COMMONWEALTH OF VIRGINIA
Meeting of the Virginia Prescription Drug Monitoring Advisory Panel

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Agenda of Meeting
July 18, 2016
2:00 PM
Board Room 1
TOPIC

Call to Order: Ralph Orr, Program Director, PMP

- Welcome and introductions
- Reading of emergency evacuation script:
- Approval of Agenda

Public Comment:

Discussion of Background Material: Ralph Orr, Program Director, PMP

- Options for Unsolicited Reporting: (PDMP Center of Excellence Report)
- North Carolina experience: (UNC Injury Prevention Research Center)
- Assorted PMP data
- Draft Recommendations

Adjourn

VIRGINIA ACTS OF ASSEMBLY -- 2016 SESSION

CHAPTER 98

An Act to amend and reenact § 54.1-2523.1 of the Code of Virginia, relating to Prescription Monitoring Program; disclosure of information.

[H 657]

Approved March 1, 2016

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2523.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

A. The Director shall develop, in consultation with an advisory panel *which shall include representatives of the Boards of Medicine and Pharmacy*, criteria for indicators of *unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and* misuse *of covered substances by recipients* and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse *to identify unusual patterns of prescribing or dispensing of covered substances by individual prescribers or dispensers or potential misuse of a covered substance by a recipient.*

~~Upon the development of such criteria and data analysis,~~ *B. In cases in which analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse indicates an unusual pattern of prescribing or dispensing of a covered substance by an individual prescriber or dispenser or potential misuse of a covered substance by a recipient,* the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523~~, disclose information using the criteria that indicates potential misuse by recipients of covered substances to (i) their specific prescribers~~*:*

1. Disclose information about the unusual prescribing or dispensing of a covered substance by an individual prescriber or dispenser to the Enforcement Division of the Department of Health Professions; or

2. Disclose information about the specific recipient to (i) the prescriber or prescribers who have prescribed a covered substance to the recipient for the purpose of intervention to prevent ~~such~~ misuse ~~or abuse~~ *of such covered substance* or (ii) an agent who has completed the Virginia State Police Drug Diversion School designated by the Superintendent ~~of the Department~~ of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department for the purpose of an investigation into possible drug diversion.

PDMP CENTER OF EXCELLENCE

Prescription Drug Monitoring Program Center of Excellence at Brandeis

Guidance on PDMP Best Practices

Options for Unsolicited Reporting

Updated May 2016

BJA
Bureau of Justice Assistance
U.S. Department of Justice

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Guidance on PDMP Best Practices
Options for Unsolicited Reporting

Overview

Unsolicited reporting of prescription drug monitoring program (PDMP) data to prescribers, dispensers, licensing boards, and law enforcement agencies is a recognized PDMP best practice. This guidance document outlines the rationale and basic procedures for unsolicited reporting, including a discussion of criteria and thresholds in PDMP data used to select individuals for reporting. It also provides a menu of options for unsolicited reporting as illustrated by current PDMP practice. Unsolicited reports on patients meeting criteria for possible inappropriate use, such as using multiple prescribers and pharmacies in a short time period (multiple provider episodes, or MPEs), are typically sent to medical providers or law enforcement agencies, depending on a state's policies and PDMP statutes. Some PDMPs also supply reports to licensing boards and law enforcement on prescribers who fall outside the norms for their type of practice. Examples of these types of unsolicited reporting, including selection and reporting mechanisms, are drawn from a sample of states (therefore, not all states conducting unsolicited reporting are mentioned below).

This guidance document also includes examples of promising practices and innovations in unsolicited reporting that may expand the options available to states. Some involve technological innovations in making PDMP data available to end users, some expand the range of end users receiving reports, and others expand the criteria for unsolicited reporting to include indicators of unsafe prescribing besides MPEs.

Barriers to adopting unsolicited reporting are examined, as well as possible means to overcome them. The "Summary and conclusions" section lists some characteristics of unsolicited reporting, exemplified by current state practice, that appear to contribute to its effectiveness and efficiency. Overall, experience among states suggests that, given statutory support and adequate resources, unsolicited reporting is feasible for most PDMPs. Adopting unsolicited reporting can confer substantial benefits to states by increasing utilization of PDMP data, helping to reduce prescription drug abuse, diversion, overdoses, and deaths.

Background

PDMPs are effective tools in mitigating prescription drug abuse and diversion, but only when they are well utilized. Virtually all PDMPs provide prescription history reports to authorized end users on request (solicited reports), but if reports are not requested, potentially useful information goes unseen and unused. To ensure that prescription history information is more fully utilized, and to assist PDMP end users in carrying out their responsibilities, many PDMPs proactively send reports of data suggestive of questionable activity involving controlled substances, such as doctor shopping or illicit prescribing and dispensing. Recipients of

unsolicited reports or alerts[1] ordinarily include prescribers, pharmacists, law enforcement agencies, and licensing boards. These reports notify prescribers and pharmacists that patients may be abusing or diverting controlled substances, or receiving unsafe amounts or combinations; they can therefore help practitioners make better decisions about prescribing and dispensing controlled substances, thus improving clinical care. Unsolicited reporting to law enforcement agencies and health professions licensing boards concerning questionable activity by prescribers and pharmacists can assist in reducing drug diversion and ensuring safe, effective, and legal medical practice. Unsolicited reporting can also inform potential end users about the PDMP and its value, resulting in increased enrollment in PDMPs and utilization of data. Even prescribers who are mandated to check the PDMP before prescribing controlled substances can benefit from receiving alerts since their patients may encounter problems with controlled substances between office visits.

Unsolicited reporting as a PDMP best practice

Prominent stakeholders in the fight against prescription drug abuse have concluded that unsolicited reporting constitutes a best practice for PDMPs. To receive funding under the National All Schedules Prescription Electronic Reporting (NASPER) Act, the Substance Abuse and Mental Health Services Administration (SAMHSA) established that PDMPs must provide unsolicited reports to medical practitioners (SAMHSA, 2005).[2] The Bureau of Justice Assistance (BJA) included adoption of unsolicited reporting as a priority consideration for states seeking funding the Harold Rogers Prescription Drug Monitoring Program.[3] In a recent briefing, the CDC also suggests that PDMPs should "provide unsolicited reports on high-risk providers and patients to the appropriate providers, regulatory boards, as well as law enforcement agencies under certain circumstances, such as an active investigation, court order or subpoena."[4]

A growing body of evidence supports unsolicited reporting as a PDMP best practice.[5] Nevada initiated its PDMP in 1997 by sending unsolicited reports to prescribers about possible doctor shoppers, a first for any PDMP. These reports quickly generated interest in the PDMP among prescribers, sparking further requests for data (solicited reports).[6] Analyses of Nevada PDMP data from 1997 to 2002 indicate that individuals for whom unsolicited reports were sent exhibited declines in the average number of dosage units and numbers of pharmacies and prescribers visited subsequent to the reports. This suggests the reports may have influenced

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[1] Alerts notify the recipient that an individual meets criteria for questionable activity as identified in the PDMP database, but do not include prescription data and therefore are less likely to compromise patient confidentiality. The recipient of the alert is advised to consult the database to view the prescription history information.

[2] The NASPER grant program is currently unfunded but has provided support to PDMPs in earlier years.

[3] See BJA's Harold Rogers PDMP FY 2012 Competitive Grant Announcement, www.bja.gov/Funding/12PDMPsol.pdf.

[4] Centers for Disease Control, "What States Can Do to Reverse the PDO Epidemic," http://www.sa4docs.org/wp-content/uploads/2013/07/What-States-Can-Do-to-Reverse-the-PDO-Epidemic.pdf.

[5] See PDMP Center of Excellence, 2012. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, pp. 31-33. http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf.

[6] Prescription Drug Monitoring Program Center of Excellence. (2011). Nevada's proactive PDMP: the impact of unsolicited reports. NFF 2.5. Heller School, Brandeis University. Waltham, MA. http://www.pdmpexcellence.org/sites/all/pdfs/nevada_nff_10_26_11.pdf.

prescribing by providers treating these patients. Similarly, analyses of data from the Wyoming PDMP suggest that unsolicited reports helped to raise awareness of the PDMP, leading to greater requests for data, with a subsequent decline in numbers of individuals identified in the PDMP database who met thresholds for potential doctor shopping.[7]

A Massachusetts survey of prescribers receiving unsolicited reports found that only 8.4 percent of respondents were aware of most, all, or nearly all other prescribers listed on the reports, and of those who reported they had sufficient information to make a judgment, nearly 70 percent judged that the prescriptions listed in the reports were medically unnecessary.[8] A large majority of respondents reported that the reports were useful in tracking their patients' prescriptions (85.5%) and that PDMP data would help to inform their practice (90%). This indicates that unsolicited reporting of PDMP data provides new, clinically relevant information to prescribers about possible inappropriate use of controlled substances. Similarly, prescribers in Maine who received automatic threshold reports on patients took a variety of actions in response, suggesting that the reports helped to guide their medical practice.[9] A cross-state evaluation of PDMPs by Simeone and Holland indicated that states with PDMPs that engaged in unsolicited reporting reduced sales of controlled substances by 10 percent compared to states without PDMPs, potentially reducing diversion and abuse.[10] Preliminary findings from a Massachusetts study comparing individuals who were subjects of unsolicited reports to prescribers (cases) to a matched non-intervention comparison group (controls) show that in the year following the reports the cases exhibited greater declines than controls in the number of prescriptions, number of prescribers, number of pharmacies, average dosage units, and average days supply (how many days the supply of dispensed medication will last), with the greater decline in number of pharmacies and average days supply reaching statistical significance.[11] Gonzalez and Kolbasovsky report that possible doctor shoppers whose providers in a managed care organization were sent unsolicited prescription data exhibited greater reductions in opioid prescribers, pharmacies, and opioid prescriptions compared to possible doctor shoppers whose providers were not sent such information.[12] More such studies are needed to measure the impact of unsolicited reports, determine how they are best distributed and to whom, and validate the criteria of questionable activity that trigger them. However, existing research and experience of states thus far (more examples

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[7] Prescription Drug Monitoring Program Center of Excellence. (2010). Trends in Wyoming PDMP prescription history reporting: evidence for a decrease in doctor shopping? NFF 1.1. Heller School, Brandeis University. Waltham, MA. http://www.pdmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf

[8] Thomas, C., Kim, M., Nikitin, R., Kreiner, P., Clark, T., Carrow, G. Prescriber response to unsolicited prescription drug monitoring program reports in Massachusetts, *Pharmacoepidemiology & Drug Safety*, 23(9) 2014: 950-957, http://onlinelibrary.wiley.com/doi/10.1002/pds.3666/abstract.

