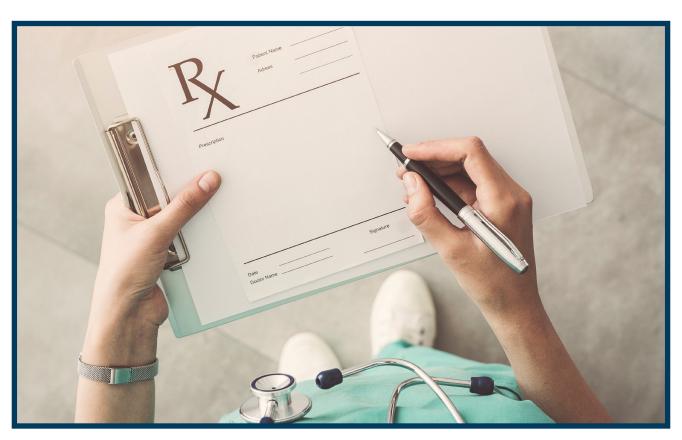


OFFICE OF RESEARCH AND EDUCATION ACCOUNTABILITY

OPIOID PRESCRIBING PATTERNS AND PRESCRIBER DISCIPLINE IN TENNESSEE



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Introduction

In May 2018, Governor Haslam signed Public Chapter 978, which directed the Comptroller's Office to complete a study about the opioid prescribing patterns of the state's doctors, nurses, dentists, and other licensed practitioners. The request asked the Comptroller's office to determine the number of prescribers whose patterns are found to be "significantly statistically abnormal," and to investigate what disciplinary responses, if any, were taken by the licensing boards against the prescribers whose patterns were found to be abnormal. To complete the request, the Comptroller's Office of Research and Education Accountability (OREA) analyzed data from the Tennessee Department of Health's controlled substances monitoring database (CSMD), interviewed Department of Health staff and members of the licensing boards, and reviewed board meeting minutes, disciplinary orders, and Department of Health investigation files.

Reforms to opioid data collection and use

In the year before Public Chapter 978 (2018) was signed, 1,261 Tennesseans died of an opioid-related overdose and medical providers treated at least 23,600 nonfatal overdoses. Fatal and nonfatal overdoses have been on the rise since 2013, and, to curb this trend, legislators sought to reduce the number of opioids prescribed in Tennessee. One step taken by the General Assembly was to increase the use of data to identify high-risk prescribers and hold them accountable.

Between 2013 and 2015, the General Assembly passed legislation that created two top prescribers lists: the top 50 prescribers, and the top 10 prescribers from small counties. The prescribers lists are generated using data from the state's controlled substances monitoring database (CSMD), which was created in 2002 by the Controlled Substance Monitoring Act to track the dispensing of opioids and other controlled substances (i.e., medications with at least some potential for abuse). Each year, after producing the top prescribers lists from the CSMD, the Department of Health must send a letter to each identified prescriber notifying them of their inclusion on a top prescribers list. The letter includes information about the practitioner's opioid prescribing patterns, such as the number of patients who were prescribed opioids and the amount of opioids prescribed to them. Practitioners who receive a letter must respond to the department and justify their prescribing patterns. The department then decides if the justification is sufficient or if further investigation is warranted.

Along with creating the top prescribers lists, the General Assembly passed legislation to increase the usefulness and relevance of the state's CSMD. Initially, dispensers (e.g., pharmacists) who provide patients with controlled substances were required to report prescriptions to the CSMD every seven days, but in 2016 Public Chapter 1002 required them to report prescriptions daily. A 2012 law, along with the 2016 law, also requires prescribers and dispensers to check the CSMD when prescribing opioids to new patients or when abuse or fraud are suspected in order to ensure that patients are not, for example, receiving multiple opioid prescriptions, at high risk for addiction, or selling their prescriptions.

The Department of Health credits these legislative reforms for the increased use of CSMD data to inform prescribing decisions and provide oversight of top prescribers. During this time of reform, the rate of opioid prescribing decreased from 2 million prescriptions in the fourth quarter of 2013 to 1.4 million in the fourth quarter of 2018. In addition, the number of patients who "doctor shop" (i.e., seek opioids from multiple prescribers and dispensers) decreased by almost 70 percent over the same time period according to a department report.¹

¹ Melissa McPheeters and Mary K. Bratton, "The Right Hammer for the Right Nail: Public Health Tools in the Struggle Between Pain and Addiction," *University of Memphis Law Review*, Vol. 48, 2018, pp. 1299-1355.

2 Million

1.5 Million

I Million

Exhibit 1: The number of opioid prescriptions per quarter, 2013 through 2018

Source: Tennessee Department of Health, Prescription Drug Overdose Program 2018 Report, Feb. 6, 2018, and Tennessee's Annual Overdose Report, 2019.

2015

2014

2013

Although these trends suggest that most prescribers are making use of the CSMD to make better prescribing decisions, inappropriate prescribing still occurs, and the Department of Health is responsible for investigating suspicious prescribing.² Historically, the department relied almost solely on complaints from other practitioners or from patients to identify potentially inappropriate prescribers. While the department also consulted the CSMD data for additional evidence after receiving an allegation of potentially inappropriate prescribing, the data was rarely used to proactively identify potentially inappropriate prescribing patterns. This began to change in 2017 when the General Assembly passed Public Chapter 483, requiring the department to regularly identify high-risk prescribers based on clinical outcomes, including patient overdoses.

2016

2017

2018

High-risk prescribers are not necessarily among the top prescribers of opioids. The top prescribers lists are based solely on the amount of opioids prescribed, while high-risk prescribers are identified using the outcomes of patients and any other prescribing patterns the department deems risky. For example, a doctor may not prescribe enough opioids to be on the top prescribers list, but the department could still deem the doctor a high-risk prescriber if a high percentage of the doctor's patients overdose while on an active opioid prescription. State law also requires the department to open an investigation into prescribers identified as high-risk through this process.

Discipline process for inappropriate prescribers

Disciplining inappropriate prescribers involves four parties: the Department of Health, which investigates potentially inappropriate prescribing; the health-related boards (e.g., Board of Medical Examiners, Board of Dentistry), which determine the appropriateness of prescribing and discipline practitioners accordingly; consultants who determine whether to seek discipline from the boards against prescribers; and administrative law judges to oversee the process.

The department's role as investigator includes identifying inappropriate prescribers, gathering evidence, and presenting its case to the relevant boards. Consultants are licensed practitioners who evaluate evidence compiled by investigators and decide whether the department should seek discipline against prescribers. The health-related boards have statutory authority to determine whether practitioners' prescribing patterns are inappropriate based on evidence provided by the department and discipline practitioners accordingly. To ensure the fairness and impartiality of the process, administrative law judges preside over these cases and can sign subpoenas, determine the admissibility of evidence, and enforce due process rules.

² Prescribers who engage in potentially illegal prescribing, however, are referred to the Tennessee Bureau of Investigation for criminal investigation.

Prescribing patterns are identified as potentially inappropriate through a complaint from other practitioners or from patients, or through an internal process at the department, such as the identification of a practitioner as a high-risk prescriber. Once a prescriber is identified, a query is opened and the department pulls the prescriber's CSMD records for review by a consultant. Consultants are typically employees of the Department of Health who are licensed in the same profession as the practitioner who is being investigated. For example, the department's consultant about medical doctors is a licensed doctor employed by the department who is knowledgeable about the standard of care in that field of medicine. (For the Board of Dentistry, however, the consultant is not a department employee, but rather a member of the Board of Dentistry.) An official investigation is opened if the consultant determines that the information from the CSMD indicates potentially inappropriate prescribing.

Investigators from the department's Office of Investigations then interview those who may have knowledge of the potentially inappropriate prescribing, and pull records of patient appointments, called charts. These charts contain information about the medication, procedures, and information provided to patients and include notes from the practitioner about their appointments. If the department needs to issue subpoenas for documents or testimony, an administrative law judge can approve those orders.

