

Report Highlights

Why DLA Performed This Audit

The audit was performed to determine if there is a continued need for the board and if its termination date should be extended. The board is set to sunset on June 30, 2022, and will have one year from that date to conclude its administrative operations.

What the Legislative Auditor Recommends

1. The board chair and DCBPL's director should improve procedures and training to ensure applicants meet requirements prior to licensure.
2. The board should adopt regulations for renewing outsourcing facilities and third-party logistics provider licenses.
3. Applicable occupational boards and DCBPL's director should continue to coordinate efforts to improve the monitoring and enforcement of CSPD requirements.
4. DCCED's commissioner should allocate sufficient resources to ensure licensees holding a DEA registration number are

(continued on following page)

A Sunset Review of the Department of Commerce, Community, and Economic Development (DCCED), Board of Pharmacy (board)

July 15, 2021

Audit Control Number 08-20126-22

REPORT CONCLUSIONS

Overall, the audit concluded that the board served the public's interest by effectively conducting its meetings and actively amending regulations; however, improvements over the board's licensing function are needed. Further, the audit concluded that Division of Corporations, Business and Professional Licensing (DCBPL) staff investigated complaints unrelated to the controlled substance prescription database (CSPD) in a timely manner and activity worked toward implementing new CSPD requirements.

At the time of the audit, occupational boards were not effectively monitoring or enforcing CSPD requirements. Additionally, DCBPL licensing staff were not consistently entering the existence of a Drug Enforcement Administration (DEA) registration number into DCBPL's licensing database, which prevented the licensing database from being used to monitor compliance with CSPD registration requirements.

In accordance with AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2022. We recommend that the legislature extend the board's termination date six years, to June 30, 2028, which is less than the eight-year maximum allowed in statute. The reduced extension reflects the need for more timely oversight of the board's evolving role in combating the public health opioid crisis.

Report Highlights (Continued)

consistently recorded in DCBPL's licensing database.

5. DCCED's commissioner should allocate sufficient resources to ensure the CSPD requirements are enforced.

ALASKA STATE LEGISLATURE

LEGISLATIVE BUDGET AND AUDIT COMMITTEE

Division of Legislative Audit



P.O. Box 113300
Juneau, AK 99811-3300
(907) 465-3830
FAX (907) 465-2347
legaudit@akleg.gov

November 22, 2021

Members of the Legislative Budget
and Audit Committee:

In accordance with the provisions of Title 24 and Title 44 of the Alaska Statutes (sunset legislation), we have reviewed the activities of the Board of Pharmacy and the attached report is submitted for your review.

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
BOARD OF PHARMACY
SUNSET REVIEW
July 15, 2021

Audit Control Number
08-20126-22

The audit was conducted as required by AS 44.66.050(a). Per AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2022. We recommend the legislature extend the board's termination date to June 30, 2028.

The audit was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Fieldwork procedures utilized in the course of developing the findings and recommendations presented in this report are discussed in the Objectives, Scope, and Methodology.

A handwritten signature in black ink, appearing to read "Kris Curtis".

Kris Curtis, CPA, CISA
Legislative Auditor

ABBREVIATIONS

AAC	Alaska Administrative Code
ACN	Audit Control Number
AS	Alaska Statute
CDC	Centers for Disease Control and Prevention
CISA	Certified Information Systems Auditor
COVID-19	Coronavirus Disease 2019
CPA	Certified Public Accountant
CSPD	Controlled Substance Prescription Database
DCBPL	Division of Corporations, Business and Professional Licensing
DCCED	Department of Commerce, Community, and Economic Development
DEA	Drug Enforcement Administration
DLA	Division of Legislative Audit
FY	Fiscal Year
HB	House Bill
MME	Morphine Milligram Equivalent
PDMP	Prescription Drug Monitoring Program
SB	Senate Bill

CONTENTS

Report Sections	Organization and Function	1
	Background Information	5
	Report Conclusions	11
	Findings and Recommendations	25
	Objectives, Scope, and Methodology	31
Agency Responses	Department of Commerce, Community, and Economic Development	47
	Board of Pharmacy	51
	Legislative Auditor’s Additional Comments	53
Appendices	Appendices Summary	35
	Appendix A: Controlled Substance Prescription Database Statutes	37
	Appendix B: Analysis of Public Need Criteria	45
Exhibits	Exhibit 1: Board of Pharmacy Members as of March 31, 2021	1
	Exhibit 2: Controlled Substance Prescription Database Timeline, April 2008 through January 2021	7
	Exhibit 3: Controlled Substance Prescription Database, Schedule of Revenues and Expenditures, FY 18 through January 31, 2021	9

CONTENTS

(Continued)

