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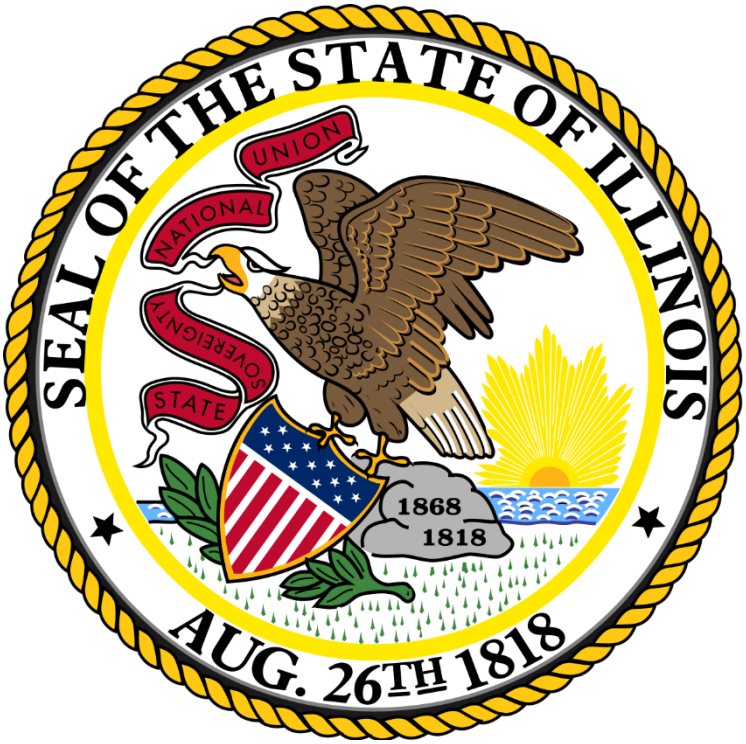

Performance Audit of the
Illinois Prescription Monitoring Program
September 2021

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Performance Audit of the
Illinois Prescription Monitoring Program
Department of Human Services

September 2021

RECOMMENDATIONS – 11

Accepted – All
Partially Implemented – All

Introduction

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, PMP(s) or Program) operated by the Department of Human Services (DHS). The Resolution contained five audit determinations which are as follows:

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

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

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.

The Illinois Department of Human Services (DHS) is the supervising entity over the Act. 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. Due to the number of other entities involved, the ILPMP process is complex.

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 % 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, 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. Auditors 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 DFPR licensing data, auditors 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 (IDPH) 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 IT 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 IDPH 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.

Accountants' Findings and Recommendations

1. DHS should fully implement an ILPMP in accordance with State requirements by ensuring all EHRs are fully interfaced with the ILPMP, as required.

FINDING: *(Fully Implemented Administrative Rules 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.

DHS RESPONSE:

DHS accepts the recommendation. DHS took extensive steps to provide marketing and outreach for PMPnow. DHS currently has 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. DHS 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, auditors 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.

UPDATED RESPONSE:
Accepted. Corrective Action in Progress:

DHS has divided the enormous task of interfacing **ALL** EHRs into manageable subsections.

1. Hospitals 98% complete
2. FQHC (Federally Qualified Health Center) 93% complete
3. Opioid Treatment Program 47% complete
4. Pharmacies 36% complete
5. Long Term Care 32% complete
6. Additional Healthcare Locations 92% complete
7. EHR Vendors 25% of known EHRs in use are connected
8. DHS is continuing to develop a plan to create a master file of all health care locations that are required to integrate under the statute. DHS will continue to review these identified locations and work with the necessary partners to get the integration complete. 25% complete
9. DHS is in the process of establishing a long-range plan to keep connections active. 5% complete

Estimated Date of Completion: Connection of **ALL** EHRs as defined in statute is a moving target as Healthcare Organizations are constantly changing. As new healthcare offices open, DHS will need to connect these. As offices close, DHS will need to ensure for these appropriately too. DHS has no way of knowing about such situations until they are contacted by the relative entity. DHS is also experiencing Healthcare Organizations changing their EHR systems, hence causing changes to DHS connections as well.