[9] Sorg, M., Labrie, S., & Parker, W. (2009). Analysis and evaluation of participation by prescribers and dispensers in the Maine state prescription monitoring program. Margaret Chase Smith Policy Center, University of Maine.

[10] Simeone, R. & Holland, L. (2006). An evaluation of prescription drug monitoring programs. Simeone Associates, Inc. Albany, NY. www.simeoneassociates.com/simeone3.pdf.

[11] Young, Leonard, "Massachusetts Prescription Monitoring Program," presentation for the 2012 PDMP National Meeting, http://www.pdmpassist.org/pdf/PPTs/National2012/3_Young_StatePanelInnovationsMassachusetts.pdf.

[12] Gonzalez, A.M. & Kolbasovsky, A. (2012), Impact of a Managed Controlled-Opioid Prescription Monitoring Program on Care Coordination, Am J Manag Care. 2012;18(9):516-524.

will be discussed below) support unsolicited reporting as a PDMP best practice worthy of consideration by all PDMPs.[13]

Current status of unsolicited reporting

The number and proportion of PDMPs conducting unsolicited reporting has increased over the past decade. A 2006 survey of PDMPs by the BJA/IJIS Institute PMP Committee found that 25 of the 31 existing PDMPs were authorized to provide unsolicited reports to one or more categories of end users, but only 13 (42 percent) were actually doing so.[14] According to surveys conducted by the PDMP Training and Technical Assistance Center (TTAC), in 2012, 38 of the 49 existing PDMPs were authorized to provide unsolicited reports or alerts to one or more categories of end users, and 26 (53 percent) were actually doing so. By 2015, 42 of the 49 PDMPs were authorized to send them and 33 (79 percent) were doing so. Of the PDMPs providing reports in 2015, 24 were sending them to prescribers, 18 to dispensers, 18 to law enforcement, and 14 to health professional licensing boards.[15] That over three quarters of the states are now engaged in at least some unsolicited reporting suggests that it is within the capacity of most PDMPs, hence an attainable best practice. The benefits and feasibility of unsolicited reporting are inducements for the remaining states to amend their PDMP legislation to authorize it, or to implement it should authorization already be in place.

Options for unsolicited reporting

Procedures for unsolicited reporting of patients to prescribers and dispensers

Criteria for possible inappropriate use. The process of unsolicited reporting to prescribers and dispensers begins with analyses of PDMP data to identify patients meeting criteria for possible inappropriate use of controlled substances or for receiving possibly dangerous quantities and/or combinations of prescription drugs. Criteria ordinarily include receiving prescriptions for the same drug type from multiple prescribers and pharmacies in a relatively short time period (MPEs), being prescribed more than a certain average daily dose of opioids (e.g., above 100 morphine milligram equivalents), or receiving simultaneous prescriptions of opioids and benzodiazepines.[16,17] Although a particular criterion for unsafe prescribing or

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[13] See PDMP Center of Excellence, 2012. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, pp. 31-33. http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf.

[14] PMP Committee Phase II PMIX Pilot Project Survey of State Prescription Monitoring Programs at: http://www.kms.ijis.org/db/share/public/PMIX/ijis_pmix_survey_ta_report_20070204.pdf and Appendix E: Survey Tabulation Worksheets—available upon request from IJIS Institute or PDMP Center of Excellence at Brandeis University: www.pdmpexcellence.org.

[15] PDMP Training and Technical Assistance Center, 2012 and 2014 state surveys.

[16] Dunn, K.M., Saunders, K.W., Rutter, C.M., Banta-Green, C.J., Merrill, J.O., Sullivan, M.D., Weisner, C.M., Silverberg, M.J., Campbell, C.I., Psaty, B.M., & Von Korff, M. (2010). Opioid prescriptions for chronic pain and overdose. *Annals of Internal Medicine, 152*(2), 85—93.

[17] Maine's PDMP statute specifies multiple possible criteria for unsolicited reporting: "The Office shall review prescription monitoring information related to individual patients to determine which patients have surpassed threshold levels of controlled substances. These threshold levels may include any of the following:

dispensing may produce false positives, prescribers and dispensers following up on a PDMP report make the final determination on whether a patient's controlled substance behavior warrants intervention. Unsolicited reporting can, therefore, err somewhat on the side of greater sensitivity, identifying possible inappropriate use, without compromising good medical care. However, too many false positives may produce "alert fatigue" among recipients and undermine the credibility of the PDMP, so a reasonable degree of specificity is needed.[18] Research on criteria for inappropriate use as identified in PDMP and other data is ongoing and will serve to inform and improve best practices in unsolicited reporting.[19] Optimal criteria for unsolicited reporting may vary by state.

Setting a threshold. A given threshold for possible inappropriate use—for example, being prescribed opioids by four or more prescribers and being dispensed those prescriptions from four or more pharmacies in a three-month period—will identify a certain number of individuals for reporting. Depending on the threshold and the population of the state, individuals identified can number in the thousands. To make unsolicited reporting manageable, states can set an initial threshold commensurate with their capacity to send reports or alerts. That capacity will, of course, depend on the reporting mechanism itself, which may be conducted via mailed paper reports, fax, or email. As a state increases its capacity and if the number of individuals meeting a particular threshold declines,[20] the threshold can be lowered as appropriate, so long as the rate of false positives is acceptable.[21] Some states such as Maine (see below) also allow prescribers to set their own thresholds for triggering unsolicited reports.

Frequency of reporting. States vary in the interval at which unsolicited reports to prescribers on patients are issued, most commonly either quarterly or monthly. Monthly reporting can potentially notify prescribers earlier in the course of a patient's possible progression to problematic involvement with controlled substances, but may require a greater commitment of PDMP staff and resources, depending on the reporting method. In order to avoid alert fatigue, reports on the same patient to the same prescribers, should that patient continue to

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- high number of prescribers in a short time period, as determined by the Office [of Substance Abuse];
- high number of doses during a short time period, as determined by the Office;
- days supply of prescriptions for the same drug overlapping by more than a few days;
- unhealthy combinations of controlled substances, as determined by the Office;
- more than one method of payment within a short time period;
- more than one out of state prescriber for the same patient, during a short time period, as determined by the Office;
- more than one pharmacy on the same day;
- more than one pharmacy in different public health districts within one month; AND/OR
- dangerous levels of specific drugs, as determined by the Office."

[18] Morgan, et al. The Use of Prescription Monitoring Programs to Reduce Opioid Diversion and Improve Patient Safety, *Journal of Pain & Palliative Care Pharmacotherapy*. 2013;27:4–9

[19] See PDMP Center of Excellence, 2011, "Identifying probable doctor shopping and other questionable activity using prescription monitoring data: some preliminary findings," http://www.pdmpexcellence.org/sites/all/pdfs/COE_rpt_dr_shopping_6.pdf and PDMP Center of Excellence, 2012. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, pp. 21-24, http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf.

[20] The number of individuals meeting a threshold can decline in response to use of the PDMP, including both unsolicited and solicited reports. See PDMP Center of Excellence, NFF 1.1, http://www.pdmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf.

[21] See "Electronic and mailed alerts in Louisiana" below for an example of adjusting the threshold in response to excessive false positives.

meet a report threshold, may be withheld for an appropriate interval (see "Electronic alerts in Massachusetts" below). Unsolicited reporting on practitioners to licensing boards and law enforcement normally proceeds on a continuing basis, as possible aberrant prescribing or dispensing comes to light in periodic analyses of PDMP data.

Unsolicited reporting to medical providers

Unsolicited reporting in Maine. In 2005, Maine began sending prescribers quarterly threshold notification reports via U.S. mail (paper-based reporting), but in 2013 moved to monthly emailed alerts. Alerts were originally sent to prescribers enrolled in the PDMP when a patient 1) exceeds a certain number of prescribers and pharmacies in a three-month period; 2) exceeds a specified average daily dose of acetaminophen coming from prescriptions of opioid-acetaminophen combination drugs (e.g., Vicodin, Percocet); or 3) is prescribed buprenorphine (a partial opioid agonist used in treating opioid dependence in office-based settings) and another opioid in a 30-day period. In 2015, two new criteria were added that trigger alerts: multiple overlapping prescriptions for medications containing opioids, and prescriptions for more than 300 morphine milligram equivalents daily for more than 45 consecutive days within a 90 day period. The alerts instruct recipients to log in to their accounts to see the patient's prescription history, which includes the other providers who prescribed to the patient, the pharmacies that dispensed to the patient, drugs and quantities and other details of prescriptions dispensed for the past three months. Prescribers not enrolled with the PDMP with patients who meet alert criteria are mailed hard-copy reports with this information. The state has also recently enabled prescribers to request reports setting their own thresholds, for instance to check if patients with controlled substance agreements are receiving opioids from more than just one prescriber.

A 2009 survey of prescribers who received mailed threshold reports found that substantial proportions of respondents took action in response, including looking up the patient's prescription history in the PDMP, calling other prescribers, talking to the patient, and conducting a substance abuse screening and brief intervention.[22] The reports' effect on prescriber behavior, and that of the more recent electronic alerts, may well have contributed to the steady decline in the rate of multiple provider episodes in Maine from 2010 to 2014.[23] The automated data analyses, report production, mailing and alert distribution are currently handled by Maine's PDMP vendor. The fee for reporting is built into the vendor contract, not charged on a per-report basis.

Electronic alerts in Massachusetts. From January 2010 to December 2012, the Massachusetts Prescription Monitoring Program (MA PMP) sent paper-based unsolicited reports on over 100 individuals exceeding thresholds for doctor and pharmacy shopping. A

[22] Sorg et al., 2009, op cit., p. 34.

