

Technical Assistance Guide

PDMP Suggested Practices to Ensure Pharmacy Compliance and Improve Data Integrity

This project was supported by Grant No. 2011-PM-BX-K001 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, and the Office for Victims of Crime. Points of view or opinions in this document are those of the author and do not represent the official position or policies of the U.S. Department of Justice.



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Executive Summary

Complete and accurate prescription drug information is vitally important to support efforts to reduce the incidence of prescription drug abuse and diversion. Healthcare providers (prescribers and dispensers) have a vested interest in ensuring that quality data is transmitted to, and available from, prescription drug monitoring programs (PDMPs). In October 2014, the PDMP Training and Technical Assistance Center (TTAC) convened a work group, primarily comprised of PDMP Administrators and staff, to examine the issues surrounding prescription data including timely transmission, identifying errors, and processes to ensure errors are corrected. The work group examined promising practices for PDMPs in identifying the universe of dispensers required to transmit prescription data, effective ways to monitor dispenser's compliance, and how to provide dispensers with information about what data should be transmitted and how. The work group also examined where data errors may potentially occur, how PDMPs may identify the errors and processes to ensure timely corrective actions. This Technical Assistance Guide (TAG) details the areas where prescription data errors may occur, some procedures PDMPs employ to detect those errors, and steps to ensure the erroneous data is corrected. Additionally, the TAG provides suggestions for prescribers, dispensers, and other stakeholders to consider to prevent data errors from occurring. The TAG has three (3) major sections: Data Submission Compliance, Data Quality, and Error Remediation.

Data Submission Compliance

While the vast majority of dispensers transmit prescription data in accordance with a PDMP's requirements, there are some who do not. In order to maintain and provide a complete prescription history for authorized PDMP users, PDMPs must ensure that all of the dispensers, required to transmit prescription data, do so in accordance with the laws of the state. PDMPs have several sources (state and federal) of information available to them or their data collection vendor to identify dispensers. This information exists within their agency or with the licensing authority. In cases where the PDMP allows exemptions or waivers from electronic reporting of prescriptions, it is important to have procedures and policies in place to enable dispensers to request such exemptions or waivers and a process by which the PDMP can monitor the status of exempted or waived dispensers. This section examines other reasons why dispensers fail to submit data including technological issues, lack of knowledge concerning procedures or requirements, or intentional non-compliance. Recommendations are included about several practices to maximize compliance; such as, validating data transmissions, transmitting data to the PDMP daily unless real-time transmission is required, testing licensees' knowledge of applicable statutes and regulations, and comparing data from pharmaceutical drug distributors to dispenser records transmitted to PDMPs.

Data Quality

Unintentional data errors may occur anywhere in the process of prescribing or dispensing a controlled substance prescription. Prescription data errors may be the result of a prescriber's illegible handwriting, data entry errors at the pharmacy, or procedural flaws to name a few. Common errors are broken down into four categories of information (patient, medication, prescriber, and dispenser) and three types of errors (minor, serious, and fatal). Electronic prescribing of controlled substances will have an immediate impact on reducing and eliminating common prescription errors; however, it is still years away for most states. PDMPs have processes in place to identify errors before the prescription records become part of the PDMP database. This section explains in detail the most common prescription errors, the data quality checks to identify those errors, and actions that stakeholders can take to reduce their incidence.

Error Remediation

Identifying the errors is only a part of the process to ensure that PDMPs have complete, accurate information. PDMPs have the responsibility to have in place a system that identifies errors, informs dispensers of the errors, and monitors corrections. The policies and procedures in error remediation must facilitate the ability of the dispenser to clearly understand whether the error is with a single record, series of records, or entire data file. The instructions to the dispenser about correcting the errors must be precise and clear. This section details promising practices in the error notification process and tracking of error corrections. It concludes with suggestions and methods to improve efficiency within these processes.

Introduction

Prescription Drug Monitoring Program (PDMP) information is utilized for public health, regulatory compliance, criminal investigations, intervention and prevention programs, and educational purposes. PDMPs are experiencing an increase in usage due to increased awareness of a PDMP's effectiveness. Currently, there are 23 states with legislative action requiring prescribers or dispensers to request a PDMP report on their patients or make PDMP data an established part of medical practice.¹ Therefore, it is imperative that prescribers, dispensers, and PDMPs make every effort to ensure the prescription information is complete, accurate, and current. Stakeholders who request or are proactively provided (unsolicited reports) PDMP reports must be assured the best possible data has been collected and a PDMP has taken appropriate steps to ensure the data's accuracy. PDMP reports play an increasingly important role in the care a patient receives by a prescriber or dispenser; drug courts rely on PDMP reports to assist in determining a participant's compliance; regulatory boards depend on the data to help determine if a medical provider is meeting the standards of practice. Data reliability and accuracy become even more challenging as PDMPs reduce their reporting frequency to 7 days, 24 hours, or at point of sale.

TTAC convened a work group to examine and identify effective processes employed by PDMPs and to suggest enhanced processes that PDMPs may use to manage data compliance and ensure data integrity.

¹ Data from the PDMP Training and Technical Assistance Center, 2014 State PDMP Survey, <http://www.pdmpassist.org/content/state-profiles-reports>

The work group consisted of PDMP representatives from Kentucky, Maine, Maryland, Texas, and Washington, as well as participation by researchers from Brandeis University. The work group met over a period of 3 months (October through December 2014) and discussed a number of topics, including:

- Identifying processes to ensure data submission compliance
- Identifying common data problems
- Identifying processes for error remediation

This Technical Assistance Guide (TAG) is the result of the work group's efforts and is intended to 1) provide techniques and policies PDMPs may wish to consider employing as they strive to provide quality prescription information to their authorized users and 2) detail suggested practices for prescribers, dispensers, and other stakeholders to reduce the incidence of data errors. The TAG also includes two appendices: Summary of Recommended Practices and Data Resources Links.