2. 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.**

FINDING: *(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.

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, auditors 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. Auditors 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.

DHS RESPONSE:

DHS 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. DHS will develop and implement a formal pharmacy compliance plan for dispensing reporting requirements.

UPDATED RESPONSE;

Accepted. Corrective Action in Progress:

1. Draft revision of Administrative Rules and send to JCAR. 100% complete
2. Update Submitter's Guide to reflect the required fields Pharmacies and LTCs must send (i.e. Date Sold/Date Dispensed). 15% complete
3. Update Atlantic Associates with required field values. 0% complete
4. Test with Atlantic Associates. Add LTC DB field values to MySQL/SQL Server that are not included in the ASAP format such as patient weight, etc.
5. Update data validation and cleansing operations to incorporate new fields. 0% complete

6. Develop LTC contact list of locations for dissemination of PMP related notifications. 100% complete
7. Develop monitoring method utilizing Atlantic Associates existing reports. 20% complete
8. Send out notice to non-conforming Pharmacies/LTC Locations what field values must be set to the PMP and on what schedule (LTC weekly/Pharmacies daily). 0% complete
9. Utilize DEA and DFPR resources to obtain all CS Pharmacy locations in Illinois. 100% complete
10. Provide go live date. 0% complete
11. Update Policy and Procedures Manual to reflect changes. 0% complete

Estimated Date of Completion: December 2022

3. DHS should establish general IT 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 PMP data and reporting with respect to that data cannot be relied upon.

FINDING: *(Lack of Controls Over the Data)*

DHS has not established general IT 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.

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

DHS worked with 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.

DHS REVIEW #4525: Performance Audit – Illinois Prescription Monitoring Program

After numerous requests and meetings, useable data was finally obtained from DHS. However, the datasets provided by DHS were problematic, and auditors 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 DHS' 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 or database) and because auditors are unable to determine the adequacy of the service providers' general IT controls over the Prescription Monitoring Program, ***auditors are not able to rely on the data and reporting with respect to the 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 EIU 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, auditors are unable to design suitable audit procedures to determine if changes to the PIL were properly controlled.

In addition, auditors 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, auditors obtained the population of active users. Auditor's 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, **auditors are unable to determine how DHS is validating the user's license** with the DFPR 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, auditors 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.**

DHS RESPONSE:

DHS accepts the recommendations. Although DHS currently applies various data validation methods to the data that it receives and aggregates, auditors will continue to improve upon DHS's IT 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 IT 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, auditors were unable to rely on the data and reporting with respect to our testing of the Prescription Monitoring Program.

UPDATED RESPONSE:

Accepted. Corrective Action in Progress:

DHS REVIEW #4525: Performance Audit – Illinois Prescription Monitoring Program

1. Contractual Services 20% complete

   Update IT related contracts to include SOC requirement.

   - LogiCoy contract amendment to provide for review of the security or development of PMPnow connections.
   - Hanson contract to provide reports that Data center controls have been implemented and are operating correctly.
   - Atlantic Associates contract to require a review of internal controls related to security and cleansing of the data.
   - EIU contract to require documentation of internal controls related to development and maintenance of the PIL.

2. Business Processes 20% complete

   - Develop reconciliation process to ensure the accuracy and completeness of third-party data (DFPR/DOJ/DPH/HFS/Redbook).

3. Change Control 20% complete

   - DHS will adopt a change control template policy.
   - Define/document standard procedures.
   - Develop web/written templates that will include relevant fields such as the requestor, function/activities, planned timeline, and who monitored/executed/controlled/closed the request.
   - Update Policies and Procedures Manual with current documentation.
   - Create segregation of duties to the extent that available resources allow.

4. Disaster Recovery 30% complete

   - PMP will detail specific procedures for disaster recovery scenarios, outlining the specific steps needed to restart, reconfigure, and recover systems and networks.
   - PMP will work with its Vendors to address the roles and specific responsibilities of recovery team members.

5. Security 50% complete

   - Compile list of expired DEA license numbers.
   - Compile list of expired DFPR license numbers.
   - Deactivate expired accounts or accounts that have not logged in over a year.