[23] Maine Substance Abuse and Mental Health Services and Prescription Drug Monitoring Program Center of Excellence, "PBSS Data Brief: Patient Risk Measures for Controlled Substance Prescriptions in Maine, 2010-2014," 2015, http://www.pdmpexcellence.org/sites/all/pdfs/Maine%20PBSS%20data%20brief.pdf.

total of 2,087 unsolicited reports were sent to the prescribers associated with these individuals' prescriptions, with some prescribers receiving reports on two or more individuals. As noted above in the section "Unsolicited reports as a PDMP best practice," a large majority of prescribers responding to a survey reported being unaware of all the other providers prescribing to these patients, indicating that the reports functioned to notify them about possible clinically inappropriate use of controlled substances.[24]

The MA PMP has discontinued paper-based unsolicited reports to prescribers and now issues monthly electronic notifications (alerts); the first alerts were sent out in July 2013. The PDMP system identifies individuals meeting a threshold based on experience with the database, peer-reviewed literature, and recommendations from the MA PMP's Medical Review Group (MRG). The MRG, composed of physicians, dentists, and pharmacists, is charged with assisting the Massachusetts Department of Public Health in the evaluation of prescription information. Alerts for each flagged individual are generated and emailed automatically to all the prescribers registered with the PDMP who issued prescriptions to those individuals. The system is designed to allow the PDMP to set the repeat interval for when a prescriber would receive another email alert concerning the same patient (to avoid "alert fatigue"). Outcomes thus far have been positive: subsequent to the first round of alerts there was a surge in prescriber queries to the database and there was a decline in multiple provider episodes in the six months following initiation of alerts.[25] Costs associated with the system were primarily generated during the design, testing, and implementation phases; operating costs are minimal.

Electronic and mailed alerts in Louisiana. Louisiana's PDMP has conducted unsolicited reporting to both prescribers and dispensers since January 2010.[26] As in Massachusetts' electronic system described above, patients meeting a threshold for questionable activity are identified via an automated search of the PDMP database. A prescription history profile for each patient is generated and made available for download in the relevant provider's PDMP account. If a prescriber is enrolled in the PDMP, an alert is sent via email to the prescriber informing them that the profile is available for viewing, along with the profile's query number and the patient's name and date of birth. If a prescriber is *not* enrolled, they receive a hard-copy letter notifying them about the patient and suggesting they enroll in the PDMP so they can view the profile.[27] Dispensers only receive hard-copy letters, addressed to the pharmacist-in-charge. As in Massachusetts, no prescription data are transmitted in any

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[24] Thomas, C., Kim, M., Nikitin, R., Kreiner, P., Clark, T., Carrow, G. Prescriber response to unsolicited prescription drug monitoring program reports in Massachusetts, *Pharmacoepidemiology & Drug Safety*, 23(9) 2014: 950-957, http://onlinelibrary.wiley.com/doi/10.1002/pds.3666/abstract.

[25] Electronic Alerts for Prescribers: Massachusetts Prescription Monitoring Program Experience, PDMP Center of Excellence, February, 2015, http://www.pdmpexcellence.org/sites/all/pdfs/MA%20PMP%20electronic%20alert%20NFF.pdf.

[26] As of March 2016, Louisiana has temporarily suspended unsolicited reporting due to reorganization of its PDMP. However, this case study is included since it illustrates the procedures involved in electronic alerts and the adjustment of the reporting threshold to limit false positives.

[27] A presentation on Louisiana's unsolicited reporting that includes the text of the letter can be viewed at http://www.pdmpassist.org/pdf/PPTs/South2012/UnsolicitedReportingLA.pdf.

alerts; this serves to protect patient confidentiality and incentivize enrollment and system use. Before alerts are released, each patient's prescription history is reviewed by the PDMP administrator to ensure that it is truly indicative of questionable activity, helping to prevent false positives. The design and implementation costs for the unsolicited reporting system were estimated at approximately $40,000.

When alerts were first sent in 2012, the alert threshold identified 1,106 patients, which would have resulted in 5,817 alerts to prescribers and 5,784 to dispensers. However, after review, enough patients who met the threshold were judged false positives (i.e., they were judged to have legitimate reasons for being prescribed the controlled substances listed in their histories) that the decision was taken to raise the threshold. Fewer individuals are automatically identified at this higher threshold, but their prescription histories are more likely to merit alerts, thus reducing the administrator's time spent weeding out likely false positives. Recently, the Louisiana Medical Board requested a list of prescribers not enrolled in the PDMP that received the most alert letters—that is, those that had the most possible doctor shoppers in their practice. The Medical Board then contacted those physicians to encourage enrollment, after which they registered with the PDMP and began requesting patient profiles. Only the PDMP's proactive identification of possible doctor shoppers in these practices enabled the Medical Board to take such action.

Electronic alerts in Arizona. After originally sending unsolicited reports to prescribers by fax and mail, Arizona has moved to monthly electronic (emailed) alerts as a more efficient means of notification. This change was prompted by adopting a lower threshold for possible doctor shopping in May 2015, one which identified many more individuals than under the previous threshold, thus making mailed unsolicited reports unfeasible. In January of 2016, 250 patients met the revised threshold, generating 1219 alerts to prescribers. Of these, 720 were delivered and 499 were not, due to inaccurate or missing prescriber email addresses. As more prescribers join the PDMP, their email addresses will be verified, thereby increasing the proportion of successful notifications. Processing the alerts takes approximately a day's work by two PDMP employees.

Unsolicited reporting to law enforcement and licensing boards

Reports to law enforcement on doctor shopping

Some states either require or permit unsolicited reporting of possible doctor shoppers to law enforcement. Here are four examples:

North Carolina. The North Carolina PDMP statute requires that "unusual patterns" of patient behavior be reported to the Attorney General. The North Carolina PDMP flags patients who meet a threshold of prescribers and pharmacies suggestive of doctor shopping and controlled substance diversion. Before forwarding prescription history reports on these patients to the Attorney General, the information is carefully reviewed to rule out explanations other than doctor shopping and to find any recent indications of behavior change, such as prescriptions for buprenorphine used in office-based opioid addiction treatment. The threshold used and

the careful review in North Carolina's unsolicited reporting to the Attorney General help to focus law enforcement attention on the most serious cases of possible doctor shopping and drug diversion detectable in PDMP data.

Kansas. Kansas passed legislation in 2012 allowing the PDMP Advisory Committee to review and analyze PDMP data for the purpose of identifying patterns of activity of concern, such as possible doctor shopping. The Committee is currently conducting a pilot project to review patient data for 2015 to determine if there are indicators necessitating unsolicited reports to law enforcement. The project also includes referring prescribers and dispensers who have been identified as having a significant number of patients meeting the criteria for possible doctor/pharmacy shoppers or diverters to the appropriate regulatory board for further review.

Wyoming. Wyoming's PDMP will sometimes notify local law enforcement officials about individuals in their area who exhibit patterns of suspicious behavior that show up in PDMP data, such as traveling out of state to obtain prescriptions while simultaneously using local providers. Such individuals may or may not meet a standard threshold for questionable activity used for sending out unsolicited reports to medical providers. The decision to report to law enforcement is based upon the accumulated experience and discretion of PDMP staff in deciding which prescription histories indicate likely instances of diversion that merit criminal investigation, as opposed to instances of possible addiction or abuse best brought to the attention of medical providers.

Texas. The Texas PDMP routinely conducts data analyses to identify possible doctor shoppers for law enforcement investigation. For further details, see "Reports on providers to law enforcement" below.

Unsolicited reporting on medical providers

Unsolicited reporting is applicable concerning medical providers who, whether intentionally or not, may be engaging in risky or illegal prescribing or dispensing. The CDC recommends that PDMPs focus resources on "prescribers who clearly deviate from accepted medical practice in terms of prescription painkiller dosage, numbers of prescriptions for controlled substances, and proportion of doctor shoppers among their patients."[28] Alerts concerning questionable activity by providers may be appropriately addressed to licensing boards, peer review committees, third-party payers, Medicare and state Medicaid, and other bodies charged with monitoring medical practitioners. When analysis of PDMP data identifies probable criminal activity, such as prescribing and/or dispensing by pill mills, referral to law enforcement agencies is appropriate.

Indicators of possible problematic prescribing detectable in PDMP data might include, for example, opioid prescriptions and/or doses in excess of accepted norms for the type of practice (e.g., a dentist routinely prescribing and renewing a month's supply of 80 mg oxycodone); primarily prescribing combinations of drugs known to be "drug cocktails" (e.g.,

[28] CDC, Policy Impact: Prescription Painkiller Overdoses, at http://www.cdc.gov/drugoverdose/pdf/policyimpact-prescriptionpainkillerod-a.pdf.

the combination of hydrocodone or oxycodone, alprazolam, and carisoprodol); having many patients in a practice that meet criteria for doctor shopping; and prescribing for many out-of-state or geographically distant patients. Data on deaths, overdoses, and other adverse health outcomes associated with prescription drug abuse among a prescriber's patients would also be relevant. Signs of possible problematic *dispensing* by pharmacists and physicians include high proportions of cash payments for prescriptions dispensed, especially for prescriptions that duplicate those covered by Medicaid, filling what are obviously forged prescriptions, and filling duplicate or excessive prescriptions without seeking confirmation from prescribers.[29] Reliable criteria in PDMP and other data of questionable activity by providers need further research and validation.[30]

As PDMPs review provider prescription records that might trigger unsolicited reports, they consider possible legitimate reasons for what might appear to be problematic prescribing or dispensing, such as pain management specialists practicing in a hospital-based pain clinic. Even after such review, it is important to note that unsolicited reports on providers are only preliminary, possible indicators of a problem. Determining whether a problem exists and any further investigation is appropriate is a matter for further consideration by the body receiving the report (e.g., licensing board, peer review committee, or law enforcement agency). Such investigations can involve coordination among some or all of those bodies charged with maintaining good medical practice and ensuring public safety.

Reports on providers to licensing boards

Even if possible problematic prescribing or dispensing does not reach a level or type meriting law enforcement investigation, it may nevertheless be appropriate for reporting to medical and pharmacy licensing boards. Here are two instances of such reporting:

Kentucky. As part of its legislative mandate for proactive use of PDMP data, Kentucky's PDMP—the Kentucky All Schedule Prescription Electronic Reporting system (KASPER)—conducts unsolicited reporting on prescribers in coordination with the Drug Enforcement and Professional Practices branch of the Office of the Inspector General (OIG). Reporting is based upon criteria established by the Governor's KASPER Advisory Council, which is composed of representatives from Kentucky licensing boards, professional associations, law enforcement, and other key stakeholders. Prescription history reports on the top prescribers of the most commonly abused and diverted controlled substances are reviewed by OIG investigators, who evaluate the reports to see if further investigation of potentially inappropriate or illegal prescribing is warranted. Initial prescriber reviews were conducted based on KASPER Advisory Council criteria specifying the top two percent of prescribers issuing prescriptions for oxycodone, hydrocodone, oxymorphone, methadone, alprazolam, and the drug "cocktail" (see "Unsolicited reporting on medical providers" above). The OIG

[29] For definitions of prescriber and dispenser risk measures developed by the Prescription Behavior Surveillance System (PBSS) see http://www.pdmpexcellence.org/sites/all/pdfs/Definitions%20of%20PBSS%20Measures.pdf, sections five and seven.