Exhibit 2: The investigation process, before a case can be brought before a board

A query is opened about a prescriber

An investigation is opened

The department investigates

A complaint from other practitioners or patients can trigger a query. The department can also identify a prescriber to open a query through other means, such as evidence in the CSMD.

evidence is enough to seek

would be appropriate.

disciplinary action and what action

Once a query is opened, a prescriber's CSMD data is reviewed by a consultant. If the consultant decides that the CSMD data contains evidence of potentially inappropriate prescribing, an investigation is opened.

After a consultant chooses to open an investigation, the department sends investigators to gather evidence, such as charts, CSMD data, and testimony from patients and other practitioners.

Consultants review evidence The department seeks a settlement with the practitioner Once evidence has been compiled, consultants decide whether the

The department seeks the level of discipline determined by the consultant through a settlement with the prescriber.

If the settlement is agreed upon:

The board determines whether to approve a settlement. If approved, the investigation is closed and the agreed upon discipline is given.

If the settlement is <u>not</u> agreed upon:

The department can then choose to bring the case before the board in a contested case hearing.

Steps taken by the Department of Health

Steps taken by the health-related boards

Once the department's Office of Investigations has assembled its case, it again seeks the opinion of consultants. Consultants help the department determine if the boards are likely to take disciplinary action based on the evidence compiled, and what discipline, if any, is most likely to be given. The consultants also use past board decisions as a guide to the actions boards are likely to take in new cases. Cases do not move forward without the approval of the consultant. The consultant process was designed to ensure that standards of care for medical professionals are set and judged by those within the profession rather than by lawyers or judges. If the consultant believes discipline is warranted, the department's Office of General Counsel continues developing the case and begins preparing for a potential contested case hearing.

If the department decides to move forward with a case against a prescriber, the practitioner is offered a chance to settle. In a settlement, a practitioner must admit fault and accept the discipline agreed upon by the department and the practitioner. Discipline given in settlements can range from public reprimands to the loss of a practitioner's license. The department seeks a settlement with each prescriber because the law grants the health-related boards considerable discretion in judging whether discipline is warranted and, if so, at what level. Contested case hearings are also a lengthy process because the department must secure witnesses, continue developing the case, and find times when all parties (e.g., the board, an administrative law judge, witnesses) are available. The department usually attempts to settle with prescribers before bringing cases before the boards. This is partly because of uncertainty about how the boards will rule and partly to avoid the lengthier process of a contested case hearing since prescribers may continue practicing until the board issues its decision in a case. If a settlement is not reached and the department chooses to continue with the case, a contested case hearing is held before the relevant board. If a settlement is reached, the relevant board must also approve the terms of the settlement before the agreed upon discipline is given.

Cases brought to the boards by the department are called contested case hearings. The administrative law judges preside over contested case hearings, ensuring procedure is followed and the hearing is fair. The board, however, makes the

final determination as to whether the practitioner's behavior warrants discipline and assigns any disciplinary action to the practitioner. Disciplinary action ranges from public reprimands and additional education requirements up to permanently revoking the prescriber's license. For example, if a dentist is under investigation for inappropriate prescribing, the Board of Dentistry determines if the prescribing patterns were inappropriate and any disciplinary action based on evidence presented by the department and arguments made by the practitioner's defense attorney.

Types of discipline that could be given to prescribers by health-related boards

- Public reprimand
- Fines and penalties
- Additional education requirements
- Probationary licensure status
- License suspension
- Permanent license revocation³

At any point leading up to or during the contested case hearing, a prescriber can choose to settle with the department. If the department and the prescriber agree on the level of discipline and the board approves the settlement, no further action is taken. Absent an approved settlement, the contested case hearing continues until the relevant board makes a final determination as to whether the practitioner's behavior warrants discipline and assigns any disciplinary action to the practitioner.

The genesis of this study

In 2018, members of the General Assembly expressed frustration with the disciplinary process (as outlined above) due to high-profile cases in which prescribers were allowed to continue prescribing opioids despite evidence of inappropriate prescribing. For example, one case involved an east Tennessee advanced practice registered nurse (APRN) who was prescribing upwards of 51 pills per day to patients and who sold hundreds of thousands of pills over a two-year period. The Department of Health's General Counsel stated that this prescriber "was a machine that dispensed prescriptions without regard for any professional responsibility" and that taking the number of pills prescribed by the APRN would lead to a fatal overdose. After the department presented its case, the Board of Nursing chose to put the nurse's license on probation, which allowed the APRN to continue prescribing but with some oversight. Within this context, the General Assembly passed Public Chapter 978 (2018) and mandated this study.

³ The Board of Nursing does not permanently revoke licenses.

Section 1: Practitioners with Statistically Abnormal Prescribing Patterns

As outlined in Public Chapter 978 (2018), the Comptroller's Office is required to identify prescribers whose patterns are "significantly statistically abnormal." The law asks for the study to investigate all practitioners who are licensed under Title 63, which includes doctors, APRNs, physician assistants, dentists, and veterinarians. This section outlines the methodology used to determine which prescribers are considered "significantly statistically abnormal" and discusses characteristics of the prescribers deemed to have abnormal prescribing patterns.

Methodology

To complete this study requirement, the Comptroller's Office of Research and Education Accountability (OREA) requested data from the Department of Health that detailed all prescribers who reported an opioid prescription to the CSMD in 2017. Data from 2017 was analyzed because it is the most recent year for which all data had been entered, cleaned, and organized by the department.⁴

Once data was received, OREA then used a statistical definition of "outlier" to begin identifying which prescribers' patterns were "significantly statistically abnormal." (See Appendix 1 for the statistical definition and outlier formulas used by OREA.) To compare practitioners to others in the same medical field, analysts classified prescribers based on the licensure type listed in the department's Licensure and Regulatory System (LARS) or the National Provider Identifier (NPI) registry. Doctors, APRNs, and physician assistants were analyzed together because they practice similar forms of medicine and have similar abilities to prescribe, while dentists were analyzed separately. Veterinarians are not included in this analysis because they are hard to identify based on LARS and the NPI registry. One reason for this is that many veterinarians dispense opioids in their office, similar to a pharmacist, but are often not as well equipped as a retail pharmacy to report their data to the CSMD. Veterinarians also have different rules for reporting (i.e., every 14 days instead of daily, and only certain types of prescriptions must be reported).

Important Terms

Outlier: prescribers were outliers if their prescribing patterns were above the threshold calculated using a statistical outlier test. The number of outliers found for each metric ranged from four prescribers to 1,469 prescribers.

Prescribers identified for further investigation by OREA: Public Chapter 978 (2018) directed the Comptroller's Office to determine the number of prescribers whose patterns were "significantly statistically abnormal" and to investigate what disciplinary response was taken by the licensing boards against each prescriber. Too many prescribers were outliers to thoroughly investigate each one. Prescribers identified for further investigation, therefore, are outliers who represent the most "significantly statistically abnormal" cases and were investigated by OREA.

The prescribing patterns of practitioners were analyzed based on five metrics. The first four metrics concern opioids prescribed for pain, while the fifth concerns opioid prescriptions for medication-assisted treatment (MAT). MAT is the use of medications – along with other interventions – to treat opioid addiction and substance abuse disorders. There are three drugs approved for the treatment of opioid dependence – buprenorphine, methadone, and naltrexone – but only the use of buprenorphine is recorded in the CSMD.

The first two metrics, which measure potentially high-risk opioid prescribing for pain, are (1) the number and percent of patients on long-term prescriptions, and (2) the number and percent of patients prescribed a high daily dose of opioids.⁶

⁴ Records maintained by the department come from many sources, including death certificate records, hospital discharges, and prescriber reporting, and combining these sources correctly takes time.

⁵ The department's online licensure and regulatory system (LARS) allows practitioners to apply for licensure or update their existing license. The National Provider Identification registry is a directory of all active National Provider Identifier (NPI) records. It is maintained by the Centers for Medicare and Medicaid Services.

⁶ In consultation with the department, OREA chose to define a long-term dose as any prescription that lasted for over 180 days and a high daily dose as a milligram morphine equivalent (MME) per day of 90 or more. MME is used because it measures the relative potencies of different types of opioids.