Exhibit 4: Board of Pharmacy, Licensing and Registration Activity, FY 18 through January 31, 2021	13
Exhibit 5: Board of Pharmacy, License, Registration, and Permit Fees, FY 18 through FY 21	14
Exhibit 6: Board of Pharmacy, Schedule of Revenues and Expenditures, FY 18 through January 31, 2021	15
Exhibit 7: Board Monitoring of CSPD Registration and Reporting Requirements, Status as of December 31, 2020	17
Exhibit 8: Controlled Substance Prescription Database, Extent Prescribers Reviewed Database, FY 18 through FY 20	18
Exhibit 9: Disciplinary Matrices Addressing CSPD Requirements, Status as of January 31, 2021	20
Exhibit 10: Controlled Substance Prescription Database, Number of Board Reports, FY 18 through January 31, 2021	21
Exhibit 11: Number of Prescriber Report Cards, FY 18 through January 31, 2021	22

ORGANIZATION AND FUNCTION

Board of Pharmacy (board)

The board was established for the purpose of controlling and regulating the practice of pharmacy in Alaska. According to AS 08.80.005, effective control and regulation is necessary to promote, preserve, and protect the public's health, safety, and welfare.

As shown in Exhibit 1, the board is composed of seven members. By statute, five board members must be licensed pharmacists actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding appointment. The remaining two positions are to be filled by individuals from the general public. Statutes prohibit public members from having a direct financial interest in the health care industry.

The board regulates admission into the practice of pharmacy, establishes and enforces competency by ensuring compliance with professional standards, and adopts regulations. The board is also required to establish and maintain a controlled substance prescription database; establish standards for the independent administration by a pharmacist of vaccines, related emergency medications, and opioid overdose drugs; and maintain a link to the United States Food and Drug Administration's website that lists all currently approved interchangeable biological products.

The board licenses pharmacists, pharmacy interns, and pharmacy technicians. The board also licenses pharmacies and wholesale drug distributors located inside the state, and wholesale drug distributors,

Exhibit 1

Board of Pharmacy Members as of March 31, 2021

Richard Holt, Chair
Licensed Pharmacist

Lana Bell
Licensed Pharmacist

James Henderson
Licensed Pharmacist

Leif Holm
Licensed Pharmacist

Justin Ruffridge
Licensed Pharmacist

Tammy Lindemuth
Public Member

Sharon Long
Public Member

Source: Office of the Governor, Boards and Commissions website.

**The Department
of Commerce,
Community,
and Economic
Development’s Division
of Corporations,
Business and
Professional Licensing
(DCBPL)**

outsourcing facilities,¹ and third-party logistics providers² located out of the state. Additionally, drug rooms located within an institutional facility are licensed. The board registers pharmacies located outside of the state if a pharmacy ships, mails, or delivers prescription drugs to consumers in the state.

DCBPL provides administrative and investigative assistance to the board. Administrative assistance includes budgetary services and functions such as collecting fees, maintaining files, receiving application forms, publishing notices for meetings, and assisting with board regulations.

Alaska Statute 08.01.087 gives DCBPL authority to act on its own initiative or in response to a complaint. DCBPL may:

1. Conduct an investigation if it appears a person is engaged or about to engage in a prohibited professional practice.
2. Bring an action in Superior Court to enjoin the act.
3. Examine or have examined the books and records of a person whose business activities require a business license or licensure by a board listed in AS 08.01.010 or whose occupation is listed in AS 08.01.010.
4. Issue subpoenas for the attendance of witnesses and records.

To support board operations, DCBPL employs two licensing examiners and an executive administrator who reports directly to the board. To assist the board in developing, implementing, administering, and managing the controlled substance prescription

¹ “Outsourcing facility” is defined as a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location.

² “Third-party logistics provider” is defined as an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

database, DCBPL employs a program coordinator who reports to the board's executive administrator.

Alaska Statute 08.01.065 requires the department to adopt regulations that establish the amount and manner of payment of application, registration, and license fees.

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BACKGROUND INFORMATION

The controlled substance prescription database (CSPD) was required by law in 2008.

Senate Bill 196, passed in 2008, required the Board of Pharmacy (board) to establish and maintain a CSPD.³ The law was passed with the intent to improve patient care and foster the goal of reducing misuse, abuse, and diversion of controlled substances. The statute requires each dispenser submit to the board, by electronic means, information regarding each prescription dispensed for a controlled substance. The CSPD electronically collects information from in-state pharmacies, as well as other dispensers of controlled substance prescriptions.

The Division of Corporations, Business and Professional Licensing (DCBPL) administers the CSPD on behalf of the board as part of its federally funded Prescription Drug Monitoring Program (PDMP).

Lack of effective statutes and regulations limited the CSPD's impact.