Section I - Data Submission Compliance

Dispensers are required by law to send controlled substance prescription information to a PDMP; Oklahoma is currently the only PDMP that requires real-time transmission, 18 PDMPs (36%) require daily transmission, 28 PDMPs (56%) every 2-7 days, and 3 PDMPs (6%) have a transmission requirement greater than 7 days.² Nationally, there are approximately 70,000 pharmacies registered with the Drug Enforcement Administration (DEA) to dispense controlled substances.³ It is incumbent upon each PDMP to ensure dispensers in their state are transmitting data within the timeframes required by state laws. This section will describe techniques to identify dispensers, determine compliance and propose practices to increase the compliance rate.

Identifying Dispensers

The first step to determine compliance is to identify the population of licensed dispensers required to transmit data to the PDMP. The term 'dispensers' includes pharmacies that dispense controlled substances, and may also include prescribers that dispense controlled substances directly to their patients. In some states, certain pharmacies may be exempt from transmitting information to the PDMP. This may include pharmacies that dispense medications to nursing home residents, methadone clinics, or pharmacies that are part of a correction facility or system. Pharmacies are licensed by a licensing agency (Board, Health, Consumer Protection, etc.) in the state where the pharmacy is located; in many cases, pharmacies must also be licensed in each state into which they dispense medications (e.g., mail order pharmacies). In addition, there are 37 states that require prescribers who dispense controlled substances from their offices to transmit prescription data to the PDMP.⁴ All dispensers must have a valid Drug Enforcement Administration (DEA) controlled substances registration.

² Data from the PDMP Training and Technical Assistance Center, 2014 State PDMP Survey, <http://www.pdmpassist.org/content/state-profiles-reports>

³ Data from the Drug Enforcement Administration, Office of Diversion Control, Registrant Population by State and Business Activity, <https://www.deadiversion.usdoj.gov/webforms/jsp/odrReports/odrStateReport.jsp>

⁴ Data from the PDMP Training and Technical Assistance Center, 2014 State PDMP Survey, <http://www.pdmpassist.org/content/state-profiles-reports>

It is important to note that DEA does not issue a registration without a dispenser providing proof they are first licensed in a state. This fact plays an important role in PDMPs monitoring dispensers' compliance. Due to the DEA policy of requiring state licensing first, this may at times result in gaps between when a dispenser is licensed by a state and when a DEA registration is issued. It is possible to have a dispenser listed in the state licensing file and not in the DEA registrant file. It is also possible to have a dispenser close and be removed from the state licensing file before the DEA has removed them from their files. Therefore, it is important for the PDMP to use both state licensing files and DEA registrant files to ascertain the current status of a particular dispenser and to obtain continuous updates. When a PDMP uses a vendor to monitor dispenser reporting requirements, the PDMP must ensure the vendor is utilizing the most current information available. PDMPs can contact the appropriate state licensing agency and the DEA to obtain a current copy of the licensees/registrants; ideally, an online, real-time connection to the state license/DEA registration files should be established. The state license/DEA registration files can be matched against the records transmitted by the dispensers for a certain time frame to create a list of dispensers that did not transmit data to the PDMP.

Possible Causes for Non-Compliance by Dispensers

The overwhelming majority of dispensers complies with PDMP requirements and transmits data to a PDMP on schedule. Non-transmission or late transmission of data may be explained by several factors, including the following.

Exemptions or Waivers: It should be noted that not every licensed or registered dispenser is required to report. As previously mentioned, many states have statutes/regulations to waive or exempt certain dispensers from reporting in the manner specified by statute under certain conditions. These conditions typically include health system pharmacies, correctional facility dispensaries, veterinarians, pharmacies that do not dispense controlled substances or dispense below a certain amount and dispensers who are unable to electronically transmit prescription data. A PDMP waiver should only be issued for a certain period of time or until such time the condition, for which the waiver was issued, no longer exists.

Technology: Technical problems, either at the dispenser, the vendor, or the PDMP, sometimes prevent the transmission of the data to the PDMP or receipt of the data by the PDMP. These problems may include computer crashes, server connectivity issues, power failures, etc. Some dispensers may not be aware their data has not been transmitted or received.

Knowledge: Dispensers' failure to comply with the reporting requirements, at times, may be related to a lack of knowledge of the law or regulations. This is particularly true with a new pharmacy or practitioner or an out of state pharmacy that is required to report to a PDMP in the state where the patient resides.

Willful Non-Compliance: There are unscrupulous dispensers, albeit a very small number, that willfully do not transmit data or transmit partial data to the PDMP because they are engaged in unlawful and harmful activity (i.e., prescription fraud, dispensing prescriptions from a pill mill, Medicaid fraud, practicing without a valid license) or do not feel obligated to report.

Recommended Practices for Maximizing Compliance

Exemptions or Waivers:

- PDMPs should have written guidelines detailing the exemption/waiver processes. These guidelines should be reviewed by the PDMPs legal office and should be made known to the pharmacy community and the state's regulatory boards.
- If a dispenser is exempted or has a waiver, the PDMP guidelines should set a time limit for which the exemption/waiver is valid. For example, the PDMP should require that the dispenser reapply for an exemption/waiver every year or in conjunction with their license renewal.
- PDMPs, by policy or regulation, should require the dispenser to notify the PDMP if their status changes, thus making them no longer eligible for the exemption/waiver.
- The validity of the dispenser's reasons to obtain an exemption/waiver should be independently confirmed by the agencies that have the authority to perform inspections at a dispenser's location or by the PDMP staff. This should occur before the exemption/waiver is issued and at least once during each exemption/waiver period. For example, if a waiver or exemption is requested because the dispenser does not dispense controlled substances, a reasonable effort should be made to inspect the premises or request sales records to verify that fact.

Validation of Data Transmission:

- PDMPs should encourage a dispenser to compare the number of records transmitted to the number of records successfully received by the PDMP or its vendor. Discrepancies in these numbers should be reported to the PDMP or its vendor in a timely manner for resolution.
- Dispensers, if allowed by the PDMP, should be encouraged to routinely (e.g., quarterly) query the PDMP for a listing of prescriptions that have been dispensed from their location to compare to their internal records.

Technology

- Test transmissions should be performed upon any change/modification to software or hardware by the dispenser, PDMP, PDMP software vendor (if applicable), or by dispenser-system vendors.
- PDMPs vary in their transmission frequency requirement; however, none prohibit transmitting data in a shorter time frame. To avoid instances of late reporting, dispensers should transmit data to the PDMP every night unless there is the requirement to report data in real-time. Many dispensers program their systems to comply with the requirements of the law and may not be aware of the ability to transmit data daily. PDMPs should inform dispensers of this and include it in their brochures and outreach materials.