Although justifiable medical reasons exist for long-term and high-dose prescriptions, they are also associated with negative health outcomes. Long-term opioid use creates a higher potential for addiction and high-dose prescriptions pose a higher risk for overdoses. OREA examined both the number and the percent of patients for these two metrics in order to reduce the risk of flagging legitimate prescribing patterns. For example, practitioners who prescribe long-term or high-dose opioids to a relatively high number of patients compared to other practitioners may also see a high volume of patients compared to others in their field. The number of patients with long-term or high-dose opioid prescriptions for such practitioners, however, may also constitute a low percentage of their overall volume of patients, indicating long-term or high-dose prescribing is not the norm for them. Conversely, the data for a practitioner who sees a low volume of patients overall may show that a high percentage of patients are prescribed a long-term or high-dose opioid prescription based on just a few patients. When the percent of patients and the number of patients are both outliers, however, this indicates that long-term or high-dose prescriptions are part of a regular pattern.

The next two metrics concern whether patients are prescribed multiple controlled substances. One of these metrics is the number of patients with concurrent opioid and benzodiazepine (e.g., Xanax or Valium) prescriptions. When prescribed together, opioids and benzodiazepines present a higher risk for overdoses. The second metric is the number of patients with concurrent opioid prescriptions, which indicates prescribers may not be using CSMD tools to ensure their patients are not "doctor shopping." For both of these metrics, only the number of patients is used and not the percent. There are fewer medically acceptable reasons for these combinations, and high numbers alone indicate high-risk prescribing.

The final metric concerns medication-assisted treatment (MAT).⁷ Members of the General Assembly have expressed concern that opioids prescribed for MAT may be diverted (i.e., when legally prescribed drugs are sold or transferred to individuals for whom they were not prescribed). To identify prescribers whose MAT prescribing patterns indicate a higher potential for diversion, OREA examined the average milligrams prescribed for MAT per patient, per day. A higher average suggests that a prescriber is prescribing significantly more opioids for MAT per patient than their peers. (Because dentists are not able to administer MAT, they were not included in this analysis.)

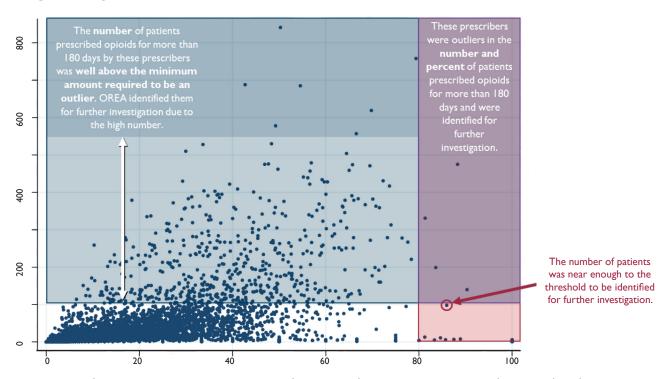
Using an outlier calculation, OREA established a statistical norm for each of the five metrics outlined above. Any prescriber whose prescribing patterns were above the thresholds were outliers. For some metrics there were few outliers and all outliers were identified for further investigation by OREA. For other metrics, too many prescribers were outside the statistical norm to thoroughly investigate each outlier. In these cases, the number of prescribers was narrowed to focus attention on prescribers with the most high-risk prescribing. The process outlined below details how OREA established a statistical norm and narrowed the focus when necessary to identify prescribers for further investigation.

For long-term and high-dose prescriptions, thresholds were set for both the percent and the number of patients. Prescribers who were above the threshold for both were statistical outliers. OREA also considered prescribers as candidates for further investigation if the number of patients was well above the threshold, regardless of the percent. For example, doctors, APRNs, and physician assistants who prescribed long-term opioid prescriptions to at least 103 patients, representing at least 79.5 percent of patients, were outliers. Four prescribers met both criteria and were identified by OREA for further investigation. Other prescribers did not meet the 79.5 percent threshold, but were well above the 103 patient threshold. In such cases, OREA identified any practitioner with at least 550 patients on long-term opioid prescriptions, regardless of the percentage, for further investigation. (See Exhibit 3.)

⁷ This analysis examines only buprenorphine prescriptions used for MAT, because buprenorphine is the only MAT drug currently reported to the CSMD.

⁸ Analysts also used discretion if a prescriber was just below the outlier threshold, but represented a clear deviation from the norm. In these cases, OREA chose to include those prescribers as outliers. For example, based on the outlier test, any prescribers with average milligrams prescribed for MAT at 24.92 or above were outliers. One prescriber's average, though, was 24.26 and there was a noticeable gap between that prescriber and all other prescribers. In that case, the prescriber was also considered an outlier.

Exhibit 3: Percent and number of patients prescribed long-term opioids for pain by each practitioner, with explanations as to who was identified for further investigation by OREA

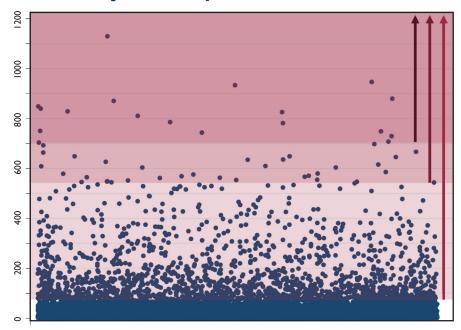


For some metrics, there were too many practitioners whose prescribing patterns represented statistical outliers to thoroughly investigate each. For example, any doctor, nurse practitioner, or physician assistant who had 79 or more patients with concurrent opioid prescriptions were outliers; 1,469 prescribers met this criterion. (See Exhibit 4.) OREA then took further measures to focus on the subset of such practitioners that represented the most high-risk cases. OREA narrowed the focus for metrics in which a large number of prescribers were outliers by running a second outlier calculation on only those prescribers who were above the threshold used in OREA's first outlier calculation. For example, using only the 1,469 prescribers, as identified above, a second outlier calculation was completed. This calculation yielded a second outlier threshold of 545 patients with concurrent opioid prescriptions (as compared to the threshold of 79 patients found in the first outlier calculation). Fifty out of 1,469 prescribers met this second criterion.

In some cases, a second outlier test sufficiently narrowed the number of prescribers and OREA identified all of them for investigation. In other cases, there were still too many outliers for OREA to fully investigate. In these cases, OREA chose to identify the top third of prescribers for further investigation. Using the same example as above, out of the 50 prescribers who were outliers after two outlier tests, OREA identified the top 17 prescribers, representing the top third, for further investigation. (See Exhibit 4.)

⁹ Investigating each identified prescriber included requesting additional information from the Department of Health, pulling licensure information from LARS, reading board minutes and decisions, and synthesizing information from multiple sources. Due to time constraints – the data was received in summer 2019 and the report was completed by January 2020 – OREA identified a limited number of prescribers for further investigation to ensure review of all identified prescribers was thorough.

Exhibit 4: Number of each prescriber's patients who were prescribed an opioid for pain while the patient was on another opioid prescription, with an explanation of how statistically abnormal prescribers were identified



The top third of prescribers (out of the 50), were identified by OREA for further investigation.

In the second outlier calculation, 50 prescribers were identified as outliers.

In the first outlier calculation, 1,469 prescribers were identified as outliers.

Note: Each prescriber was assigned an identifier, which was used in this exhibit to spread prescribers along the X axis so they could all be viewed.

Results: Doctors and physicians, APRNs, and physician assistants

Of the doctors and physicians, APRNs, and physician assistants identified using the LARS and NPI registries, 32,522 were recorded in the CSMD as having prescribed at least one opioid prescription for pain in 2017. Using the methodology outlined above, OREA identified 35 prescribers for further investigation based on their prescribing patterns. These prescribers were all statistical outliers and represent the most high-risk cases for at least one of the four metrics that measure opioids for pain.

Exhibit 5 outlines the thresholds set after OREA performed outlier tests to identify the most high-risk cases. For example, using an initial outlier test, 108 practitioners were identified as an outlier in the number and percent of patients prescribed high-dose prescriptions. OREA completed a second outlier test to narrow the focus and calculated thresholds of at least 399 patients and 24.6 percent of patients who had been prescribed long-term opioids. Four prescribers met the criteria, as shown in the second line of Exhibit 5.10

¹⁰ Patients were included only if they had been prescribed an opioid for pain. The percent of patients prescribed high-dose or long-term opioid prescriptions, therefore, is based on the total number of patients prescribed opioids for pain by each practitioner.