[30] See for example the presentation by Ringwalt et al. at http://www.pdmpassist.org/pdf/TTAC_Webinar_Algorithms_20160324.pdf and page 13 of this report, North Carolina's reporting or prescribers to licensing boards.

investigators are registered pharmacists and certified peace officers in Kentucky who review the provider's prescribing history, the type of practice, prior record of disciplinary action, and several other factors. If the review indicates a substantial likelihood of problematic prescribing, the information is forwarded to the appropriate licensing board for further review. A second set of prescriber reviews is underway based upon revised criteria provided by the KASPER Advisory Council after evaluating the results of the initial reviews.

If a report forwarded to a licensing board results in a prescriber investigation, the licensing board notifies authorized personnel in the OIG, Attorney General's office, and Kentucky State Police Drug Enforcement/Special Investigations unit, using the Prescriber Information for Licensure Boards and Law Enforcement System (PILLS). Using the PILLS system assists in case coordination and de-confliction (such as identifying when an investigation of the same provider is underway by a sister agency). Since unsolicited reporting began in July 2012, KASPER reports have triggered over 80 licensing board investigations of prescribers, including physicians, advance practice registered nurses and dentists. These have resulted in retirements, agreed orders setting out sanctions and terms to be imposed upon the prescriber, and controlled substance license revocations, with the result that some problematic prescribers have modified their practices or have been removed from the system. Without proactive analysis of KASPER data and reporting to boards, these prescribers would likely have gone undetected.

North Carolina. In collaboration with the North Carolina Medical Board, NC Division of Mental Health, Developmental Disabilities and Substance Abuse Services, and the State's Division of Public Health, the UNC Injury Prevention Center has developed a set of measures based on the State's PDMP (Controlled Substances Reporting System, (CSRS) that are designed to help identify practitioners with prescribing patterns that may suggest possible inappropriate medical practice.[31] The measures examined included rates of prescriptions for daily doses of opioids greater than 100 morphine milligram equivalents (MMEs); co-prescribing benzodiazepines and doses of opioids greater than 100 MME; temporally overlapping (or redundant) prescriptions; average daily dose in MMEs; the total MMEs for each prescription; and the prescribing rates for opioids, benzodiazepines, and stimulants. The measures were validated by examining PDMP data on practitioners who had prescribed opioids to patients who had subsequently died from opioid overdoses within 30 days of the providers' prescriptions. Practitioners who had prescribed to decedents were most likely to be among those identified by the first three measures specified above, namely high levels of opioid prescription, prescriptions for opioids and benzodiazepines, and overlapping prescriptions. The North Carolina Medical Board, with guidance from an internal advisory committee, is using selected measures as impartial, objective criteria to identify practitioners for investigation of possible problematic prescribing; the same sorts of analyses could potentially be used to identify problematic dispensing. Outcomes of the investigations and further review of the measures will be used to minimize the possibility that legitimate practitioners are inadvertently selected for investigation.

[31] A slide presentation on this initiative can be found at http://www.pdmpassist.org/pdf/TTAC_Webinar_Algorithms_20160324.pdf.

Reports on providers to law enforcement

Some states conduct unsolicited reporting on medical providers to law enforcement, usually in coordination with licensing boards, so that cases are referred to the most appropriate agency. Here are two examples:

Texas. The Texas PDMP, the Texas Prescription Program, housed in the Department of Public Safety (DPS), conducts frequent analyses of its database to detect possible problematic prescribing and dispensing, as well as doctor shopping. Automated algorithms generate reports on providers meeting pre-defined criteria suggestive of diversion, such as being among the most frequent prescribers or dispensers of certain controlled substances. Prescription data are reviewed to help rule out legitimate reasons for what seems to be diversionary prescribing or dispensing, as well as to scan for indicators warranting further exploratory or targeted data analyses. When a provider or a possible doctor shopper is identified as reportable to law enforcement, staff decides whether to refer the case to investigators within the DPS or to another law enforcement agency—federal, state, county, or local. Investigators receive a complete prescription history report; in some cases, copies of prescriptions are included. Cases on medical providers not deemed appropriate for law enforcement investigation are referred to licensing boards. Care is taken to coordinate with other agencies in order not to compromise investigations already underway (de-confliction) and to supply PDMP data relevant to those investigations. The Texas PDMP has produced an average of 20-25 prescription drug cases a month for law enforcement investigation, making it among the most active PDMPs for this type of unsolicited reporting. Recently, several doctor shopping cases have been initiated and successfully prosecuted with the help of PDMP data.

New Jersey. The New Jersey statute enabling the PDMP, which started in September 2011, permits unsolicited reporting of medical providers to law enforcement. Periodic analyses are conducted to look for concerning patterns of prescribing and dispensing, such as identifying the state's top prescribers and pharmacies for controlled substances commonly encountered in cases of illegal prescribing. Database searches are conducted using drug therapeutic codes and dosage types (e.g., 30 mg Roxicodone) and payment type. If suspicious departures from normal prescribing practice are detected, the appropriate law enforcement agency (or licensing board, depending on the level and type of activity) is contacted. Recent analyses related to possible diversion have focused on top prescribers of oxycodone where payments for prescriptions are made in cash. The PDMP also runs ad hoc analyses to further explore patterns identified in quarterly reviews or investigate developments reported to the PDMP by other agencies. For example, law enforcement agencies may report that promethazine with codeine syrup is turning up on the street, so analyses are run for promethazine. The PDMP hopes to add more regular analyses using preset criteria as resources permit.

Promising practices and innovations

Besides the types of unsolicited reporting surveyed above, some PDMPs have explored novel approaches to proactive dissemination of data that expand the range of analyses, end users receiving reports, and means of dissemination. Although the efficacy and general applicability of these approaches need further study, they are worth noting as examples of how states develop and test innovative applications of PDMP data.

Tennessee letters to top prescribers. Beginning in mid-2013, in accordance with statutory requirements of Section 3 of Public Chapter 396, letters are sent each year by the Tennessee Department of Health (TDH) to the top 50 prescribers of controlled substances. The letters – in effect unsolicited reports to prescribers on their own prescribing – are delivered by registered mail and contain information on quantities of significant controlled substances prescribed, numbers of patients prescribed to, and the morphine milligram equivalents (MMEs} prescribed. Recipients are instructed to respond within 15 business days with an explanation justifying the amounts of controlled substance prescribed. The law provides for follow-up investigation of the prescriber if the response is determined to be inadequate, and TDH has the discretion to withhold letters if the prescriber is already under investigation.

Of the first group of 50 top prescribers sent letters in 2013, five were not registered with the state's PDMP. Before receiving the letters, during the 12 months between April of 2012 through March 2013, the top 50 prescribers prescribed 14 percent of the state's 9.8 billion opioid MMEs, i.e., 1.43 billion MME. Following the letters, a review of these prescribers' PDMP data showed that their annual prescribing (January through December of 2014) decreased by 18 percent, i.e., a reduction to 1.17 billion MME. In addition, 18 (36%) of the original cohort were no longer among the top 50 prescribers. In 2015, the state enacted Public Chapter 476, which provides that in addition to the top 50 prescribers in the state, the top 10 prescribers from all of the combined counties having populations of fewer than 50,000 will also receive letters.

Prescriber report cards. Starting with Arizona, a number of states have begun distributing so-called "report cards" to prescribers. These unsolicited reports contain data comparing an individual practitioner's recent prescribing to averages for those in the same specialty. In some cases, they also include the number of patients seen by the prescriber who meet various risk criteria (e.g., meeting a threshold for multiple provider episodes or being prescribed over 100 MME daily). In Arizona, report cards are sent quarterly via email to practitioners who have prescribed at least one controlled substance. The report shows in graphical format how prescribers compare to their peers in the same specialty in prescribing carisoprodol, benzodiazepines, hydrocodone, oxycodone, and other pain relievers, and informs the recipient if they are an "outlier": one, two, or three standard deviations above mean prescribing levels. Report cards also include the number of the prescriber's patients meeting the following criteria: receiving over 100 morphine milligram equivalents (MMEs) daily, being issued multiple controlled substance prescriptions, receiving prescriptions from other prescribers for more than one type of controlled substance, and receiving controlled substances prescriptions from five or

more prescribers or visiting five or more pharmacies in the past quarter. Outcomes related to the report cards and other initiatives to change prescribing in Arizona are encouraging, with prescribers in the four counties where report cards were first piloted showing increased PDMP enrollment and utilization, and reductions in prescribing and outlier status.[32] Arizona is in the process of expanding the report card initiative to the entire state; in February of 2016 over 10,000 prescribers received them. Anecdotal reports suggest that overall the report cards are well received and prompt recipients to re-evaluate their prescribing practices.

Kentucky and Ohio have also implemented report card programs that make data available to prescribers on how they compare to peer norms in prescribing (Kentucky) and on patients who meet risk criteria (Ohio). In Kentucky, prescribers can request their report card once logged into the PDMP, so these are solicited, not unsolicited reports. Ohio, like Arizona, sends report cards ("Practice Insight Reports") to prescribers, and in addition prescribers can request the report via their PDMP account.[33]

Indiana and Wisconsin user-led reports. In Indiana, a practitioner who has retrieved PDMP data suggestive of a patient's questionable activity has the option to email alerts to prescribers and dispensers mutually treating the patient, thus called a "user-led report." The alerts contain a hyperlink to the patient's prescription history report that registered users can use to view the report. If an alert recipient is *not* registered with the PDMP, they must register before the link enables them to view the report. The alerts thus function to encourage enrollment in the program as well as to notify those already enrolled that a patient may be involved in medically unnecessary prescription drug use, may be receiving controlled substances from more than one or multiple prescribers, or possibly involved in controlled substance diversion. In May 2012, 140 practitioners sent 2,284 alerts on 214 unique patients; recipients of alerts included 770 registered PDMP users and 1,690 unregistered users.[34] By enabling providers to send alerts as part of their medical practice, Indiana increases the proactive dissemination of PDMP data at virtually no cost to the program.

Starting in July of 2013, Wisconsin implemented a similar user-led reporting system – "peer-to-peer" alerts – in which prescribers and dispensers can notify their fellow practitioners about patients whose prescription histories trigger concern. (Peer-to-peer alerts can also be issued if a practitioner discovers unauthorized use of a DEA number or in case of a lost or stolen prescription pad or number.[35]) After being initiated by the practitioner, alerts are automatically routed to the PDMP, which reviews them to ensure that they contain information not included in

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[32] For further details, see the COE report "Using PDMP Data to Guide Interventions with Possible At-Risk Prescribers", pp 4-5, http://www.pdmpexcellence.org/sites/all/pdfs/Using_PDMP_Data_Guide_Interventions_at_Risk_Prescribers.pdf.