Knowledge:

- PDMPs and licensing/regulatory agencies should provide detailed information concerning any change to existing statutes/regulations that impacts a dispenser's practice well in advance of the changes being enacted. A good policy is to notify all dispensers registered to report to the PDMP as well as the pharmacy system vendors and chain pharmacies. The information could also be compiled and included with license renewals.
- PDMPs and licensing/regulatory agencies should have links on their respective websites to full text versions of current statutes/regulations.

- PDMPs should have links on their websites to the technical specifications for transmitting prescription information.
- Articles, frequently asked questions (FAQ) documents, instructional guides and/or training modules, providing real-world scenarios, should be made available to dispensers on the interpretation and application of statutes/regulations. These can be provided as inserts with registration applications or renewals, presented during conferences, included in newsletters or mass distribution, or recorded and linked to appropriate agency websites. TTAC has several guidance documents that may assist in the development of these resources (<http://www.pdmpassist.org/content/guidelines>).
- PDMPs should work with their licensing/regulatory agencies to include licensee testing on current statutes/regulations as a requirement to obtain or renew a license.
- PDMPs should make every effort to present at professional conferences or submit articles to professional organizations' newsletters.

Willful Non Compliance:

- Agencies, with the legal authority to inspect dispenser locations, should obtain a PDMP report on the dispenser's prescription history to use as a reference guide when performing audits or inspections. PDMPs should strive to foster a collaborative relationship with such licensing/regulatory agencies and provide training on PDMP reports that are available to such agencies and how to best utilize the reports to carry out their responsibilities.
- PDMPs, if allowed, should obtain a list of controlled substances that have been ordered by a dispenser from DEA (ARCOS data), drug manufacturers, and drug distributors and compare to the dispensing history within the PDMP's database. Several states require licensed distributors to report to the state all the sales of controlled substances made to pharmacies, healthcare facilities and practitioners. If a PDMP does not have such authority, it should request assistance from the state agency that does.
- PDMPs should consider cross-checking the date the prescription was filled with date the prescription was transmitted to identify the dispensers who reported beyond the statutory time frame.
- PDMPs should review a dispenser's data transmission history for a given period of time to reveal gaps in transmitted data, statistically significant variations in the number of records sent per transmission, and anomalies in dispensing trends to identify potential compliance issues.
- PDMPs should have a published process for authorized recipients of PDMP reports to report missing data to the PDMP for investigation.
- PDMPs should report any suspected administrative or criminal violation, by a dispenser, to the appropriate licensing/regulatory and/or law enforcement agency, if allowed under the State's statutes/regulations.
- PDMPs and licensing/regulatory agencies should have links on their respective websites detailing the consequences of non-compliance.

Section II - Data Quality

The data transmitted to PDMPs originates from a prescription that may be handwritten, electronically prescribed or telephonically communicated by the prescriber or prescriber's staff to the pharmacy. Consequently, errors may be introduced unintentionally during the process of prescribing or dispensing of the prescription. The likelihood of errors increases when the written prescription information is incomplete, inaccurate, or illegible resulting in the possibility of misinterpreting the prescription information. In order to alert and inform prescribers and dispensers about potential medication errors, The Joint Commission developed a 'Do Not Use' list which identifies medical abbreviations that prescribers should not use when writing prescriptions.⁵ In addition, the Institute for Safe Medication Practices published the 'List of Error Prone Abbreviations, Symbols, and Dose Designations'.⁶

Errors may also occur when entering prescription data into the pharmacy system for subsequent transmission to the third party payer, if applicable, and the PDMP. For example, many pharmacy systems use a 'pick list'. Simply put, a pick list is an alphabetical list of names from which to select the prescriber or patient; once selected, the system automatically inputs the information into the system. Although the use of pick lists saves the dispenser a tremendous amount of time, errors may occur. The information on the pick list may not contain the most current information (i.e. a patient's address) or, in some cases, the wrong name is selected resulting in a different patient or prescriber being associated with that prescription. Electronic prescribing of controlled substances is not currently widely adopted, but holds significant promise to help reduce data reporting errors.⁷ In March 2016, New York State will require all prescriptions, including controlled substances, to be electronic prescriptions.

Common Data Errors

The quality of data which is eventually sent to a PDMP is very much dependent on the accuracy and completeness of the information initially provided by the dispenser. Generally, the information, transmitted to a PDMP, is the result of manual data entry by a pharmacist or pharmacy technician of prescriptions that are handwritten or transmitted by a prescriber or a prescriber's staff member. Furthermore, there are times when data is entered in the wrong field (i.e., the date when a prescription is filled or dispensed may be accidentally placed in the patient DOB field). Considering the thousands of data elements most pharmacies record daily, the data provided to a PDMP is usually of good quality. However, there is room for improvement and a necessity to consciously ensure accurate information as even the slightest error or omission may impact how a patient receives care. This section will identify the most common errors in PDMP data, list methods used by PDMPs to discover the errors, offer possible causes, and propose practices to reduce or eliminate error occurrence.

⁵ "Do Not Use List," The Joint Commission, <http://www.jointcommission.org/>, (June 27, 2014)

⁶ "List of Error Prone Abbreviations, Symbols, and Dose Designation," Institute for Safe Medication Practices, <http://www.ismp.org/default.asp>, (2013)

⁷ Gabriel, M., Yang, Y., Vaidya, V., & Wilkins, T. (2014), "Adoption of Electronic Prescribing for Controlled Substances Among Providers and Pharmacies", <http://www.ajmc.com/publications/issue/2014/2014-11-vol20-sp/adoption-of-electronic-prescribing-for-controlled-substances-among-providers-and-pharmacies/1>

Information on a prescription may be categorized into four (4) main informational groups: patient, medication, prescriber, and pharmacy. Data errors may be found in one or more of these informational groups and can be introduced when the prescription is issued or dispensed. Following are the most common of the possible errors for each of the four informational groups.

Patient information

In most states, the patient information on a prescription consists of first and last name, complete address of the patient, date of birth, and patient identification number (e.g., driver license, military id).