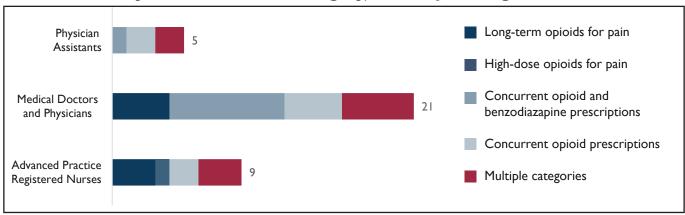
Exhibit 5: The criteria determined using a series of calculations and the number of prescribers identified for further investigation by OREA for each metric examined about opioids for pain

Metric	Threshold	Count		
Number and percent given long-term prescriptions	Over 97 patients and 79.5 percent of patients, or over 550 patients	12		
Number and percent given high-dose prescriptions	Over 399 patients and 24.6 percent of patients	4		
Number of patients on concurrent opioid and benzodiazepine prescriptions	Over 490 patients	15		
Number of patients on concurrent opioid prescriptions	Over 707 patients	17		
Total (some prescribers were outliers for multiple metrics)				

Note: For the number and percent on long-term prescriptions, one prescriber did not meet the criteria, but was very close to the cut-off. This prescriber was included in the 12 prescribers who were identified. The criteria for the number of patients on concurrent opioid and benzodiazepine prescriptions was set by taking the top third of prescribers who had at least 411 patients. The criteria for the number of patients on concurrent opioid prescriptions was set by taking the top third of prescribers who had at least 545 patients.

About 30 percent of identified prescribers were outliers in multiple categories related to opioid prescriptions for pain. Of the 35 prescribers identified as statistical outliers, three were outliers for three metrics, while seven were outliers for two metrics. In total, 10 of the 35 prescribers were identified for further investigation in more than one category, representing 29 percent of identified doctors and physicians, APRNs, and physician assistants. The largest overlap was for prescribers with a high number of patients on concurrent opioid prescriptions as well as a high number of patients on concurrent opioid and benzodiazepine prescriptions, for which five prescribers overlapped.

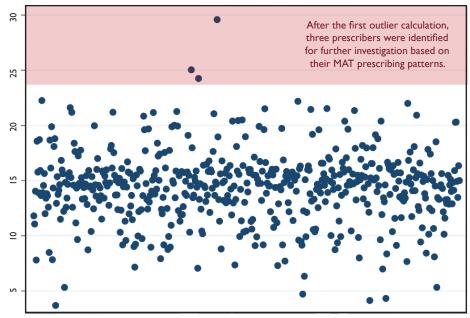
Exhibit 6: The number of doctors, APRNs, and physician assistants who were found to be statistically abnormal in each category, or multiple categories



Doctors made up 60 percent of the medical prescribers who were deemed statistically abnormal. Twenty-one doctors were identified, followed by nine APRNs, and five physician assistants.

Three additional prescribers were identified based on the fifth metric: average milligrams prescribed for MAT per patient, per day. In 2017, 1,532 doctors, physician assistants, and APRNs were identified in the CSMD as having prescribed opioids for MAT. On average, practitioners prescribed 15.4 milligrams per patient, per day. The three prescribers identified for further investigation prescribed an average of 24.25 milligrams or more per patient, per day.

Exhibit 7: Average milligrams prescribed for MAT per patient, per day, by each prescriber



Note: Each prescriber was assigned an identifier, which was used in this exhibit to spread prescribers along the X axis so they could all be viewed. Only those with at least 10 patients receiving MAT were included in the graph.

Results: Dentists

Of the dentists identified using the LARS and NPI registry, about 4,100 were recorded in the CSMD as having prescribed at least one opioid prescription for pain in 2017. Using the steps outlined in the methodology, OREA identified 24 prescribers for further investigation based on their prescribing patterns of opioids for pain.

The 24 identified prescribers were outliers for at least one of the following three metrics: number and percent of patients given high-dose prescriptions, number of patients on concurrent opioid and benzodiazepine prescriptions, and number of patients on concurrent opioid prescriptions. No prescribers were identified for further investigation based on long-term opioid prescriptions because 99.8 percent of dentists who prescribed opioids for pain did not prescribe any long-term opioid prescriptions. Nine dentists each prescribed one patient a long-term opioid prescription, but none of these were statistical outliers.

Exhibit 8 outlines the thresholds set after steps were taken to identify the most statistically abnormal prescribers. For example, using two outlier tests, OREA classified a prescriber as statistically abnormal if they prescribed opioids to at least 119 patients whose opioid prescription ran concurrent with a benzodiazepine prescription; 14 prescribers met this criterion. (See the second line in Exhibit 8.)

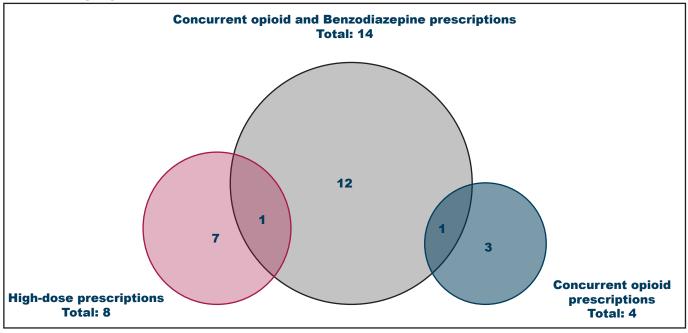
Exhibit 8: The criteria determined using a series of calculations and the number of prescribers deemed statistically abnormal for each metric examined

Metric	Threshold	Count		
Number and percent given high-dose prescriptions	Over 6 patients and 4.6 percent of patients	8		
Number of patients on concurrent opioid and benzodiazepine prescriptions	Over 119 patients	14		
Number of patients on concurrent opioid prescriptions	Over 111 patients	4		
Total (some prescribers were outliers for multiple metrics)				

Note: For all three metrics, there were prescribers who did not meet the criteria but were very close to the cut-off; they were also identified for further investigation by OREA.

Of the 24 prescribers identified for further investigation, two were deemed abnormal based on two metrics: (1) the number of patients on concurrent opioid and benzodiazepine prescriptions and (2) either the number and percent of patients on high-dose opioid prescriptions or the number of patients on concurrent opioid prescriptions. (See Exhibit 9.)

Exhibit 9: The number of prescribers identified for further investigation by OREA in each category



Section 2: Disciplinary Action Taken by Licensing Boards Against Prescribers Identified by OREA

Public Chapter 978 (2018) directs the Comptroller's Office to investigate the disciplinary response of the health licensing boards against prescribers identified in section 1 of this report. OREA requested information from the Department of Health about the 24 doctors and physicians, nine APRNs, five physician assistants, and 24 dentists identified by OREA as outliers in at least one category. The requested information included all complaints filed against each prescriber, any steps taken by the department to investigate each practitioner's prescribing patterns, and any board actions taken. In addition, OREA interviewed board members and department staff, reviewed Tennessee's licensure verification site for public discipline records, and examined board meeting minutes. This section outlines whether prescribers were disciplined by the relevant licensing board and outlines reasons why some prescribers received no disciplinary actions.

Overview

As outlined in section 1, 62 prescribers were outliers for at least one of the five opioid prescribing metrics examined by OREA and were identified for further investigation.¹¹ It is important to note that identification by OREA for further investigation alone does not indicate inappropriate prescribing. The CSMD data can be used as a tool to find potentially inappropriate prescribing, but a fuller range of information is necessary to determine if an identified prescribing pattern is inappropriate. For example, in 2017 the department analyzed benzodiazepine prescribing by dentists and found six dentists whose prescribing patterns were outside the norm for their profession. The department launched investigations into each prescriber, and ultimately three dentists were disciplined by the Tennessee Board of Dentistry due to their prescribing patterns. Other dentists identified by the department's analysis, though, were not disciplined after an investigation by the department found their prescribing patterns to be appropriate. Two of these dentists served

¹¹ The 62 prescribers were outlined in section 1. They include 24 dentists, 21 doctors and physicians, 9 APRNs, and 5 physician assistants who were identified based on their prescribing of opioids for pain, and three doctors who were identified based on their prescribing of opioids for MAT.

a high percentage of patients with jaw conditions, and some benzodiazepines can be used to relieve the symptoms associated with such conditions. Although outside the norm, these dentists' prescribing patterns were not found to be inappropriate given the needs of their patients. Thus, the data in this report by itself does not prove that inappropriate prescribing has occurred or that discipline is warranted.