[33] Details of all three report card programs, as well as suggestions for a model prescriber report card, can be found in the PDMP Training and Technical Assistance "Prescriber Report Card" technical assistance guide, http://pdmpassist.org/pdf/Report_Card_TAG_20160315_final.pdf.

[34] A presentation on this initiative can be viewed at http://www.pdmpassist.org/pdf/PPTs/National2012/2_Allain_StatePanelInnovationsIndiana.pdf.

[35] The alert system is described in the "Training Guide for Wisconsin Practitioners and Pharmacists," pp. 45-50, http://dsps.wi.gov/Documents/PDMP/Practitioners_Pharmacists_Training_Guide.pdf.

earlier alerts. If so, the alerts are then forwarded to those practitioners who have also prescribed or dispensed to the patient. As of February of 2016, over 1,500 such alerts had been distributed, and 124 were judged duplicative and thus not sent. It has been suggested that alerts should be recorded as part of the patient's PDMP data so that those who missed an alert can be apprised of a possible problem when reviewing patient reports. Future enhancements of the PDMP may include this feature.

Massachusetts outreach to at-risk prescribers. As a strategy to increase provider enrollment in the MA Online PMP, Massachusetts' Drug Control Program, identified so-called "at-risk" prescribers: those with significant numbers of patients meeting criteria for possible doctor and pharmacy shopping. In 2012, the PDMP sent an outreach letter to 150 at-risk prescribers who were not yet enrolled to use the online PDMP. The letter informed the provider that MA PMP data showed that their practice had a high proportion (relative to the state average) of doctor and pharmacy shoppers and suggested they enroll in the MA Online PMP. As of April 2013, approximately 40 percent of these prescribers had registered with the PDMP. To assess the impact of PDMP enrollment of at-risk prescribers on doctor shopping, analyses of PDMP data were conducted comparing a group of at-risk prescribers enrolled in the PDMP for at least one year (N=20) to a non-enrolled group of at-risk prescribers (N=70). From 2009 to 2012, prescribers who eventually enrolled had a 65 percent decrease in the number of patients who met criteria for doctor and pharmacy shopping, while prescribers who did not enroll had a 35 percent decline.[36] These findings suggest that use of the PDMP by at-risk prescribers can help reduce the prevalence of doctor and pharmacy shopping.[37, 38]

Mississippi unsolicited reporting to patients. In a 2011 pilot project,[39] the Mississippi PDMP sent letters to 40 individuals who had used more than one pharmacy, visited more than 10 practitioners, and received more than 24 controlled substance prescriptions in a 180-day period. The letter notified recipients that it was "a good faith effort to prevent you from circumventing state and federal laws in obtaining prescription drugs and assist you if you need medical help." It included a toll-free number for the Mississippi Department of Mental Health's helpline on drug prevention and treatment resources. Prior to notification, these individuals on average were receiving eight prescriptions and 278 dosage units per month. Dosage units for these patients in the month prior to sending the letters totaled 11,435. Three months after the letters were sent this total dropped to 7,295, a 36 percent decline. Follow up on these individuals showed that in May 2013, 10 had no PDMP prescription activity, while the 30 who did have activity averaged two prescribers, two pharmacies, and four prescriptions in that month. These data suggest that the letters may have had an effect on

[36] The fact that non-enrolled prescribers also exhibited a decline, albeit not as great, in the percentage of doctor and pharmacy shoppers in their practices indicates that there are likely other factors involved in these downward trends. Further research is necessary to identify these factors and determine the relative contribution to changes in doctor shopping measures. Unsolicited reports on patients were also being sent to some prescribers during this time.

[37] A presentation on this study can be viewed at: http://www.slideshare.net/OPUNITE/new-focuses-forpdmpseffortsfinal (see slides 47-66).

[38] For other examples of interventions with possible at-risk prescribers, see the COE report Using PDMP Data to Guide Interventions with Possible At-Risk Prescribers.

[39] A presentation on this program can be viewed at: http://www.pdmpassist.org/pdf/PPTs/South2012/UnsolicitedReportingMS.pdf.

these individuals' access to controlled substances, at least as measured by PDMP data (there were no data gathered in this study on comparable individuals who were not sent letters).

Barriers to unsolicited reporting

As noted above in "Current status of unsolicited reporting," some states do not conduct unsolicited reporting despite the fact that it is considered a PDMP best practice. There are a variety of barriers to adopting unsolicited reporting that need to be addressed, including:

Legislative restrictions. Some states either expressly forbid unsolicited reporting to one or more types of end users in their PDMP-enabling legislation or do not specifically provide for it in legislative or regulatory language. Amending legislation and/or regulations to permit such reporting requires building support for such a change among stakeholders and finding legislators and policy makers who understand the issue and will support the needed changes. The evidence in favor of the efficacy and positive impact of unsolicited reporting, some of which is mentioned above, can help build such support. Washington State's 2007 enabling legislation[40] was farsighted in its inclusion of specific language permitting the PDMP to provide data to a wide range of end users, including medical providers, law enforcement, licensing boards, Medicaid, workers' compensation, and the Department of Corrections. States considering legislation bearing on unsolicited reporting may wish to consult the PMP Model Act 2010 revision Section 7 on providing prescription monitoring information.[41]

Resource limitations. Even if their legislation permits unsolicited reporting, many PDMPs are under-resourced, whether in staff, funding, or analytical and reporting capacities, so they cannot undertake new initiatives. For a PDMP to implement unsolicited reporting, among other PDMP best practices, it may be necessary to secure additional resources. Again, marshaling evidence for the effectiveness of unsolicited reporting can help a PDMP make the case for the requisite staffing or operational capacity. Issuing electronic alerts, as described above in Maine, Massachusetts, Arizona and Louisiana, involves relatively little ongoing expense once the necessary systems and software are in place; likewise for user-led reports as instituted by Indiana and Wisconsin. States embarking on unsolicited reporting can learn from other PDMPs' experience and perhaps improve on original designs and find additional ways to reduce costs.

Concerns about unintended consequences. Use of PDMPs to monitor possible questionable activity by patients and practitioners, including sending unsolicited reports, sometimes sparks concerns about unintended consequences. For example, some have suggested that practitioners might worry about becoming a target of a licensing board or law enforcement investigation triggered by a PDMP report and thus could choose to cease prescribing controlled substances altogether; or patients whose prescriber misinterpreted a PDMP report and wrongly accused them of doctor shopping could be fired by their doctors, leaving them

[40] See http://apps.leg.wa.gov/RCW/default.aspx?cite=70.225.040.

[41] See http://www.pdmpassist.org/pdf/PMPModelActFinal20100628.pdf.

without access to needed pain medications. Examining the validity of such concerns is beyond the scope of this report, but it should be noted that PDMPs, cognizant of the downsides of false positives, are generally conservative in setting thresholds for detecting inappropriate use among patients, using higher rather than lower numbers of providers and pharmacies for MPE thresholds. In reporting possible questionable activity by medical providers, PDMPs consult with licensing boards, peer review and advisory committees, and law enforcement agencies to ensure that the criteria for reporting only flag cases meriting their attention. Moreover, unsolicited reports (and PDMP data in general) are themselves never conclusive evidence of aberrant behavior, but simply one piece of information considered by their recipients in determining whether an investigation or intervention should be initiated. PDMPs are careful to note the limitations of their data when providing them to end users. Such considerations may help allay fears among providers and patients that PDMPs are overzealous in unsolicited reporting and thus inadvertently discouraging legitimate medical practice. However, if instances of such outcomes resulting from unsolicited reporting or other PDMP activity occur, they should be examined and taken into appropriate account in setting PDMP policy.

Prescriber mandates and patient risk flags as replacements for unsolicited reporting. Some states have adopted mandates for prescribers to view PDMP data before prescribing controlled substances,[42] while others identify at-risk patients according to various criteria, visible when prescribers access their PDMP accounts.[43] These practices work well to increase the likelihood that prescribers will view PDMP data and become aware of at-risk patients, in which case they may be perceived as replacements for unsolicited reporting of such patients. However, these practices still involve prescriber-initiated behavior (logging into their PDMP accounts), so do not obviate the contribution of PDMP-initiated alerts, which require no action on the prescriber's part. Unsolicited reports provide notifications that appear independently of prescriber utilization of the PDMP, thus may be more timely than those received when prescribers query the database for a patient's visit. Unsolicited reports can also reach prescribers not enrolled in the PDMP, an important function for states without mandated prescriber enrollment and use. However, unsolicited reports and alerts need to be sent to recipients frequently enough to ensure that at-risk patients are detected sooner rather than later, should they have problematic involvement with controlled substances. Research is needed on the added value of unsolicited reports for states with prescriber mandates.

Summary and conclusions

The examples of unsolicited reporting surveyed here provide a menu of options for states wishing to adopt this PDMP best practice.[44] They illustrate the feasibility of unsolicited reporting and its benefits in helping to improve medical care and reduce aberrant prescribing and

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[42] See the COE Briefing on Prescriber Mandates, http://www.pdmpexcellence.org/sites/all/pdfs/COE_briefing_mandates_2nd_rev.pdf.

[43] For examples, see the TTAC's Technical Assistance Guide on Prescriber Report Cards, http://www.pdmpassist.org/pdf/Report_Card_TAG_20160315_final.pdf.

[44] Note that other PDMPs unmentioned in this guidance document also conduct unsolicited reporting in ways similar to the selected examples.

dispensing. Given sufficient funding, one or more of the approaches to unsolicited reporting described above, involving mail, fax, and email notifications, are within the capabilities of most PDMPs and will help them maximize the utilization of their data for public health and safety. Elements of effective unsolicited reporting by PDMPs include:

- Choosing criteria and thresholds for possible inappropriate use and questionable activity commensurate with PDMP capacity to issue unsolicited reports or alerts.
- Carefully and periodically reviewing thresholds for unsolicited reporting to ensure that false positives are minimized but that most questionable activity is reported.
- Improving the efficiency and reliability of alert delivery mechanisms to reduce administrative burdens on the PDMP while reaching the maximum number of appropriate recipients.
- Educating and training recipients of reports to ensure they understand the meaning, uses, and limitations of prescription history data.
- Regularly communicating with recipients of unsolicited reports to help validate report criteria and assess their utility, so that reporting can be improved.
- Consulting with practitioner groups and law enforcement agencies to determine the level and types of possible questionable activity suitable for criminal investigation instead of a medical or pre-criminal intervention.
- Facilitating cross-agency communication on unsolicited reports concerning practitioners to ensure that cases of possible aberrant prescribing or dispensing are referred to the appropriate agency (e.g., licensing board vs. drug control) and that existing or planned investigations are not compromised.
- Evaluating the outcomes and impact of unsolicited reporting—for instance, on PDMP utilization, doctor shopping, and aberrant prescribing—using PDMP and other data sources.