- *Patient's first and last name*
 - Illegible patient name
 - Variations in form of first name (e.g., James, Jimmy, Jimmie, Jim, J)
 - Animal's name used instead of owner's first name on a veterinary prescription
 - Hyphenated last names entered as a middle and last name or transposed
 - Use of maiden names in last name field
 - First, middle, and last names entered out of order
 - Miscellaneous notes, titles, or suffixes inserted in name field
 - Typographical errors
- *Address of the patient*
 - Illegible or missing address, city, state and/or zip code
 - Variations in street name abbreviations (e.g., Avenue or Ave, Street or St or Str, 2nd or Second, Route or Rte or Rt)
 - Address lists incorrect zip code
 - Typographical errors
- *Date of birth*
 - Illegible, missing or invalid date
 - Prescription issued or filled date entered
 - Wrong century; transposing date values (e.g., MM/DD/YY or YY/MM/DD or DD/MM/YY)
 - Date of injury or date of claim entered
 - Typographical errors
- *Patient identification number*
 - Illegible or missing identification numbers
 - Made up identification numbers
 - Mislabeled type of identification
 - Invalid form of acceptable identification
 - Use of different form of identification on separate prescriptions
 - Typographical errors

Medication information

The medication information consists of the name of the medication, strength, dosage form, National Drug Code (NDC), quantity, and number of days supplied for the dispensed medication. The medication, strength dosage form, and quantity with instructions for administration are provided by the prescriber. Based on the information from the prescriber, the dispenser selects the appropriate NDC and number of days supplied.

- *Medication name, strength, dosage form*
 - Illegible medication information
 - Medication not available in listed strength and/or dosage form
- *National Drug Code (NDC)*
 - Invalid NDC (i.e., NDC entered at the pharmacy as all 1s or 9s, discontinued NDC)
 - Missing NDC for ingredients in a compounded prescription
 - Typographical errors
- *Quantity*
 - Illegible, missing or invalid quantity (i.e., quantity entered as 300 rather than 30)
 - Mislabeled unit of measure (i.e., grams vs milligrams or micrograms vs milligrams)
 - Incorrect quantity for compounded medications
- *Days supplied*
 - Number of days inappropriate for quantity dispensed
 - Instructions for administration or number of days not clear

Prescriber information

All states and federal law require certain prescriber information to be on a prescription for a controlled substance. This includes the prescriber's name, address, telephone number and the Drug Enforcement Administration's (DEA) registration number. In addition to the DEA registration some states have their own controlled substances registration and require that to be on the prescription as well. The prescriber information sent to PDMPs, in most cases, consists only of the DEA controlled substance registration number and the date the prescription was issued/written. However, it can also include a DEA 'suffix' when the prescriber is a resident or intern prescribing under a hospital's authority using the institution's DEA number. One common error occurs when a pharmacist is presented with a prescription from a group practice. These prescriptions may have the names of many prescribers who are in a particular practice. If the prescriber fails to denote or check that he or she is issuing the prescription and the pharmacist is unable to decipher the signature, the pharmacist is forced to contact the office to identify the correct provider or, when that option is not available, the pharmacist must make an educated guess as to which prescriber issued the prescription.

- *DEA number*
 - Illegible, missing, or invalid DEA number
 - DEA number is expired
 - Use of incorrect DEA number when prescriber has more than one DEA number (i.e., more than one practice address in the state, registered in other states, X number for suboxone treatment)
 - DEA number used is not the correct number associated with the prescriber

- *Date issued/written*
 - Illegible, missing or invalid date
 - Date issued/written after the date filled/dispensed
 - Wrong century
 - Transposing date values (e.g., MM/DD/YY or YY/MM/DD or DD/MM/YY)
- *DEA suffix* (a unique number assigned to a resident/fellow by the institution where they are training)
 - Illegible, missing or incorrect DEA suffix

Pharmacy information

The pharmacy information, required to be on a prescription, consists of the pharmacy's DEA controlled substance registration number, date the prescription was filled/dispensed, and the Rx number assigned by the pharmacy to the prescription.

- *DEA number*
 - Missing, invalid, or expired DEA number
 - DEA number used is not the correct number associated with the pharmacy
 -
- *Date filled/dispensed/sold*
 - Missing or invalid date;
 - Date issued/written after the date filled/dispensed
 - Wrong century
 - Transposing date values (e.g., MM/DD/YY or YY/MM/DD or DD/MM/YY)
- *Rx number*
 - Missing or duplicated Rx number

Common Data Transmission Errors

In addition to errors within the data, there may also be technical errors caused during data transmission from the pharmacy to the PDMP.

- Duplicate prescriptions
- Multiple transmissions of the same data file
- Transmission of a corrected prescription mislabeled as a new prescription
- Prescription data transmitted even though prescription not dispensed to patient

Identification of Errors

PDMPs have instituted processes into their programs to minimize errors. The processes include identifying errors, dispenser notifications, and policies and procedures to correct errors. The common practice of PDMPs is that during transmission from the dispenser to the PDMP, a series of data quality checks are performed before the prescription information is added to the PDMP's database. If an error is identified, PDMPs or their vendors communicate with the reporting dispenser and request that the dispenser submit the correction to the record or entire file as appropriate. Legal issues typically preclude PDMP staff from making corrections themselves; therefore, the preferred practice is to have the dispenser make the correction and resubmit the record. Most of the operational PDMPs contract with a data collection vendor

(44 of 50 PDMPs); the others collect the data in-house. Regardless of the entity collecting the prescription data, all data should be processed through a quality check program. It should be noted that in most quality check programs, a prescription record does not have to successfully pass every quality check to be loaded into the PDMP database. Data errors are typically categorized as minor, serious, or fatal by the PDMP or its vendor. It is important to note that PDMPs and vendors do not necessarily classify data errors the same.

- ☒ Minor – Incorrect data in non-vital field (e.g., Days’ Supplied is invalid, Number of Refills Authorized is invalid). The prescription data is uploaded in the PDMP and the transmitter is notified of the error.
- ☒ Serious –Missing or inappropriate data (e.g., Invalid Date of Birth, Quantity is invalid, Date Dispensed is invalid). The prescription data may be uploaded to the PDMP and the transmitter is notified of the error.
- ☒ Fatal – Incorrect data in a vital field or entire data file contains large number of errors (e.g., NDC is invalid, Pharmacy DEA is blank or invalid, Patient Name is blank). The prescription data is not uploaded in the PDMP and the data is rejected and sent back to transmitter.