According to department records, board meeting minutes, and public discipline records, 13 percent (eight of 62) of the prescribers identified by OREA have received some level of discipline since the start of 2017. Some prescribers were disciplined before 2017, but this was not in response to the 2017 prescribing patterns analyzed by OREA. As of November 2019, the department is developing cases (e.g., gathering evidence, talking to experts, waiting for contested case hearing dates) against five of the prescribers identified by OREA. The remaining 49 prescribers (79 percent) have not been disciplined by their licensing board since the start of 2017.

Exhibit 10: Number and percent of identified prescribers who have and have not received discipline since 2017, or are currently the subject of a case being developed by the department

	APRNs	Medical Doctors	Osteopathic Physicians*	Physician Assistants	Dentists	Total
Prescribing patterns were not identified for further investigation by the department	2 (22%)	8 (36%)	2 (100%)	2 (40%)	17 (58%)	31 (50%)
Query was opened, but was closed with no discipline since 2017 ⁺	4 (44%)	9 (41%)	0 (0%)	1 (20%)	4 (29%)	18 (29%)
Received discipline since 2017	2 (22%)	3 (14%)	0 (0%)	0 (0%)	3 (13%)	8 (13%)
Subject of a current case	1 (11%)	2 (9%)	0 (0%)	2 (40%)	0 (0%)	5 (8%)

Notes: *Osteopathic physicians are a type of physician, but their licensing board is the Board of Osteopathic Physicians, while other physicians are under the Board of Medical Examiners. 'Discipline given before 2017 was not included because this analysis studied the prescribing patterns of practitioners in 2017. Any discipline given prior to 2017 was not based on 2017 prescriptions.

Prescribers who did not have a query opened by the department about their prescribing

Before an investigation can be launched or discipline can be given, a query must be opened about the prescriber. Queries are opened by the department after receiving a complaint or when the department identifies a prescribing pattern that is potentially inappropriate, such as through the high-risk prescriber list. For half (31 of the 62) of prescribers identified by OREA, no query had been opened about their prescribing.

Exhibit 11: Number and percent of prescribers identified by OREA for which the department had not opened a query about their prescribing (i.e., no complaint was submitted to the department and the prescriber was not identified by the department through an internal process), by metric

	Count	Percent
Number and percent given long-term prescriptions	0	0%
Number and percent given high-dose prescriptions	7	58.3%
Average milligrams prescribed for MAT per patient, per day	0	0%
Number of patients on concurrent opioid and benzodiazepine prescriptions	19	65.5%
Number of patients on concurrent opioid prescriptions	9	42.9%
Total (some prescribers are in multiple categories)	31	50%

A query had been opened by the department for every doctor, APRN, and physician assistant identified by OREA based on prescribing patterns for long-term opioids, high-dose opioids, or opioids for MAT. This indicates that the query process was effective in flagging prescribers who were outliers for these metrics. The department's top prescribers lists likely identified some of these individuals because they have prescribed a high number of long-term or high-dose opioid prescriptions. Being an outlier for these metrics indicates that a practitioner is prescribing a high amount of opioids as part of a regular pattern, which increases the chances of appearing on one of the department's top prescribers lists. In addition, the department is more likely to identify potentially inappropriate MAT prescribers because these individuals require additional licensing and are more highly regulated.

Prescribers identified by OREA based on a high number of patients on concurrent benzodiazepine and opioid prescriptions were less likely than other prescribers to have had a query opened by the department. Over 60 percent of these prescribers were not identified by the department as a result of their prescribing. The majority were dentists (10 of 19), but at least one prescriber from each field examined by OREA (i.e., APRNs, doctors, etc.) was identified based on the prescribing of concurrent benzodiazepine and opioid prescriptions.

Seven prescribers who did not have a query opened by the department about their prescribing were identified by OREA based on their prescribing of high-dose opioid prescriptions, and all seven were dentists.

The remaining prescribers who did not have a query opened by the department about their prescribing were identified by OREA due to their prescribing of concurrent opioids and were from various medical fields.

The evidence from OREA's review of the 2017 data suggests that monitoring of all types of prescribers with a high number of patients on concurrent opioid and benzodiazepine prescriptions was an area of potential improvement for the department. Improving how dentists were monitored based on their high-dose prescribing and how all medical professionals were monitored based on their concurrent opioid prescriptions were other areas identified by OREA. Based on OREA's review of relevant legislation and interviews with department officials, the department has increased its use of CSMD data since 2017 to identify potentially inappropriate prescribing. For example, the department created its first high-risk prescribers list in the summer of 2019. The department's data team worked with its Office of General Counsel, which prosecutes inappropriate prescribing cases, to determine the metrics used for the list. Based on the first list, 10 practitioners were identified as high-risk prescribers and several are currently being investigated by the department, as of December 2019. Given these developments, a future analysis would likely find that the department is identifying more prescribers based on CSMD data than it was in 2017.

While more prescribers are likely to be identified by the department through the new high-risk prescribers list, the department is also likely to identify different prescribers than OREA because different measures are being used, though a department official stated that they see value in also examining the metrics used by OREA in this study. The department uses five metrics to measure high-risk prescribing: the number of patients who died of an overdose while on an active opioid prescription from the prescriber, the number of nonfatal overdoses experienced by patients while on an active opioid prescription from the prescriber, the number of patients who had not taken an opioid in the last 45 days and were prescribed a high dose, the average daily opioid dose per patient per day, and the percent of patients prescribed a high-dose opioid prescription. (The department's definition of "high-dose" is different from the one used by OREA. 12) The department chose the two metrics about overdoses because they were referenced in the law that mandated the high-risk prescribers list. The other three metrics were chosen by the department after examining the top prescribers for a variety of metrics in previous years and determining whether these prescribers had been disciplined by the relevant board. By taking into account the links between specific top-prescriber metrics and cases where discipline was issued by a board in the past, the department hopes its chosen metrics will identify top prescribers who are likely to receive discipline from the boards in the future.

¹² A high dose for a patient who had not taken an opioid in the last 45 days was defined by the department as 50 milligram morphine equivalent or MMEs. The department defined a high-dose prescription (regardless of the number of opioids prescribed) as 120 MMEs; OREA defined a high-dose prescription as 117 MMEs.

The highest number of prescribers for whom the department had not opened a query were identified by OREA based on two of the metrics which the top prescribers lists and high-risk prescribers list do not measure (the number of patients on concurrent opioid and benzodiazepine prescriptions, and the number of patients on concurrent opioid prescriptions). Though not currently used for the new high-risk prescribers list, one of the metrics was used by the department to identify dentists who were ultimately disciplined. In 2017, the department reviewed CSMD data to identify all dentists who had prescribed a high number of patients with concurrent opioid and benzodiazepine prescriptions; several dentists identified by the department thereafter were disciplined by the Board of Dentistry. Further department review of outliers for these two metrics, as well as other metrics not currently part of the high-risk prescribers list, could identify additional cases of potentially inappropriate prescribing.

Prescribers who had a query opened by the department about their prescribing, but have not received discipline since 2017

The department had opened a query on 18 of the 62 prescribers identified by OREA about their prescribing but ultimately decided there was insufficient evidence since 2017 to bring their cases before the relevant boards.¹³

Exhibit 12: Of prescribers who had a query opened about their prescribing, the percent who have not been disciplined since 2017, have been disciplined since 2017, or are the subject of a current case

	Number who had a query opened about prescribing	Investigated, but have not received discipline since 2017		Have received discipline since 2017		Subject of a current case	
Type of prescriber	Total	Count	Percent	Count	Percent	Count	Percent
Advanced Practice Registered Nurses	7	4	57.14%	2	28.57%	1	14.29%
Dentists	7	4	57.14%	3	42.86%	0	0.00%
Medical Doctors*	14	9	64.29%	3	21.43%	2	14.29%
Physician Assistants	3	1	33.33%	0	0.00%	2	66.67%
Grand total	31	18	58.06%	8	25.81%	5	16.13%

Note: *No queries about prescribing were opened about the Osteopathic Physicians identified by OREA.