Estimated Date of Completion: September 2022

4. 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 DFPR outlining each agency's responsibilities related to the licensing data.

FINDING: *(Accurate Licensing Data)*

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, auditors 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, auditors verified that DFPR does not impose any fines for willful violations of the ILPMP dispensing requirements. Through communications with DHS and DFPR, auditors 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

Auditors requested DFPR data for all individuals prescribing and dispensing controlled substances in Illinois. Auditors 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, auditors 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.

DHS REVIEW #4525: Performance Audit – Illinois Prescription Monitoring Program

DHS RESPONSE:
DHS accepts the recommendation. DHS will work with DFPR to establish a process to validate licensing data. Subject to DFPR's agreement and, as necessary, DHS will establish an interagency agreement with DFPR, outlining each agency's responsibilities related to licensing data.

UPDATED RESPONSE:

Accepted. Corrective Action in Progress:

1. Initiate regular scheduled discussions with pertinent DFPR counterparts regarding gaining the ability to receive timelier data-sharing. 100% complete

2. PMP and DFPR will outline a formal interagency/data-sharing agreement. 5% complete

3. PMP will work with DFPR to obtain more current licensing data with the future intention of developing an Application Programing Interface (API) that would allow on-demand access to licensing data that can be utilized upon initial user signup and provide for weekly/daily verification of user's license status. 0% complete

Estimated Date of Completion: December 2022

5. DHS and IDPH 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.

FINDING: *(Sports and Accident Injury Data Reviews)*

According to DHS, IDPH 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 IDPH, it receives hospital discharge data quarterly from facilities.

DHS also noted four CDC grants requiring coordination between DHS and IDPH 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 IDPH, 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 IDPH are currently coordinating to exchange datasets for sports and accident injury information and creating reports. IDPH and DHS are also working to define codes related to sports injuries.

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

According to IDPH, it 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.

DHS RESPONSE:

DHS accepts the recommendation. DHS will continue efforts to work with IDPH to establish a process to conduct data reviews of sports and accident injuries as required by the Act. DHS will work to alert prescribers whose discharged patients were dispensed a

controlled substance about the risk of addiction and applicable guidelines. DPH did not actively exchange hospital discharge data or syndromic surveillance data during the audit period. DHS will work with IDPH to ensure that DHS receives this data in a timely manner.

IDPH RESPONSE:
IDPH accepts the recommendation. Specifically, IDPH'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. IDPH anticipates completing the remaining steps by December 2021, which will include the automation of data queries and data transfers, and user testing.

UPDATED RESPONSE:

Accepted. Corrective Action in Progress:

1. Discussions with IDPH regarding the data reviews for sports and accident injuries and establish timeline for data exchange. 100% complete

2. Establish an Application Programming Interface (API) between DHS and IDPH for data exchange (Dependent on DPH establishing API). 50% complete

3. IDPH will identify Hospital Discharge Data (HDD) that match diagnosis codes for sports and injuries (Dependent on DPH identifying records). 0% complete

4. IDPH Match HDD records to PMP records (Dependent on IDPH matching records). 0% complete

5. Receive matched patient records from IDPH, post records to PMP website and PMPnow, and alert prescribers of the discharge. 0% complete

6. IDPH will include syndromic surveillance data using the same process of identifying and matching records as the HDD. 0% complete

Estimated Date of Completion: September 2022

6. 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.

FINDING: *(Update the 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.

DHS REVIEW #4525: Performance Audit – Illinois Prescription Monitoring Program

In addition to the review performed of the Manual as part of the *Review of General IT Controls,* auditors 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, auditors 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 auditors 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, auditors 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 screened 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 not reporting 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 47 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 55 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 ilpmp.org website account using a web-based request form. In addition, the Act details the confidentiality requirements of ILPMP data and under what conditions DHS can share such data with law enforcement officials.

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. Auditors 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.

Auditors 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.

Auditors 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.

DHS RESPONSE:
DHS accepts the recommendation. DHS will update the ILPMP Policies and Procedures P&P) Manual.

UPDATED RESPONSE:
Accepted.