Below is a sampling of data checks that are typically performed on various fields. The data checks performed and the severity of the errors may vary among PDMPs. In addition, the fields required by a PDMP may vary among PDMPs.

Patient information

- Patient’s first and last name – cannot be blank; must be alpha characters
- Complete address of the patient – cannot be blank; zip code must match value in U.S. Postal Service zip code file
- Date of birth – cannot be blank; must be numeric; must be valid date
- Patient identification number – cannot be blank; ID format must match ID type

Medication information

- National Drug Code (NDC) – cannot be blank; must match value in NDC master file
- Quantity – cannot be blank; must be numeric (can contain decimal point)
- Days supplied – must be less than 365

Prescriber information

- DEA number – cannot be blank; must match value in DEA registration file
- Date issued/written – cannot be blank; must be numeric; must be valid date; cannot be after date filled/dispensed
- DEA suffix – no data checks performed

Pharmacy information

- DEA number – cannot be blank; must match value in DEA registration file
- Date filled/dispensed – cannot be blank; must be numeric; must be valid date; cannot be before date issued/written
- Rx number – cannot be blank

Despite the quality checks performed by PDMPs on the prescription data sent by pharmacies, errors in the data may still exist after a prescription record is loaded into the PDMP database. For example, a pharmacy may enter into the pharmacy system the wrong provider, the wrong quantity (e.g., 100 rather than 10), the wrong dispensed date, or incorrect date the prescription was written. These errors cannot be detected through the quality check system and may be subsequently identified in other ways:

- Additional quality checks performed by a PDMP
- Recipients of PDMP reports detecting incorrect or inaccurate information
- Audit of pharmacy records by an authorized regulatory agency
- Investigation into regulatory compliance or criminal violations

Recommended Practices for Minimizing Errors

The responsibility of transmitting prescription data rests upon the dispenser (e.g., pharmacy or dispensing practitioner); however, the prescriber plays a significant role in ensuring that the prescription data is complete and accurate. Below are some actions that can be taken by the prescriber, dispenser, and other stakeholders to improve the quality and integrity of the prescription data.

Dispensers

- Electronic prescribing of controlled substances is permitted under federal law. Dispensers should take the necessary steps to allow the receipt of electronic prescriptions from prescribers to reduce the incidence of typographical errors and data misinterpretation.
- Modify the data entry screens to require confirmation of key fields (e.g., prescriber DEA registration numbers).
- Enhance pharmacy software systems to perform data quality checks prior to transmission to the PDMP. The checks should match or be similar to the ones that PDMPs or their data collection vendors utilize to identify common mistakes at the source (e.g., missing or invalid data, incorrect formatting for a data field). In addition, the checks should flag 'outlier' values (e.g., prescriber zip code not in same geographic area as patient's zip code; medication quantity exceeds typical amount for days supplied).
- Ensure that the appropriate fields are entered when refilling a prescription (ASAP field DSP06) or partially filling a prescription (ASAP DSP13).
- Minimize the use of abbreviations in patient address fields or, when using them, ensure they follow the standard set by the U.S. Postal Service.
- Enhance pharmacy software systems to automatically fill in the city and state based on the zip code or auto-complete the street address information.
- Use only the most current NDC and DEA registration files as a cross reference; ideally, establish a real-time link to those files.
- To avoid errors in which data fields are transmitted to a PDMP, dispensers should transmit all the data fields that are available. PDMPs vary in the data fields they collect; however, all are capable of receiving all data fields. The PDMPs may only load the fields that are specified in their statutes or regulations.

- Patient information should be confirmed as current prior to transmittal to the PDMP. Dispensers should request positive identification of the patient to ensure it matches the information on the prescription or in the dispenser's patient files.
- Any information that is questionable should be confirmed with the prescriber prior to dispensing the medication or transmitting the information to the PDMP.

Prescribers

- Electronic prescribing of controlled substances is permitted under federal law. Prescribers should take the necessary steps to implement the use of electronic prescriptions to reduce the incidence of typographical errors and misinterpretation by the dispenser and decrease opportunities for fraudulent or altered prescriptions.
- If electronic prescribing is not a viable option, the prescriber should employ software to print allowable information on the prescription.
- If neither of the above is an option, then the prescriber should strive to write the required information legibly.
- Minimize the use of abbreviations in patient address fields or when using them, ensure they follow the standard set by the U.S. Postal Service.
- Avoid the use of nicknames for patients.
- Patient information should be confirmed prior to issuing a prescription. Prescribers should request positive identification of the patient to ensure it matches the information in the prescriber's patient files.
- Prescriber contact information should be included on the prescription to facilitate communication from the dispenser, if necessary.
- Include legible, precise instructions for use of medication.

Other Stakeholders

- The U.S. Drug Enforcement Administration (DEA) is responsible for issuing federal controlled substance registration numbers. The DEA should ensure that the registration information is updated daily when changes to a registrant's status has occurred. The registration file should be made available to appropriate stakeholders (e.g., dispensers, PDMPs) through a download or link to a real-time website.
- DEA may consider modifying their registration file format to allow separate fields for professional degree, specialty, and name suffixes.
- The U.S. Food and Drug Administration (FDA) is responsible for assigning NDCs to pharmaceuticals. In some cases, the FDA issues a range of NDCs to a pharmaceutical manufacturer. The manufacturer assigns the NDC to one of their medications and, subsequently, notifies the FDA. The FDA should maintain a listing of all NDCs in use and make the entire list available to appropriate stakeholders (e.g., dispensers, PDMPs) through a download or link to a real-time website.
- Pharmaceutical manufacturers should proactively inform the FDA of all the NDCs assigned to their medications.

- When a new medication is made available, the manufacturers should consider notifying the appropriate stakeholders (e.g., dispensers, PDMPs, data collection vendors, FDA) of the NDC prior to the medication distribution.

