring all monitoring reports required by intergovernmental agreements are completed as outlined in the agreements; and

Sufficiently monitoring ILPMP contractors through System and Organization Controls reports or internal control reviews.

IDHS Response:

The Department accepts the recommendation. The Department will work to incorporate report tracking measures. The Department will work with its Office of the Agency Procurement Officer to incorporate contract language, requiring auditing and review of internal controls for contracted vendors, requested reporting, such as System and Organization Controls (commonly referred to as SOC reports), and that such tracking measures are implemented and operating efficiency.

Recommendation #11: The Department of Human Services should address the identified ILPMP Committee weaknesses by:

Ensuring the Illinois Controlled Substance Act and the Illinois Administrative Code have the same Prescription Monitoring Program Advisory Committee (PMPAC) members listed for the PMPAC. In addition, the PMPAC charges outlined by the Act should be completed, as required.

Ensuring Peer Review Committee (PRC) members with the same profession as the prescribers or dispensers being reviewed are preparing preliminary reports and/or making recommendations, as required by the Act. In addition, PRC meetings should be held quarterly and fulfill annual reporting requirements with the required information, as required by the Illinois Administrative Code. Finally, the lists of at-risk prescribers should not be cleared and should be followed-up on.

Establishing an LTC Advisory Committee as required by the Illinois Administrative Code. This committee should be composed of healthcare professionals associated with the care of geriatric populations and include university partners performing research and longitudinal outcome evaluations.

IDHS Response: The Department accepts the recommendation.

The Administrative Code has been drafted and updates member composition to align with the statute. The proposed Code changes were presented to Illinois General Assembly's Joint Commission on Administrative Rules (JCAR) most recently on February 11, 2021.

The Department will develop a mechanism for the Peer Review Committee (PRC) members with the same profession as the prescribers or dispensers being reviewed to prepare preliminary reports and/or make recommendations, as required by the Act. The Administrative Code updating the meetings from quarterly to at least semi-annually has been submitted to JCAR. The Department will fulfill annual reporting requirements with the required information, as required by the Illinois Administrative Code. ILPMP will track all communications with at-risk prescribers for appropriate follow-up or referral to IDFPR.

The Department will analyze the need for establishing an LTC Advisory Committee as required by the Illinois Administrative Code. If the Department determines a committee is not needed, the Department will work to remove the committee from the Illinois Administrative Code.



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August 11, 2021

Honorable Frank J. Mautino Illinois Auditor General Iles Park Plaza 740 East Ash St. Springfield, IL 62703-3154

Dear Auditor General Mautino:

The Illinois Department of Public Health (IDPH) appreciates the work performed by your office in conducting the performance audit pursuant to Audit Resolution Number 154.

Enclosed with this letter is the detailed response that addresses the recommendation.

If you have any questions or comments about our response to the recommendation, please contact Ms. Candice Long at (217)-782-2497.

Sincerely,

SIGNED ORIGINAL ON FILE

Ngozi O. Ezike, M.D. Director

Enclosure

C: Justin DeWitt, Chief of Staff Candice Long, Chief Internal Auditor Internal Audit File

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SPORTS AND ACCIDENT INJURY DATA REVIEWS

RECOMMENDATION NUMBER 5

The Department of Human Services and the Department of Public Health should establish a process to conduct data reviews of sports and accident injuries as required by the Act. In addition, the Department of Human Services should alert prescribers whose discharged patients were dispensed a controlled substance about the risk of addiction and applicable guidelines.

DPH Response

The Department accepts the recommendation. Specifically, DPH's role is to identify sports and accident injuries through its surveillance systems and provide DHS with this data. The multi-step process to provide this data is nearly complete (approximately 80%), including working with DHS to define injury codes and data elements and testing the initial pull of injury data. DPH anticipates completing the remaining steps by December 2021, which will include the automation of data queries and data transfers, and user testing.