Corrective Action in Progress:

1. Develop plan and assign leadership roles for P&P manual update. 10% complete
2. Obtain a project management software to track progress toward completion of the process. 50% complete
3. Re-establish and update Table of Contents with updated P&P which may require a change in section names. 0% complete
4. Determine current procedures for PMP: Data and Access; Security and Safeguards; Law Enforcement Requests; and PIL Design. 5% complete
5. Update old and new sections with new P&P. 5% complete
6. Finalize updated P&P. 0% complete
7. Develop a system for annual review of P&P to identify and address changes as needed. 25% complete

Estimated Date of Completion: December 2022

7. 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 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.**

FINDING: *(Ensure Dispenser Requirements are Completed as Required)*

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

According to the Act, the date filled for a controlled substance and the date dispensed 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.

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

During testing, auditors 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, auditors 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, auditors requested the last 12 months of active data from the PIL. After numerous requests and meetings with DHS officials, auditors 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. Auditors shared this information with DHS, and DHS confirmed both the total number of prescriptions and monthly breakdown provided. Auditors 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 auditors confirmed the total and monthly breakdown of prescription records with DHS, auditors 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*, auditors 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, auditors 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

Auditors 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.

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
- 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.

- 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.

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).

Auditors 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. Auditors 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, auditors 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 five prescription records for patients in LTC to determine whether DHS was collecting these additional fields. In addition, two 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 nine additional LTC records included **for a total of 16 LTC prescription records reviewed** 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.

DHS RESPONSE:

DHS 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 DHS' Office of Legislative Affairs where legislation may be required.

UPDATED RESPONSE:

Accepted. Corrective Action in Progress:

1. DHS will work with its Legislative arm to align both the PMP related statute and administrative rules to adopt the same data fields and data definitions where necessary to mitigate confusion and reduce redundant fields. For example, removing the need for sending the Dispenser's Full Name as this is available from looking up the DEA number of the Dispenser. 50% complete

2. PMP will incorporate new verbiage in its Pharmacy Submitter's Guide to more clearly define data field requirements. 60% complete

3. PMP will develop correspondence to periodically send to non-conforming Submitters and remind them of PMP data field current requirements. 0% complete

4. PMP will research implementing algorithms that could assist in exposing problematic data elements in free form fields such as patient name and date of birth. 10% complete

Estimated Date of Completion: December 2022

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

FINDING: *(Ensure Prescribers are Registered with the ILPMP as Required)*

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 IDPH 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 REVIEW #4525: Performance Audit – Illinois Prescription Monitoring Program

DHS Program Assessment Information

Auditors 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).

Auditors 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 in certain circumstances. DHS did not elaborate further, but auditors 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).

Auditors 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 **auditors cannot rely on this data or these 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 auditors reviewed these reports that DHS listed as being used for program assessment, auditors 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). Auditors 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.

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.

DHS RESPONSE:
DHS accepts the recommendation. DHS will work with DFPR to make ILPMP registration a required condition for Controlled Substance license approval and renewal.

UPDATED RESPONSE:

Accepted. Corrective Action in Progress:

1. Initiate meetings with DFPR to review Audit Recommendation- 100% complete
2. Audit of prescribers who have not registered for PMP 0% complete
3. Develop communication to non-compliant-license holders- 75% complete
4. Work with DFPR for letter distribution- next meeting 12/14- 50% complete

5. Work with DFPR to make registration a condition of the next license renewal – 0% complete
   316 Podiatrist CS next renewal is 1/31/2023.
   336 Physician CS next renewal is 7/31/2023.
   346 Optometrist CS next renewal is 3/31/2022.
   385 Physician Assistant CS next renewal is 3/1/2022.
   377 APRN-FPA CS next renewal is 5/31/2022.
   319 Dental CS is currently in renewal (Expiration date is 12/31/2021). Next renewal is 9/30/2024.

Estimated Date of Completion: 9/30/2024 remaining action is dependent on DFPR as the enforcement agency for controlled substance licenses.