Section III - Error Remediation

For PDMPs to have the most impact on the prescription abuse and diversion problem and to support efforts in treatment, education, and research, it is imperative that the data sent to authorized users be as accurate as possible. In spite of great strides made towards data quality, some erroneous information will be transmitted to PDMPs. It is, therefore, necessary that proper policies and procedures be in place to identify and correct the information. Ultimately, it is the responsibility of the dispenser to ensure the accuracy of the prescription information as part of the dispensers' professional responsibilities and in compliance with the intent and spirit of the law. PDMPs also have the responsibility to ensure that policies and procedures are in place for timely notification and correction of erroneous data. Notifying a dispenser about which errors need correction is only half of the solution. Processes need to be implemented to ensure that the corrections are made and the PDMP database is updated appropriately and in a timely manner. This section will detail some of the current processes PDMPs employ to notify the dispenser of an error and track error resolution. In addition, this section will propose practices to facilitate these processes in an effort to increase efficiency.

Error Notification Process

Regardless of whether data is transmitted to the PDMP directly or through a data collection vendor, dispensers are almost immediately notified when serious errors or fatal errors are identified or records are rejected. With most PDMPs, the dispensers are sent an electronic message via the data transmission portal informing the dispenser of the problem and detailing that there are errors with a single record, series of records, or the entire data file. The dispenser is instructed to make the necessary corrections and retransmit the corrected prescription records through the data transmission portal.

In some cases, PDMPs that receive prescription data directly from the dispensers do not have the ability to notify dispensers of errors or rejected records via a data transmission portal. Those PDMPs will notify the dispenser via secure email, facsimile, or U.S. mail with instructions to remedy the problem. Prescription errors identified in the data transmittal process or discovered by subsequent review by the PDMP or by some other means are made known to the dispensers. After making the necessary corrections, the dispenser retransmits the corrected prescription records through the data transmission portal or sends the corrections via an alternative method.

It is important to note that many of the national chain pharmacies send their prescription records to a central, corporate database from which the records are transmitted to the appropriate PDMPs. Consequently, error notifications are often routed to the transmitting location instead of the dispenser's location. If errors cannot be resolved at the central, corporate level, then the error notifications are forwarded by the corporate location to the dispenser's location to remedy.

Error Tracking

The common practice among PDMPs is that every prescription transmitted to a PDMP undergoes a series of quality checks prior to being uploaded. The prescription records that fail to pass any of these checks are annotated with an error message. Depending on the severity of the error, the record is either rejected (all fatal errors and some serious errors) or uploaded (all minor errors and some serious errors).

When a record is rejected, a log file is created containing the prescription information, the error notation, and date the record was returned to the transmitting location. The log file is routinely reviewed, either by the PDMP staff or the data collection vendor, to ensure that rejected prescriptions are corrected and retransmitted to the PDMP within the required timeframe. The dispenser makes the corrections and updates the Transaction Header of the prescription record to reflect that the transmission is an error correction. If the error is corrected in the data transmission portal, then the record is automatically removed from the error log. If an alternative method is used, then the error log is manually updated.

In some cases, records containing minor errors are uploaded. However, the errors are resolved by the PDMP staff as time and resources allow. Typically, this involves contact with the dispenser via electronic or written communication detailing the issue, and the manner and timeframe for correction. The dispenser makes the corrections and updates the Transaction Header of the prescription record to reflect that the transmission is an error correction. The error log is manually updated.

Recommended Practices for Error Remediation

PDMPs

- Maintain accurate contact information for individual dispensers, vendors, and chain pharmacies.
- Promptly notify dispensers when errors are discovered, preferably by electronic means.
- Send error notifications to both the dispenser and transmission location, if they are not the same.
- Provide sufficient information about the prescription record and problem to the dispenser to assist in locating the record and remedying the issue.
- Notify dispensers of their requirements under the statute or regulation to correct erroneous information and the possible consequences for failing to meet those requirements; i.e., administrative fines, criminal charges, sanctions on their license.
- Maintain an electronic file on error notifications that identifies the dispenser, prescription, and error type.
- Develop a program that automatically generates a listing of past due error notifications.
- Maintain an electronic file on errors corrected that identifies the dispenser, prescription, original information, updated information, date record was corrected, and who made the correction(s).
- Maintain an electronic file listing the dispensers with the number of errors for each reporting period, most common errors made, average timeframe to resolve errors, and number of unresolved errors.
- Use the files listed above to create training sessions or educational packets on common errors for dispensers.
- Notify the appropriate state authority of dispensers who have a history of excessive errors or fail to correct errors within the specified timeframe.

Dispensers

- Promptly correct errors when notifications are received by the PDMP or the data collection vendor.
- Verify that corrections were accepted and error notification records were appropriately updated.
- Process corrections electronically, if possible.
- Use PDMP error notifications to identify common errors and take steps to prevent future occurrences of similar errors such as conducting staff training, changing business procedures, software modifications, etc.
- Maintain an electronic file of the records that have been corrected noting which records were corrected, the corrections made, the date the error notifications were received, the date the records were corrected and sent to the PDMP, and the name of the person making the corrections.

Vendors

- Promptly notify dispensers when errors are discovered, electronically, if possible.
- Send error notifications to both the dispenser and transmission location, if they are not the same.
- Provide sufficient information about the prescription record and problem to the dispenser to assist in locating the record and remedying the issue.
- Develop a program that automatically generates a listing of past due error notifications and alert the PDMP and dispenser of these issues.
- Provide a weekly electronic report to PDMPs on error notifications that include the identity of the dispenser, prescription, and error type.
- Provide a weekly electronic report to PDMPs on errors corrected that includes the identity of the dispenser, prescription, original information, updated information, date record was corrected, and who made the correction(s).
- Provide a quarterly electronic report listing the dispensers with the number of errors for each reporting period, most common errors made, average timeframe to resolve errors, and number of unresolved errors.

Conclusion

The importance of PDMPs in addressing this country's prescription drug abuse epidemic has been clearly demonstrated and recognized. The use of substandard data may negatively impact and impede necessary progress to curb the epidemic. It is therefore vital for stakeholders to access complete, accurate, and current PDMP data. Certainly, the proper assessment of a patient's prescription history is an important concern and PDMP data is the best resource for that information. It is also vital for regulatory/licensing boards and law enforcement to use this information to ensure prescribers and dispensers are practicing medicine effectively and legitimately and meeting the established standards of care. The use of PDMP data by researchers can help formulate policies and laws for governmental entities. The recommended practices in this guide will enable PDMPs, dispensers, prescribers, and other stakeholders to improve the quality of the prescription data resulting in PDMP data to be more dependable for use by all the stakeholders.