As shown in Exhibit 10, dentists were the least likely of the prescriber types to have a query opened on them, and, as shown in Exhibit 12, were also more likely than other prescribers to have their case closed by the department after a query was opened because of insufficient evidence. One reason for this is that dentists had lower outlier thresholds than doctors, APRNs, and physician assistants. For example, a doctor, APRN, or physician assistant had to have prescribed high-dose opioid prescriptions to at least 399 patients to be considered an outlier, while the threshold for dentists was six patients. A higher number of practitioners will be identified when lower thresholds are used, and the prescribing patterns for many of these practitioners are more likely to be medically explainable.

Of the 18 prescribers who had been investigated but were not disciplined since 2017, six had been disciplined before 2017. Three had been disciplined in either 2015 or 2016 and the other three were disciplined earlier. During 2017, the year for which OREA analyzed prescribing patterns, three of these prescribers were being monitored or subject to screening panels due the discipline they received before 2017. In addition to discipline received before 2017, four of the six prescribers have had queries opened by the department and closed by a consultant since their previous discipline.

¹³ Two prescribers received discipline before 2017, and have not had a query opened about their prescribing since that discipline. Both, however, were under supervision or a screening in 2017, the year for which OREA analyzed prescribing patterns, and insufficient evidence was presented to the department through that process to pursue additional discipline.

The role of consultants in closing queries

As explained on pages 3 and 4, it is consultants who determine whether or not to close a query, either after an initial review of CSMD data and before an official investigation is opened, or after investigators have completed their investigation. For 16 of the 18 cases reviewed by OREA, a consultant chose to close queries about the prescriber without pursuing discipline. OREA was not able to determine at which point in the process a consultant decided to close the queries into the 16 prescribers who have not received discipline since 2017 because the department maintains full investigation files no longer than 90 days after a case is closed, due to security and storage reasons.

Generally, consultants who work on prescribing investigations of medical doctors, APRNs, and physician assistants are employees of the department and are licensed in the field for which they consult.¹⁵ Consultants are hired by the department, but the boards may vet consultants. Consultants who work on investigations of dentists are members of the Board of Dentistry and are licensed dentists. The consultant process was designed by the department and the boards to ensure that standards of care for medical professionals are set and judged by those within the profession, not by lawyers or judges. As professional peers of those investigated, consultants make the final decision as to whether the department can proceed with pursuing discipline from a health-related board against a prescriber.

Consultants work closely with the department's Office of General Counsel while reviewing evidence and making a final determination whether discipline – either through a settlement or a contested case hearing – will be pursued. This process is completed in meetings called case reviews. During a case review, the Office of General Counsel presents the evidence, explains the relevant laws or rules, answers questions, and deliberates the case with the consultant. When evaluating evidence and making a determination, consultants rely on their professional judgment and also consider whether a board is likely to find an accused practitioner guilty of an offense, and what discipline, if any, is most likely to be given or approved by the board.

Consultants try to anticipate how boards are likely to rule in order to avoid using time and department resources if a case is unlikely to result in discipline. If a case brought before a board does not result in discipline, the board may be required to pay the accused practitioner's legal fees. There is no formal set of guidelines used by consultants or members of the various boards that addresses the types of cases that should be brought before the board and the discipline that would likely be given by the board for such cases. In the absence of such guidelines, consultants develop a sense about how a board is likely to rule largely based on comments made by members in past board meetings and previous board rulings. Board members may attend case reviews and share their views with a consultant as each case is discussed, though board members who attend case reviews cannot approve settlements or judge contested case hearings for these cases. The Board of Medical Examiners and the Board of Nursing often split into panels, however, which allows these boards to approve settlements and hear and rule on contested case hearings without the board member who has attended the relevant case reviews. Other than the members of the Board of Dentistry, who also serve as consultants, the majority of board members have not attended a case review.

Board members and officials from the department's Office of General Counsel expressed trust in the consultants while also noting that consultant decisions, which determine whether a case will be closed or discipline will be sought, can lead to questions and disagreements at times. For example, the department's Office of General Counsel usually defers to the consultant's opinion, but disagreed with the consultant's decision not to move forward with discipline in one of the cases examined by OREA. After discussions between the consultant and the Office of General Counsel about this case, the consultant authorized the department to pursue public discipline if the prescriber does not take additional education courses. If the additional courses are taken, however, the prescriber will receive a private letter of warning and the case will be closed.

¹⁴ In the other two cases, the prescribers received discipline before 2017, and have not had a query opened about their prescribing since that discipline. Both, however, were under supervision or screening in 2017, the year for which OREA analyzed prescribing patterns. OREA did not find evidence that the monitors and screening panels presented further evidence to the department, however, that required a review and decision from a consultant.

¹⁵ The department employs a full-time medical doctor and full-time APRN, who act as consultants for prescribing cases. The department also has a part-time pain management specialist to consult on pain management cases, and a full-time medical doctor to act as a consultant on non-prescribing cases. Consultants can also be brought in when needed and receive a per-diem for any days they work.

Actions taken by the department when no discipline was sought

In six cases, the department sent practitioners a private letter of warning and discipline was not pursued through the relevant board. In these cases, the consultants decided the evidence was not strong enough to bring a contested case hearing to a board, but still concluded that a private letter of warning, which informs the practitioner they have been identified by the department and the reasons for identification, was warranted.

Prescribers who have received discipline since the start of 2017

Since 2017, eight prescribers identified by OREA have been disciplined by their relevant licensing board. Seven of the practitioners were disciplined for prescribing violations, while one was disciplined for a reason not related to prescribing. These eight prescribers represent 13 percent of the prescribers identified by OREA for further investigation.

Exhibit 13: The number and percent of prescribers identified by OREA for further investigation who have been disciplined since 2017, and whether they were identified by OREA based on one metric or multiple metrics

	Count	Percent
Prescribers who were identified based on one metric	6	12%
Prescribers who were identified based on multiple metrics	2	17%

As shown in Exhibit 13, the likelihood of receiving discipline was higher for prescribers identified by OREA based on multiple metrics than those identified based on a single metric. Those identified by OREA based on multiple metrics were also more likely to have had a query and investigation opened by the department, which increased their likelihood of receiving discipline.

OREA confirmed that the department used CSMD data to determine whether to pursue discipline, although most prescribers who received discipline were identified through complaints received by the department. CSMD data was not referenced by any of the licensing boards when issuing their disciplinary orders against the prescribers; instead, patient charts and medical histories were cited by the boards. Other types of evidence are presented to the boards by the department because CSMD data alone is not sufficient proof of inappropriate prescribing.

Of the seven prescribers who received discipline due to prescribing patterns, four had their license placed on probationary status, two voluntarily surrendered their license, and one is unable to practice pending the outcome of a criminal case brought against them based on prescribing patterns.

As explained on page 4, once the department decides to move forward with a case against a prescriber, the practitioner is offered a chance to settle. In a settlement, practitioners must admit fault and accept the discipline that was negotiated between them and the department. Discipline given in settlements can range from public reprimand to the loss of a practitioner's license. The department usually attempts to settle with prescribers before bringing cases before the boards. In six of the eight cases in which a prescriber received discipline, a settlement was reached. Of the other two cases, one was brought before a board for a contested case hearing and the other case's progress was suspended pending the outcome of a criminal case brought against the prescriber.

Once an agreement is reached between the practitioner and the department, a consultant must approve the terms of the settlement before it is presented to the board. In making their decision, consultants consider the level of discipline that would likely be approved by the relevant board, which must determine whether or not to approve all settlements. Members of the Board of Medical Examiners and Board of Nursing expressed trust in consultants, while also noting that they, at times, have questioned the terms of some settlements approved by consultants.

Boards either approve or reject the settlements brought before them. Practitioners may continue prescribing until the board gives final approval to a settlement that removes the practitioner's prescribing authority. ¹⁶ Unlike a contested case hearing where all evidence that is ruled admissible by an administrative law judge is presented to the board, a comprehensive list of admissible evidence against a prescriber is not presented to the board for every settlement. Board members usually choose to trust the judgment of the consultant, who has reviewed all the evidence. On occasion, however, board members question whether the discipline included in a settlement is too lenient or too strict based on the limited evidence presented for settlements.