Although unsolicited reporting is a recognized PDMP best practice, promising and innovative approaches to unsolicited reporting being explored by states still need to be evaluated for efficiency and effectiveness. As new information technologies become available and PDMP information is better integrated into health care systems, more cost-effective means to alert end users of at-risk individuals will likely be developed, for example, a practitioner desktop alert that appears independently of accessing the PDMP or patient records. The range of standard criteria for triggering reports may expand as well to include, for example, acetaminophen dose thresholds, dangerous drug combinations, and simultaneous prescriptions for drugs in the same therapeutic class.

Universal adoption of unsolicited reporting and its identified best practices will require overcoming legislative, regulatory, and resource barriers and addressing possible concerns about unintended consequences. The experience of states engaged in unsolicited reporting, some of which is summarized above, can provide direction for PDMPs seeking to become more proactive in disseminating prescription history information to help mitigate the prescription drug abuse epidemic.

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Using the NC Controlled Substances Reporting System to Identify Providers with Unusual Prescribing Practices: A Partnership of the State of North Carolina, UNC Injury Prevention Center, and the N.C. Medical Board

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Disclosure statement

None of the presenters has any relevant, real or apparent personal or professional financial relationships or conflicts of interest with proprietary entities that produce health care goods and services.

Project Goals

- To develop and validate a set of algorithms from metrics that utilize data from NC's PMP, the Controlled Substances Reporting System (CSRS), as a screening tool to identify prescribers with unusual and uncustomary prescribing patterns
- To support proactive reporting of these providers to the N.C. Medical Board for further screening and potential investigation

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Project roles

- Mr. Asbun: data source for UNC's analyses and for the NC Medical Board
- Drs. Ringwalt and Schiro: Developed algorithms
- Scott Proescholdbell, N.C. Division of Public Health, Injury and Violence Prevention Branch: matched opioid overdose-related decedents to CSRS data
- Dr. Kirby: assessing utility of the screening tool to identify high-risk prescribers

Key Characteristics of N.C.'s CSRS

- State Controlled Substances Authority: NC Department of Health and Human Services, Division of Mental Health, Developmental Disabilities, and Substance Abuse Services
- Schedules or drugs monitored by the State's CSRS: Schedule II, III, IV and V
- Requirements for controlled substances reporting system
- Authority to require nonresident pharmacies to report to CSRS
- Types of authorized recipients
- CSRS's confidentiality

Challenges with Use of PMPs to Detect Inappropriate Prescribing

- Lack of clarity as to which indicators may serve as a good screening tool
- Concerns about the potential for many false positives
- Lack of resources to investigate providers identified by these screens
- Lack of information in PMPs concerning provider specialty (e.g., oncologists, end-of-life treatment specialists)
- Concern that providers treating chronic patients may:
  - Dismiss those prematurely
  - Treat them sub-optimally
  - Decline to accept these patients into their practices

How do Regulatory Authorities Detect Inappropriate Prescribing Now?

- Complaints from patients and colleagues
- Audits of medical records
- Investigations by coroners or chief medical examiners

However, currently, there is no standardized screening tool to apply to Prescription Drug Monitoring Programs for this purpose

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Candidates for Metrics
Providers who Write the Highest:

- Rates of prescriptions for *daily* doses of opioids >100 milligrams of morphine equivalents (MMEs)
- Average *daily* dose of MMEs
- *Total* MMEs for each prescription
- Rates of prescriptions for following drug classes, irrespective of dose:
  - Benzodiazepines
  - Opioids
  - Stimulants
- Rates of co-prescribed *benzodiazepines* + *opioids* >100 MMEs
- Temporally overlapping prescriptions

Candidates for Metrics
Providers with Patients who:

- Travel long distances from their homes to their:
  - Providers
  - Pharmacies
- Fill prescriptions received from multiple providers (doctor shopping) for:
  - Opioids
  - Stimulants
  - Benzodiazepines
  - Any controlled substance
- Fill prescriptions at multiple pharmacies (pharmacy hopping)

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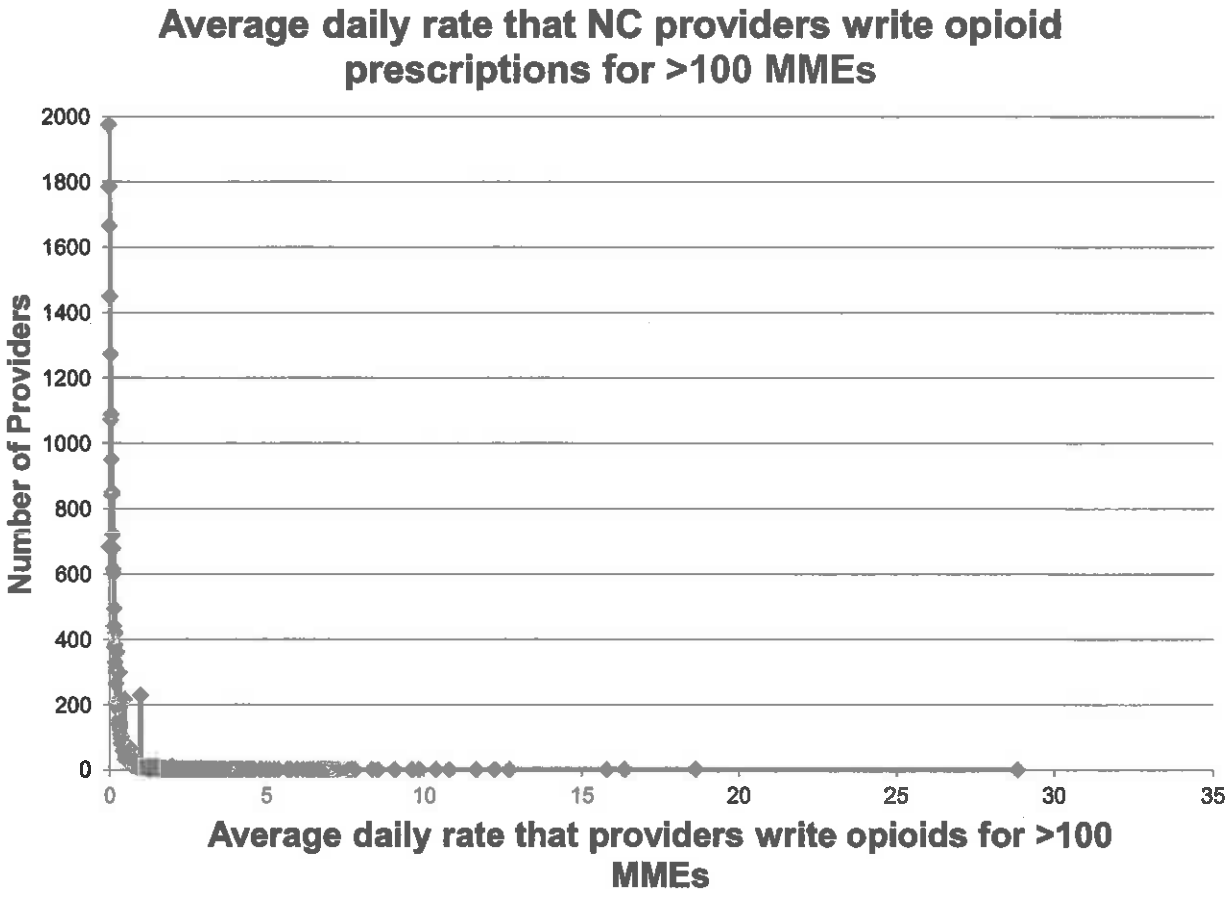
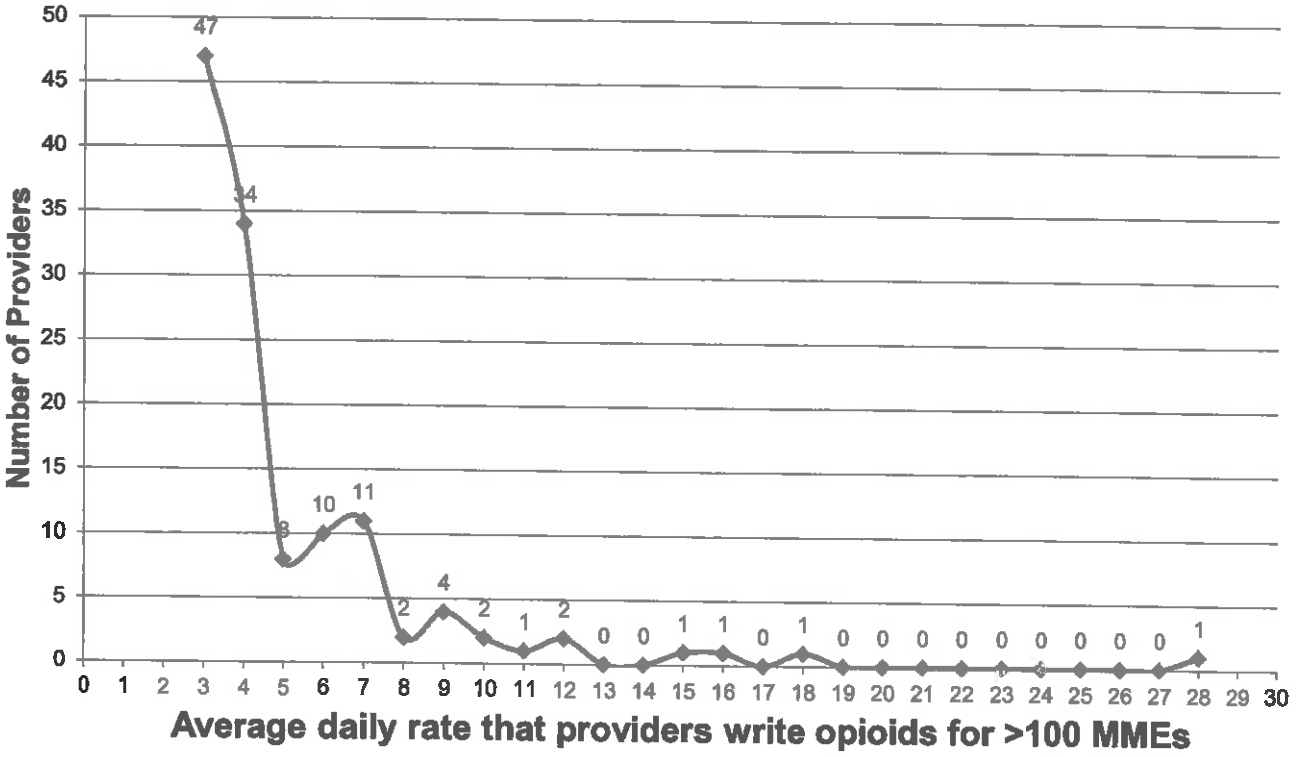
Example of metric distribution