Appendix A – Summary of Recommended Practices

STAKEHOLDER	TOPIC	RECOMMENDATION
	Data Submission Compliance	PDMPs should encourage a dispenser to compare the number of records transmitted to the number of records successfully received by the PDMP or its vendor. Discrepancies in these numbers should be reported to the PDMP or its vendor in a timely manner for resolution.
		Dispensers, if allowed by the PDMP, should be encouraged to routinely (e.g., quarterly) query the PDMP for a listing of prescriptions that have been dispensed from their location to compare to their internal records.
		Test transmissions should be performed upon any change/modification to software or hardware by the dispenser, PDMP, PDMP software vendor (if applicable), or by dispenser-system vendors.
		PDMPs vary in their transmission frequency requirement; however, none prohibit transmitting data in a shorter time frame. To avoid instances of late reporting, dispensers should transmit data to the PDMP every night; unless there is the requirement to report data in real-time.
	Data Quality	Electronic prescribing of controlled substances is permitted under federal law. Dispensers should take the necessary steps to allow the receipt of electronic prescriptions from prescribers to reduce the incidence of typographical errors and data misinterpretation.
		Modify the data entry screens to require confirmation of key fields (e.g., prescriber DEA registration numbers).
		Enhance pharmacy software systems to perform data quality checks prior to transmission to the PDMP. The checks should match or be similar to the ones that PDMPs or their data collection vendors utilize to stop common mistakes at the source (e.g., missing or invalid data, incorrect formatting for a data field). In addition, the checks should flag for 'outlier' values (e.g., prescriber zip code not in same geographic area as patient's zip code; medication quantity exceeds typical amount for days supplied).
		Ensure that the appropriate fields are entered when refilling a prescription (ASAP field DSP06) or partially filling a prescription (ASAP DSP13).
		Minimize the use of abbreviations in patient address fields or, when using them, ensure they follow the standard set by the U.S. Postal Service.
		Use only the most current NDC and DEA registration files as a cross reference; ideally, establish a real-time link to those files.
		To avoid errors in which data fields are transmitted to a PDMP, dispensers should transmit all the data fields that are available. PDMPs vary in the data fields they collect; however, all are capable of receiving all data fields. The PDMPs may only load the fields that are specified in their statutes or regulations.
		Patient information should be confirmed as current prior to transmittal to the PDMP. Dispensers should request positive identification of the patient to ensure it matches the information on the prescription or in the dispenser's patient files.
	Error Remediation	Promptly correct errors when notifications are received by the PDMP or the data collection vendor.
		Verify that corrections were accepted and error notification records were appropriately updated.
		Process corrections electronically, if possible.
Use PDMP error notifications to identify common errors and take steps to deter future occurrences of similar errors; such as staff training, change in business procedures, software modifications, etc.		
Maintain an electronic file of the records that have been corrected notating which records were corrected, the corrections made, the date the error notifications were received, the date the records were corrected and sent to the PDMP, and the name of the person making the corrections.		

Appendix A – Summary of Recommended Practices (cont’d)

STAKEHOLDER	TOPIC	RECOMMENDATION
PDMPs/Data Vendors	Data Submission Compliance	The validity of the dispenser’s reason to obtain an exemption/waiver should be independently confirmed by the agencies that have the authority to perform inspections at a dispenser’s location or by the PDMP staff. This should occur before the exemption/waiver is issued and at least once during each exemption/waiver period. For example, if a waiver or exemption is requested because the dispenser does not dispense controlled substances, a reasonable effort should be made to inspect the premises or request sales records to verify that fact.
		PDMPs should have written guidelines detailing the exemption/waiver processes.
		If a dispenser is exempted or has a waiver, the PDMP should set a time limit for which the exemption/waiver is valid. For example, the PDMP should require that the dispenser reapply for an exemption/waiver every year or in conjunction with their license renewal.
		PDMPs, by policy or regulation, should require the dispenser to notify the PDMP if their status changes, thus making them no longer eligible for the exemption/waiver.
		PDMPs and licensing/regulatory agencies should provide detailed information concerning any change to existing statutes/regulations that impacts a dispenser’s practice well in advance of the changes being enacted. A good policy is to notify all dispensers registered to report to the PDMP as well as the pharmacy system vendors and chain pharmacies. The information could also be compiled and included with license renewals.
		PDMPs and licensing/regulatory agencies should have links on their respective websites to full text versions of current statutes/regulations.
		PDMPs should have links on their websites to the technical specifications for transmitting prescription information.
		Articles, frequently asked questions (FAQ) documents, instructional guides and/or training modules, providing real-world scenarios, should be made available to dispensers on the interpretation and application of statutes/regulations. These can be provided as inserts with registration applications or renewals, presented during conferences, included in newsletters or mass distribution, or recorded and linked to appropriate agency websites. TTAC has several guidance documents that may assist in the development of these resources.
		PDMPs should make every effort to present at professional conferences or submit an article to professional organizations’ newsletters.
		PDMPs, if allowed, should obtain a list of controlled substances that have been ordered by a dispenser from DEA (ARCOS data), drug manufacturers, and drug distributors and compare to the dispensing history within the PDMP’s database. Several states require licensed distributors to report to the state all the sales of controlled substances made to pharmacies, healthcare facilities and practitioners.
		PDMPs should, if resources allow, cross-check the date the prescription was filled with date the prescription was transmitted to identify the dispensers that reported beyond the statutory time frame.
		PDMPs should, if resources allow, review a dispenser’s data transmission history for a given period of time to reveal gaps in transmitted data, statistically significant variations in the number of records sent per transmission, and anomalies in dispensing trends to identify potential compliance issues.
		PDMPs should have a published process for authorized recipients of PDMP reports to report missing data to the PDMP for investigation.
		PDMPs should report any administrative or criminal violation by a dispenser to the appropriate licensing/regulatory and law enforcement agency if allowed under the State’s statutes/regulations.
PDMPs and licensing/regulatory agencies should have links on their respective websites detailing the consequences of non-compliance.		