The president of the Board of Medical Examiners explained that these questions about the level of discipline included in a settlement may arise because most board members have not attended a case review. During a case review, consultants and members of the department review and discuss the evidence more exhaustively. Board members who have never seen the level of discussion and evidence presented in a case review may find it more difficult to trust the consultant's settlement decisions. The president also explained that knowing another board member had been present and part of the settlement conversation during the case review would help him more confidently approve settlements when he has concerns about the level of discipline outlined in a settlement.

In the high-profile case involving an east Tennessee APRN which sparked this OREA study, the department's opinion was that the discipline issued by the board was too lenient and chose to appeal the board's decision before a chancery court judge. In the summer of 2019, the judge ordered the board to reconsider the APRN's case. ¹⁷ The prescriber's attorney has appealed the chancery court's ruling, and, as of December 2019, the board has not reconsidered the case. The department did not consider the disciplinary actions taken by the boards to be too lenient in any of the cases investigated by OREA. In addition, there were no cases investigated by OREA for which the department sought discipline against a prescriber and the board did not take disciplinary action.

Prescribers currently under investigation or for whom the department is seeking discipline

As of November 2019, OREA has identified five prescribers currently under investigation (two prescribers) by the department or against which the department has already decided to pursue discipline (three prescribers).

For four of the five prescribers, the department's actions began with a query that was opened in 2017 or earlier. As explained on pages 3 and 4, the department opens queries after receiving complaints or once it identifies a prescribing pattern that is potentially inappropriate. These four prescribers have been under investigation by the department for at least two years and have not yet been brought before the relevant board. The department's Office of General Counsel indicated that scheduling contested case hearings before a board is difficult for several reasons.

Each contested case hearing requires multiple parties to be present: an administrative law judge, experts, defense and state attorneys, and board members. Identifying a date that will accommodate the schedule of all parties can be difficult, especially given that health boards meet for contested case hearings only four to six times per year. Administrative law judges preside over hearings in many fields (e.g., property assessment hearings) and contested case hearings must be scheduled based on judges' availability. The schedules of experts, who tend to be practicing doctors, must also be accommodated, as well as the schedules of accused practitioners. According to officials from the department's Office of General Counsel, defense attorneys, who represent accused practitioners, often attempt to stall contested case hearings. Accused practitioners may continue to practice until the effective date of any discipline given by the relevant board.

¹⁶ If a settlement is not reached, however, the practitioners may continue prescribing until the board issues discipline through the contested case hearing process.

¹⁷ In 2018, members of the General Assembly expressed frustration with the disciplinary process due to a high-profile case in which an east Tennessee advanced practice registered nurse (APRN) prescribed upwards of 51 pills per day to patients and sold hundreds of thousands of pills over a two-year period. After the department presented its case, the Board of Nursing chose to put the nurse's license on probation, which allowed the APRN to continue prescribing but with some oversight. Within this context, the General Assembly passed Public Chapter 978 (2018) and mandated this study.

The Board of Medical Examiners and the Board of Nursing have responded to the scheduling difficulties by forming panels of two to three board members for contested case hearings, increasing the number of cases that can be heard on a given date.¹⁸

A single case hearing is usually not sufficient for all arguments to be heard and a disciplinary decision reached by the board, which further extends the time frame. This can mean that the state's attorneys (who present evidence against the practitioner) present their case and call expert witnesses months before a decision is ultimately made. For example, the high-profile case involving an east Tennessee APRN, which sparked this OREA study, started with queries from 2012-2015, but a contested case hearing was not held until August 2017 and was not completed until February 2018.

Conclusions

The Tennessee Department of Health's controlled substances monitoring database (CSMD) is a tool that can be used to find potentially inappropriate prescribing, but more information is necessary to determine if the prescribing pattern is in fact inappropriate; thus, the data presented in this report by itself does not prove inappropriate prescribing or that discipline is warranted.

As directed by Public Chapter 978 (2018), OREA identified 62 prescribers with "significantly statistically abnormal" prescribing patterns and investigated what disciplinary responses, if any, were taken by the licensing boards against these prescribers. For half of the 62 prescribers, the department did not open a query about their prescribing because it received no complaints, and it did not identify the prescribers using the CSMD.

Evidence suggests that an area of potential improvement for the department is the monitoring of specific types of prescribing patterns.

The evidence from OREA's review of the 2017 data suggests that monitoring of all types of prescribers with a high number of patients on concurrent opioid and benzodiazepine prescriptions was an area of potential improvement for the department. Improving how dentists are monitored based on their high-dose prescribing and how all types of prescribers are monitored based on their concurrent opioid prescriptions were other areas identified by OREA.

As of December 2019, OREA's review of relevant legislation and interviews with department officials indicate the department has increased its use of CSMD data since 2017 to identify potentially inappropriate prescribing. For example, the department created its first high-risk prescribers list in the summer of 2019 and 10 practitioners were identified as high-risk prescribers. Several are being investigated by the department as of December 2019. Given these developments, a future analysis would likely find that the department is identifying more prescribers based on CSMD data than it was in 2017.

While more prescribers are likely to be identified by the department through the new high-risk prescribers list, the department is also likely to identify different prescribers than OREA because different measures are being used. The department chose two metrics about overdoses because they were referenced in the law that mandated the high-risk prescribers list. The department chose the other three metrics after examining the top prescribers for a variety of metrics in previous years and determining whether the prescribers had been disciplined by the relevant board. Based on this process, the department chose five metrics different from those examined by OREA, even though a department official stated that they see value in also examining the metrics used in this study.

OREA identified the highest number of prescribers for whom the department had not opened a query based on two metrics that the top prescribers lists and high-risk prescribers list do not measure (the number of patients on concurrent

¹⁸ The Boards of Nursing, Medical Examiners, Physician Assistants, and Osteopathic Physicians can split into panels, but the Board of Dentistry, according to board rules, cannot.

opioid and benzodiazepine prescriptions, and the number of patients on concurrent opioid prescriptions). The department has reviewed one of these metrics, however, for the Board of Dentistry. Further reviews of outliers for these two metrics, as well as other metrics not currently part of the high-risk prescribers list, could identify additional cases of potentially inappropriate prescribing.

Consultants play a significant role in determining the ultimate course of the department's investigations into prescribers.

A consultant's approval is necessary before the terms of a settlement between the department and a practitioner can be presented to a board for approval, and also before the department can seek a contested case hearing. For each case, the consultant must approve the decision to seek discipline, and the type of discipline that will be pursued. Of the 62 prescribers identified by OREA for further investigation, queries opened by the department were closed for 16 prescribers based on a consultant's opinion of the case, while six prescribers reached a settlement with the department based on the disciplinary recommendations of a consultant.

Board members and officials from the department's Office of General Counsel expressed trust in the consultants while also noting that consultant decisions can lead to questions and disagreements at times. For example, the department's Office of General Counsel usually defers to the consultant's opinion, but disagreed with the consultant's decision not to move forward with discipline in one of the cases OREA examined. In this case, no discipline was issued per the opinion of the consultant, but the Office of General Counsel sent a private letter of warning to the prescriber and convinced the prescriber to take additional continuing education courses.

The department did not consider the disciplinary actions taken by the boards to be too lenient in any of the cases investigated by OREA. In addition, there were no cases investigated by OREA for which the department sought discipline against a prescriber and the board did not take disciplinary action.

Of the seven prescribers who received discipline due to prescribing patterns since 2017, four had their license placed on probationary status, two voluntarily surrendered their license, and one is unable to practice pending the outcome of a criminal case brought against them based on prescribing patterns. In the high-profile case involving an east Tennessee APRN, which sparked this OREA study, the department's opinion was that the discipline issued by the board was too lenient and chose to bring the case before a chancery court judge, who ordered the board to reconsider its decision. As of December 2019, this case has not yet been reconsidered, but the department plans to present the case again and request harsher discipline. Based on the 2017 data, OREA did not find any cases for which the department sought discipline against a prescriber identified by OREA in which the board chose not to issue discipline, or for which the level of discipline the board issued was considered egregiously low by the department.