Example: Distribution tail



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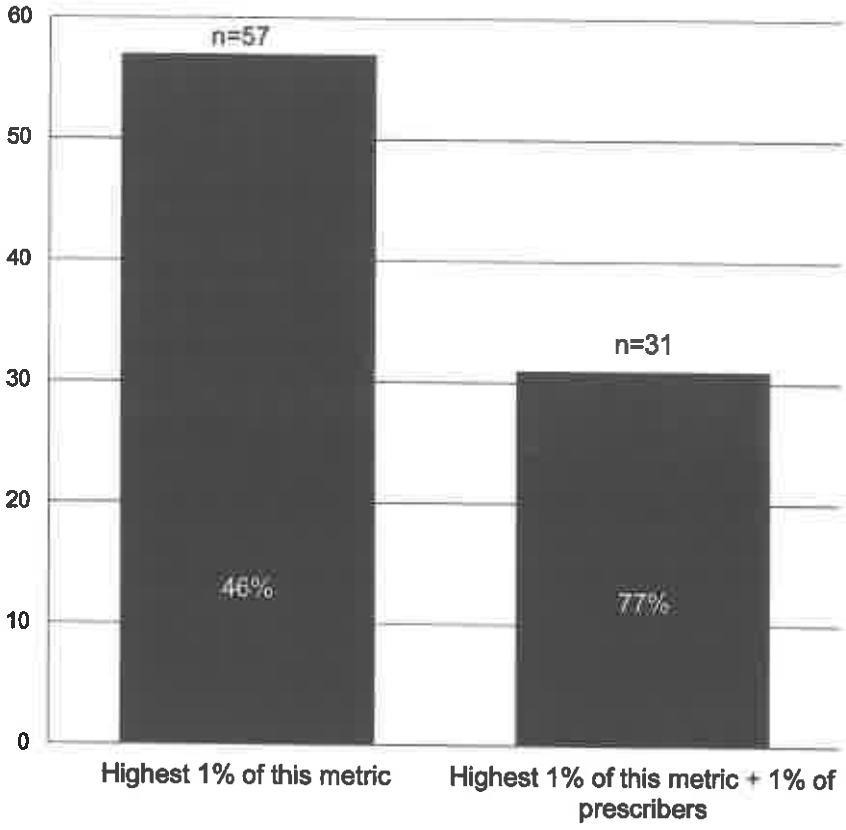
Initial Validation Strategy

- Combed NC Vital Statistics records for deaths (*N*=465) in 2012 related to opioid overdose – used t-codes representing drug-related poisonings
- Recorded DEA #s of providers who had prescribed opioids to these patients within 30 days of their death.
- Any given decedent could have received prescriptions from multiple providers (*N*=651)
- Matched these to metrics relating to:
  - *List 1:* Top 1% of prescribers of controlled substances *in each tail*
  - *List 2:* Top 1% of prescribers in each tail + top 1% of prescribers *for all controlled substances*
  - *Thus List 2 is a subset of List 1*
- Note that because the number of providers in each full distribution varies, the number in the top 1% will also

Co-prescribed benzodiazepines + opioids >100MMEs



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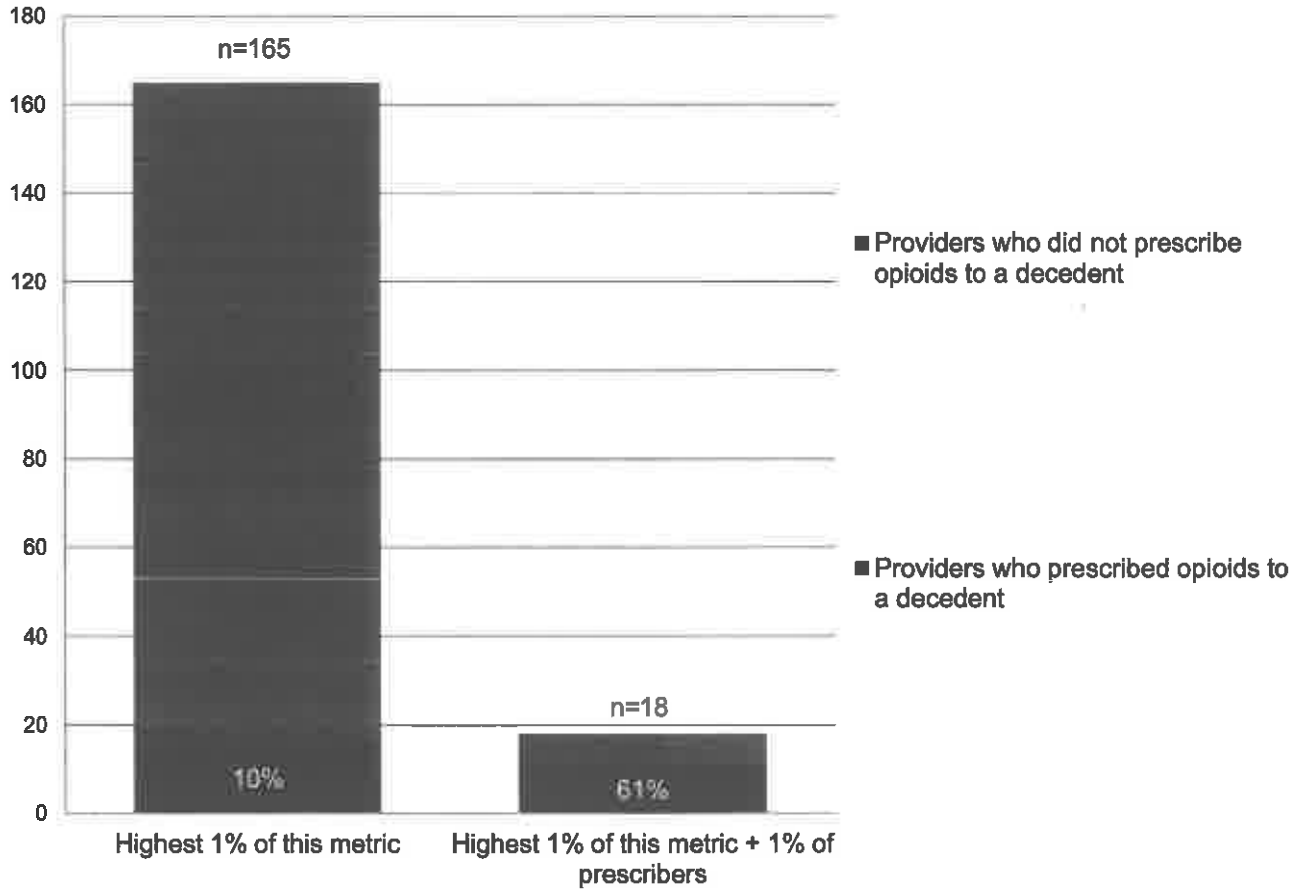
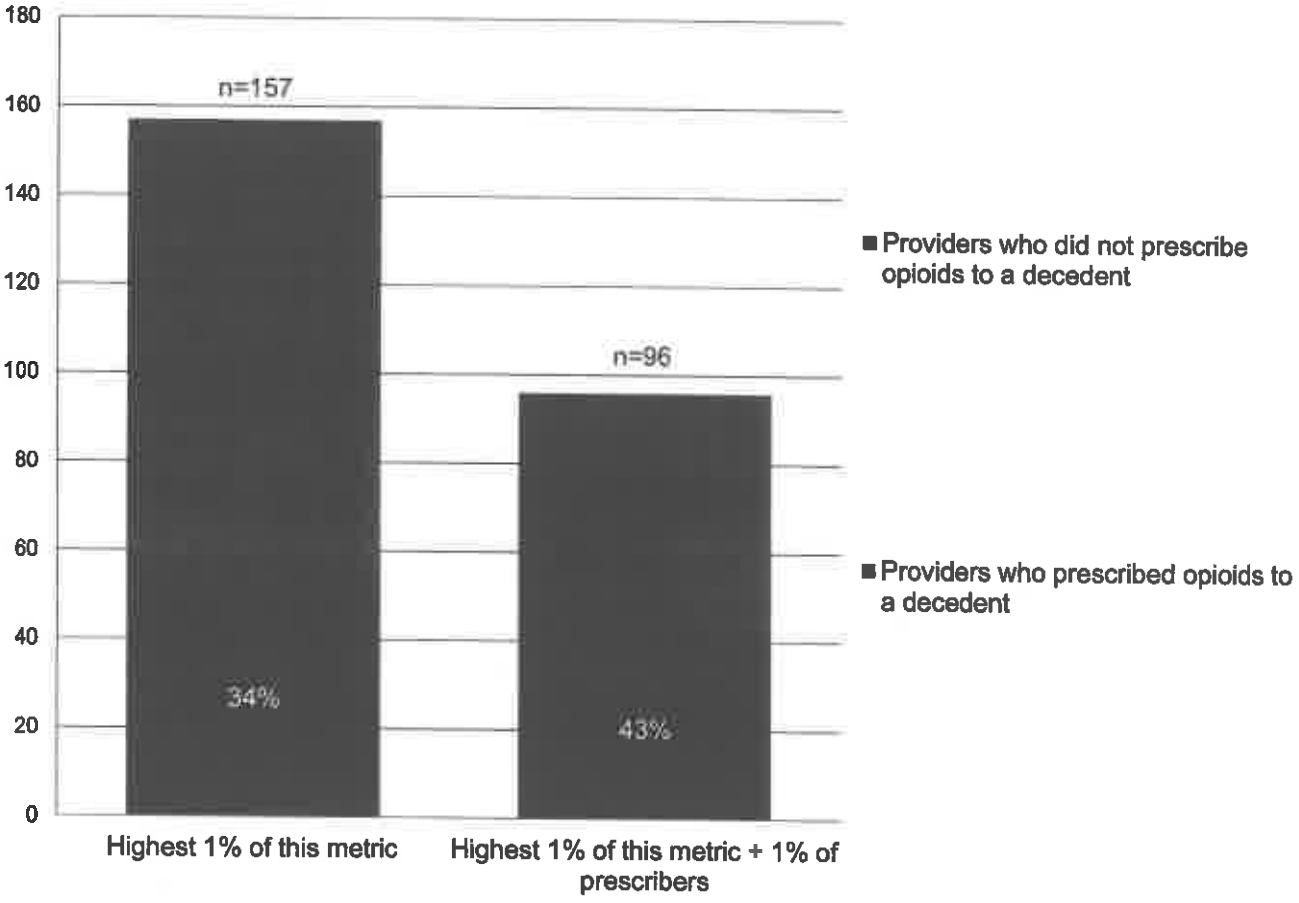
Temporally overlapping prescriptions