Appendix A – Summary of Recommended Practices (cont'd)

STAKEHOLDER	TOPIC	RECOMMENDATION
PDMPs/Data Vendors (cont'd)	Error Remediation	Promptly notify dispensers when errors are discovered, electronically if possible.
		Send error notifications to both the dispenser and transmission location if they are not the same.
		Provide sufficient information about the prescription record and problem to the dispenser to assist in locating the record and remedying the issue.
		Provide a weekly electronic report to PDMPs on error notifications that include the identity of the dispenser, prescription, and error type.
		Provide a weekly electronic report to PDMPs on errors corrected that includes the identity of the dispenser, prescription, original information, updated information, date record was corrected, and who made the correction(s).
		Provide a quarterly electronic report listing the dispensers with the number of errors for each reporting period, most common errors made, average timeframe to resolve errors, and number of unresolved errors.
		Maintain accurate contact information for individual dispensers, vendors, and chain pharmacies.
		Promptly notify dispensers when errors are discovered, preferably by electronic means.
		Notify dispensers of their requirements under the statute or regulation to correct erroneous information and the possible consequences for failing to meet those requirements; i.e., administrative fines, criminal charges, sanctions on their license.
		Maintain an electronic file on error notifications that identifies the dispenser, prescription, and error type.
		Develop a program that automatically generates a listing of past due error notifications.
		Maintain an electronic file on errors corrected that identifies the dispenser, prescription, original information, updated information, date record was corrected, and who made the correction(s).
		Maintain an electronic file listing the dispensers with the number of errors for each reporting period, most common errors made, average timeframe to resolve errors, and number of unresolved errors.
		Use the files listed above to create training sessions or educational packets on common errors for dispensers.
		Notify the appropriate state authority of dispensers who have a history of excessive errors or fail to correct errors within the specified timeframe.

STAKEHOLDER	TOPIC	RECOMMENDATION
Prescribers	Data Quality	Electronic prescribing of controlled substances is permitted under federal law. Prescribers should take the necessary steps to implement the use of electronic prescriptions to reduce the incidence of typographical errors and misinterpretation by the dispenser and decrease opportunities for fraudulent or altered prescriptions.
		If electronic prescribing is not a viable option, the prescriber should employ software to print allowable information on the prescription.
		If neither of the above is an option, then the prescriber should strive to write the required information legibly.
		Minimize the use of abbreviations in patient address fields or when using them, ensure they follow the standard set by the U.S. Postal Service.
		Avoid the use of nicknames for patients.
		Patient information should be confirmed that it is current prior to issuing a prescription. Prescribers should request positive identification of the patient to ensure it matches the information in the prescriber's patient files.
		Prescriber contact information should be included on the prescription to facilitate communication from the dispenser, if necessary.
		Include legible, precise instructions for use of medication.

Appendix A – Summary of Recommended Practices (cont’d)

STAKEHOLDER	TOPIC	RECOMMENDATION
Other Stakeholders	Data Submission Compliance	Licensing/regulatory agencies should include licensee testing on current statutes/regulations as a requirement to obtain or renew a license.
		Agencies, with the legal authority to inspect dispenser locations, should obtain a PDMP report on the dispenser’s prescription history to use as a reference guide when performing audits or inspections. PDMPs should strive to foster a collaborative relationship with such licensing/regulatory agencies.
		PDMPs and licensing/regulatory agencies should have links on their respective websites detailing the consequences of non-compliance.
	Data Quality	The U.S. Drug Enforcement Administration (DEA) is responsible for issuing federal controlled substance registration numbers. The DEA should ensure that the registration information is updated daily when changes to a registrant’s status has occurred. The registration file should be made available to appropriate healthcare entities (e.g., dispensers, PDMPs, data collection vendors) through a free download or link to a real-time website.
		The U.S. Food and Drug Administration (FDA) is responsible for assigning NDCs to pharmaceuticals. In some cases, the FDA issues a range of NDCs to a pharmaceutical manufacturer. The manufacturer assigns the NDC to one of their medications and, subsequently, notifies the FDA. The FDA should maintain a listing of all NDCs in use and make the entire list available to appropriate healthcare entities (e.g., dispensers, PDMPs, data collection vendors) through a free download or link to a real-time website.
		Medication manufacturers should proactively inform the FDA of all the NDCs assigned to their medications. In instances where a new medication is made available, the manufacturers should notify the appropriate healthcare entities (e.g., dispensers, PDMPs, data collection vendors, FDA) of the NDC prior to the medication distribution.

Appendix B – Data Resource Links

American Society for Automation in Pharmacy (ASAP)	http://www.asapnet.org/
Automation of Reports and Consolidated Orders System (ARCOS)	http://www.deadiversion.usdoj.gov/arcos/
Controlled Substance Agency Resource Directory	http://www.pdmpassist.org/pdf/controlledsubstanceagencydirectory.pdf
DEA Controlled Substances Act Registration Database	https://dea.ntis.gov/
DEA Pharmaceutical Distributors Directory	https://www.dealookup.com/PharmaceuticalDistributors.asp
DEA Pharmaceutical Manufacturers Directory	https://www.dealookup.com/PharmaceuticalManufacturers.asp
DEA Registration Validation	https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp
Electronic Prescriptions for Controlled Substances FAQs	http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm
FDA National Drug Code Directory	http://www.fda.gov/drugs/informationondrugs/ucm142438.htm
Health and Medical License Lookup	http://www.healthguideusa.org/health_license_lookup.htm
National Council for Prescription Drug Programs (NCPDP)	https://www.ncpdp.org/
National Provider Identifier (NPI) Files	http://nppes.viva-it.com/NPI_Files.html
Patient Linking Software Options	http://www.pdmpassist.org/pdf/Patient_Linking_Software_Options_TAG_rev20130816.pdf
Prescription Drug Monitoring Programs (PDMPs) Information	Contacts - http://www.pdmpassist.org/node/400 Websites - http://www.pdmpassist.org/content/state-pdmp-websites
United States Postal Service Address Management	https://www.usps.com/nationalpremieraccounts/manageprocessandaddress.htm