From opening a query to reaching an approved settlement or receiving a ruling from a board, the disciplinary process can take years to complete.

As of November 2019, five prescribers who were identified for further investigation by OREA are either currently under investigation (two prescribers) by the department or the department has already decided to pursue discipline against them (three prescribers). Four of the five prescribers have been under investigation by the department for at least two years and have not yet been brought before the relevant board. The department's Office of General Counsel indicated that scheduling contested case hearings before a board is difficult for several reasons. Each contested case hearing requires multiple parties to be present: an administrative law judge, experts, defense and state attorneys, and board members. Identifying a date that will accommodate the schedule of all these parties can be difficult. Once cases are scheduled, they often take more than one meeting to complete, which further extends the timeframe. Accused practitioners may continue to prescribe until the effective date of any discipline given by the relevant board, whether in the form of an approved settlement or a board ruling against the prescriber.

Policy Options

(1) The Department of Health may wish to contract with a third party to independently study the use of CSMD data to identify potentially inappropriate prescribers.

This study identified 31 prescribers who were identified for further investigation by OREA and had no query opened by the department about their prescribing patterns. These prescribers represented half all the prescribers identified by OREA. The 31 prescribers were identified by OREA based on 2017 data, however, and the department has increased its use of CSMD data since that time. A third party could determine if the increased use of the CSMD has improved the department's ability to identify potentially inappropriate prescribing and propose potential areas of improvement for department.

- (2) The General Assembly or licensing boards may wish to ask the department to examine additional metrics, including the metrics used by OREA for this study, when creating future high-risk prescribers lists.
- (3) The General Assembly may wish to request that the Department of Health conduct a review of the role of consultants in determining whether to seek discipline against practitioners with potentially inappropriate prescribing patterns.

Consultants play a significant role in determining the ultimate course of the department's investigations into prescribers. A consultant's approval is necessary before the terms of a settlement between the department and a practitioner can be presented to a board for approval and also before the department can seek a contested case hearing. For each case, the consultant must approve the decision to seek discipline, and the type of discipline that will be pursued. Of the 62 prescribers OREA identified for further investigation, queries opened by the department were closed for 16 prescribers based on a consultant's opinion of the case, while six prescribers reached a settlement with the department based on the disciplinary recommendations of a consultant.

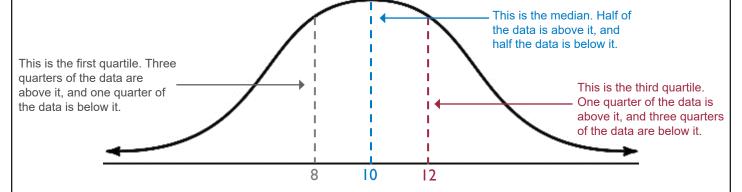
The review could address the following questions:

- a. Should boards meet annually with consultants to review the types of cases for which the consultant did or did not choose to seek discipline, as well as review previous settlement terms and how they were reached? Should the boards and consultants develop a formal set of guidelines to help guide consultant decisions over the next year? Should there be a public reporting mechanism to provide more transparency about consultants' decisions? Should all board members participate in at least one case review (meetings in which the consultants evaluate evidence and determine whether to move forward with a case) at least once per term?
- b. Should board members act as consultants, as is done with the Board of Dentistry?
- c. Should a second consultant (potentially a board member) be required to review prescribing cases? Should this be done in all cases; in over-prescribing cases in which the first consultant decides not to seek discipline; or only in cases in which the first consultant decides not to seek discipline and the Office of General Counsel disagrees with the decision?

The department's review might also address other consultant-related issues raised in this report and any other issues identified by the department.

Appendix 1a: Outlier calculation used for normal distributions

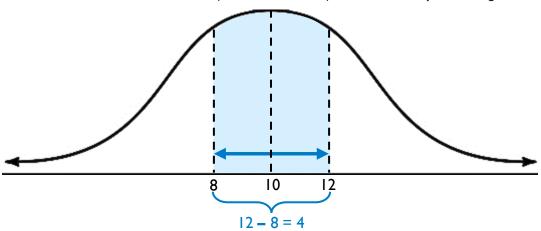
This is a normal distribution. In a normal distribution, most of the data is clustered around the median (the middle data-point), and the amount of data tapers off as the data gets further above or below the median. In this type of distribution, the tapering happens symmetrically above and below the mean.



Example: one quarter of the data is below 8, one quarter is between 8 and 10, one quarter is between 10 and 12, and one quarter is above 12.

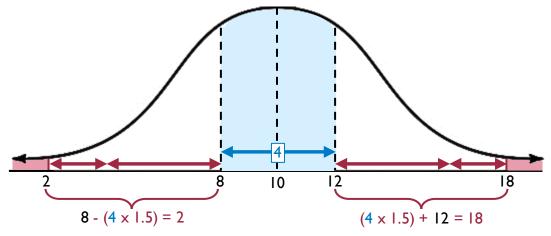
The middle half of the data is between the first and third quartiles.

The difference between the third quartile and the first quartile is the *interquartile range*.



Example: The interquartile range is 4 because the third quartile is 12 and the first is 8, and 12 minus 8 equals 4.

To find outliers, the interquartile range is multiplied by 1.5 and added to the third quartile and subtracted from the first quartile. Any data above or below these thresholds are considered outliers. This method is called the **Tukey's Box Plot** method.

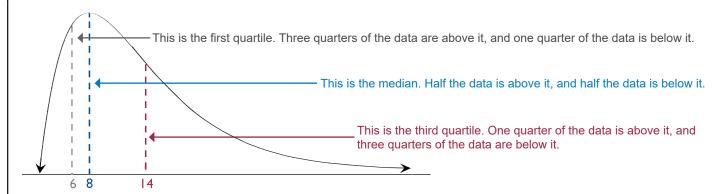


Example: In this case, the interquartile range is 4. One and a half times the interquartile range is 6 (4 x 1.5 = 6). The third quartile, which is 12, plus 6 equals 18. The first quartile, which is 8, minus 6 equals 2.

Any data above 18 or less than 2 is considered an outlier.

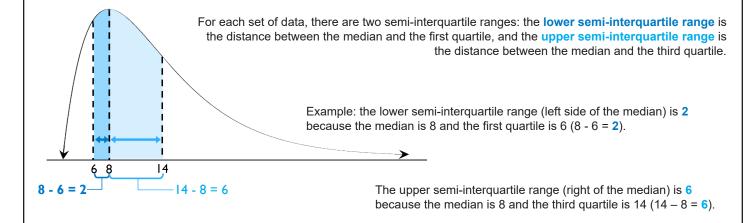
Appendix 1b: Outlier calculation used for skewed distributions

This is a skewed distribution. Like a normal distribution, half of the data is above the median (the middle data-point), and half is below the median. In this type of distribution, though, data on one side of the median is clustered more closely, while data on the other side is more spread out.

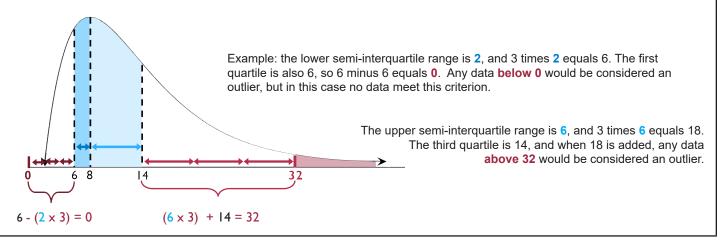


Example: this distribution is right-skewed, because the data to the right of the mean is more spread out than the data on the left. There is as much data between 6 and 8 as there is between 8 and 14, but the data between 8 and 14 is more spread out.

For a normal distribution, the interquartile range is used to determine possible outliers. With a skewed distribution, though, the interquartile range is not a good description of the data because one side is more spread out than the other. In this case, a **semi-interquartile range** is used.



To find outliers, each semi-interquartile range is multiplied by 3. The lower semi-interquartile range is subtracted from the first quartile and the upper semi-interquartile range is added to the third quartile. Any data above or below these thresholds are outliers. This is called the **Adjusted Box Plot** method.





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