Prescriptions for opioids >*100 MMEs*



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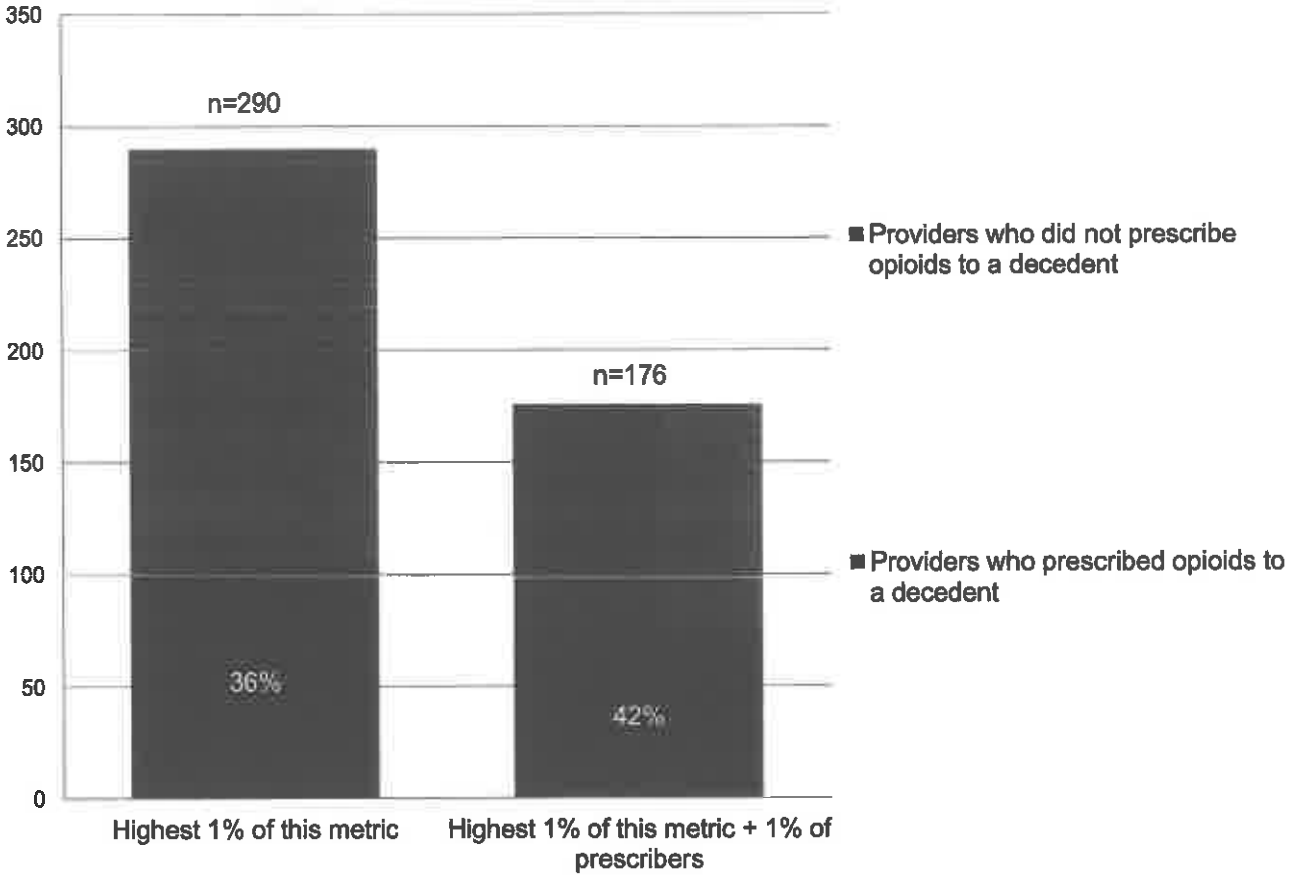
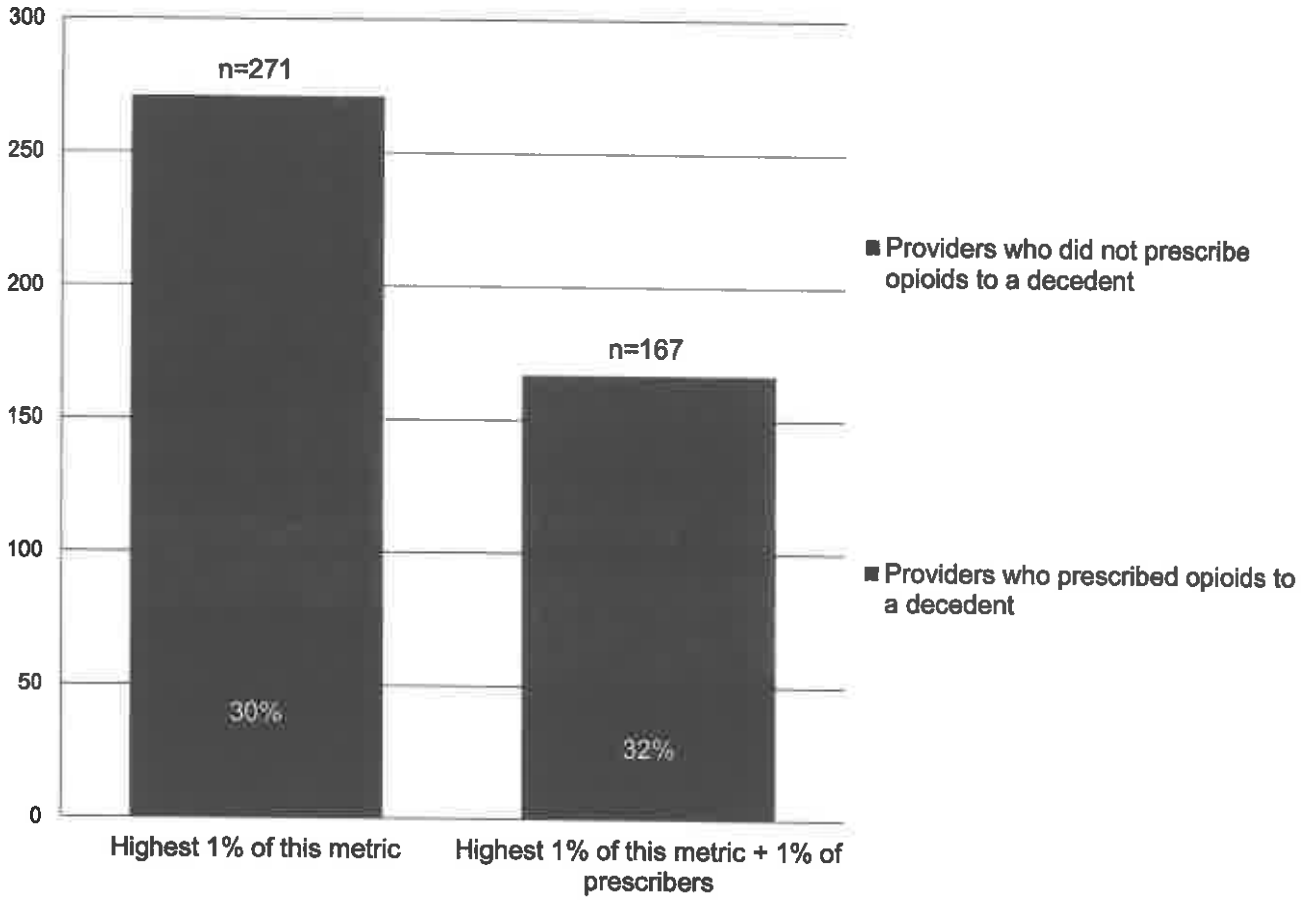
Prescriptions for *any opioids*



UNC

Prescriptions for any *benzodiazepines*



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Non-Performing Metrics*: Providers with Patients who

- Travel long distances to their
  - Providers
  - Pharmacies
- Are doctor shoppers
- Are pharmacy shoppers

** With this validation effort, at least*

Caveats

- Findings from these metrics only represent *an initial screen*
- Prescribing opioid analgesics within a month of a patient's death does *not* constitute causality
- Further, attributing deaths to opioid overdoses is not a perfect science
- Greater concurrent validity related to providers in top 1% of all prescribers of a controlled substance (2nd bar) may be a function of greater *exposure* – i.e., they wrote the most prescriptions
- Our PMP:
  - Lacks specialty information
  - Lacked (until recently) payer information

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Potential Uses for Study Findings

- State medical boards and other investigatory bodies
  - Potentially problematic providers can be quickly identified
  - Patients who have received problematic levels of prescriptions can be identified and their charts reviewed to determine if the prescriptions were appropriate
  - Metric placement (rate & rank) can assist investigations by demonstrating to providers exactly where they lie on these distributions
- North Carolina Medical Board has just adapted and is now using several of our metrics, namely:
  1. Top 1% of providers who prescribe 100 MMEs/patient/day
  2. #1 above +
     - Any benzodiazepine +
     - Top 1% of all prescribers of controlled substances by volume
- Same technology can be brought to bear on potentially problematic pharmacies (dispensers)

N.C. Medical Board's Experience

- Legislature felt CSRS information was not being used to its potential.
- We sought to:
  - Develop a structure, within existing legal restraints, to extract information from CSRS database that would identify potentially problematic prescribers in a fair and impartial manner.
  - Avoid targeting legitimate prescribers or causing unintended consequences.
  - Obtain and manage information that would result in a legally prosecutable case.
- Established a Board advisory committee to review the process and outcomes.

Final thoughts and considerations

- Need to assess impact of these efforts on appropriate prescribing patterns. Are pain patients getting what they need? Are they being pushed out of practices, or not being accepted into them? *Primum non nocere.*
- Need further review of metrics to what additional data from NC's PMP might be used to increase sensitivity, since NCMB investigations are time-consuming and may have a significant negative impact on legitimate prescribers.

Questions?

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