9. DHS 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 IDPH 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.**

FINDING: *(Program Assessment Issues)*

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. Auditors 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 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, auditors noted **approximately 90 instances** where indicators appeared to be missing data. Auditors asked DHS about the limited or missing data for these indicators. According to DHS officials, the final annual report was approved as completed 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 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 IDPH 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 IDPH, staff linked data for the ILPMP, hospital discharges, and death certificates. Although DHS and IDPH 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 IDPH 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 2022 depending on DPH's resource availability.

DHS REVIEW #4525: Performance Audit – Illinois Prescription Monitoring Program

DHS RESPONSE:
DHS accepts the recommendation. DHS will address the identified program assessment issues and related issues by working to ensure that reports contain complete and accurate information, and work with IDPH to reinstate the process of exchanging data.

UPDATED RESPONSE:
Accepted. Corrective Action in Progress:

1. Identify reports used for program assessment. 10% complete
2. Identify processes to ensure completeness and accuracy of reports. 5% complete
3. Create follow-up plans when changes, incorrect calculation, and missing information is identified. 0% complete
4. Collaborate with IDPH to exchange more in-depth data, like deaths, abuse and overprescribing. 10% complete

Estimated Date of Completion: September 2022

10. DHS 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.**

FINDING: *(Monitoring)*

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, auditors 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. Auditors 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.

Auditors 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.

Auditors 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, auditors 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.

Auditors 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, auditors 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.

Auditors 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, auditors 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. Auditors 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 IDPH 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 IDPH. The ILPMP provides IDPH 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**.**

Auditors 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.

Final Annual Report

As part of the same intergovernmental agreement, DHS was required to provide a final report to the CDC and IDPH 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).

Auditors 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.

Contractor Monitoring

Many of the responsibilities of the controls over IT and the data reside with contractors as delegated by DHS. Auditors 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.

DHS REVIEW #4525: Performance Audit – Illinois Prescription Monitoring Program

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.**

Auditors 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.

DHS RESPONSE:
DHS accepts the recommendation. DHS will work to incorporate report tracking measures and 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.

UPDATED RESPONSE:

Accepted. Corrective Action in Progress:

1. Identify reports that will require tracking measures. 30% complete

2. Incorporate tracking measures for monitoring reports. 30% complete

3. Incorporate measures to ensure reports required by IGAs are complete. 30% complete

4. Identify contracts that will require monitoring through System and Organization Controls. 70% complete

5. Amend contracts to include internal control reviews and SOC reports for contracts. 10% complete

Estimated Date of Completion: September 2022

11. DHS should address the identified ILPMP Committee weaknesses by:

- **ensuring the Illinois Controlled Substances 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.**

FINDING: *(ILPMP Committee Weaknesses)*

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 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 (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;
    b. accredited continuing education programs related to prescribing and dispensing;
    c. 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.

Auditors 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, auditors 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, auditors 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).

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, **auditors 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. Auditors reviewed the February 2021 meeting minutes and found that the guidelines for these reports were discussed, but no reports or recommendations were completed. Auditors 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 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.

Auditors reviewed the FY18, FY19, and FY20 Annual Reports to determine if the required information was included. Auditors 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, auditors 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.

Auditors 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. Auditors 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.

Auditors 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.

DHS RESPONSE:

DHS 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 JCAR most recently on February 11, 2021. DHS 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. DHS 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 DFPR. DHS will analyze the need for establishing an LTC Advisory Committee as required by the Illinois Administrative Code. If DHS determines a committee is not needed, DHS will work to remove the committee from the Illinois Administrative Code.

UPDATED RESPONSE:

Accepted. Corrective Action in Progress:

1. Compose Rules clarification regarding member composition submitted JCAR 100% complete
2. Follow up with JCAR for required forms and address questions in language 100% complete
3. Send rules for executive review 100% complete
4. First posting of Rules 0% complete
5. Annual Reporting requirements will be met 100% complete
6. Develop a method 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 for referral 100% complete
7. High prescribers identified by the PRC will be tracked and followed for outcomes and evaluation. Utilize Epi services for analysis and utilization of other vendor partners to develop methods for education 30% complete
8. Evaluate need for LTC committee. 0% complete

Estimated Date of Completion: September 2022