After implementation of the 2008 legislation, it became apparent that important authority was omitted from the law, which prevented the CSPD from meeting its intent. The most significant deficiencies were:

- The law did not provide the ability to identify all dispensers that must submit information. Consequently, the CSPD could not be monitored for completeness.
- Regulations required monthly reporting of information; however, monthly reporting was not effective for monitoring prescription practices.
- Only pharmacists were required to register with the CSPD and report prescription data.
- There was no requirement that dispensers or practitioners check the CSPD prior to dispensing, prescribing, or administering medication.
- Only the licensee that registered with the database could review or report to the CSPD, thus preventing delegation of duties.

³ Alaska Statute 08.80.030(11).

Significant changes to the CSPD were implemented in 2017 and 2018.

- The Department of Law determined that statutes did not allow CSPD information to be forwarded to practitioners or pharmacists (referred to as unsolicited reports), thus CSPD information could not be used to alert practitioners or pharmacists of unlawful or unprofessional activity.

Legislation was passed to improve effectiveness of the CSPD and to address the deficiencies noted above. CSPD access was expanded to include dispensers, dispenser delegates, and other persons or entities with a valid business need. Licensees of the following six occupational boards that prescribe or dispense controlled substances were required to register with the CSPD:

- State Medical Board;
- Board of Nursing;
- Board of Dental Examiners;
- Board of Pharmacy;
- Board of Examiners in Optometry; and
- Board of Veterinary Examiners.

Regulations were updated to require daily reporting of prescription data. Practitioners were required to check the CSPD prior to dispensing, prescribing, or administering medication, with specific exclusions. The board was authorized to provide an unsolicited notification to a pharmacist or practitioner if a patient received one or more prescriptions for controlled substances inconsistent with generally recognized standards of safe practice. The board was also authorized to issue unsolicited reports to a practitioner's licensing board. A PDMP coordinator was hired to help administer the database.

Exhibit 2 provides a timeline of key CSPD events from April 2008 through January 2021. Appendix A provides CSPD related statutes as of January 31, 2021.

Exhibit 2

Controlled Substance Prescription Database Timeline April 2008 through January 2021

April 2008	Senate Bill 196 required the board to establish the CSPD.
August 2010	The Department of Commerce, Community, and Economic Development (DCCED) entered into a contract with a vendor to provide electronic data collection of controlled substance prescription information from dispensers, provide database management, and provide secure web services.
December 2011	CSPD regulations became effective. Regulations required dispensers to report monthly.
January 2012	CSPD became available to licensees that registered.
January 2016	CSPD transitioned to a new vendor.
April 2016	Senate Bill 74 passed, which amended statutory requirements for registration, reporting, access to CSPD information, and performance measures. New statutes added registration requirements, allowed for unsolicited reports, and required weekly reporting and registration fees. Funding for a dedicated position was included in the bill. The new law had various effective dates.
June 2017	House Bill 159 passed, which required daily reporting with specific exclusions.
July 2017	Mandatory registration, review, and reporting for licensees with a Drug Enforcement Administration (DEA) registration number regulated by specific occupational boards became effective.
October 2017	CSPD contract amendment added prescriber report cards and requirements for sharing information with the DCBPL licensing database.
December 2017	First prescriber report cards were issued.
April 2018	CSPD clinical alerts to practitioners and dispensers were enabled. CSPD registration fees were implemented.
August 2018	Program coordinator was hired to administer the CSPD.
December 2018	A board executive administrator was hired.
October 2020	Contract with vendor to maintain the CSPD ended. Contractor continued to provide services until a new vendor was procured.

Source: DCBPL management; supporting documents; and SB 196, SB 74, and HB 159, which were presented during legislative hearings.

The existence of a DEA registration number helps identify whether a licensee is subject to CSPD registration requirements.

When applying for or renewing a license, applicants indicate whether the individual holds a federal DEA registration number. DCBPL staff manually record, within the licensing database, the existence of a DEA registration number, or, in the case of a pharmacist, whether the pharmacist dispenses controlled substances. As long as the existence of a DEA registration number is accurately recorded in DCBPL's licensing database, the licensing database can be matched to the CSPD to electronically monitor compliance with the CSPD registration requirement.

CSPD operations were mainly funded by federal grants.

Federal funds were used to initially purchase CSPD software. After implementation, federal grants continued to fund operational costs. Effective September 1, 2016, statutes required DCCED to establish fees for CSPD registration with the stipulation that the total amount of fees collected by DCCED should equal the total operational costs of the database minus all federal funds acquired for operational costs. A registration fee of \$25 was implemented April 2018. A schedule of CSPD revenues and expenditures is shown in Exhibit 3.

Exhibit 3

Controlled Substance Prescription Database Schedule of Revenues and Expenditures FY 18 through January 31, 2021 (Unaudited)				
	FY 18	FY 19	FY 20	July 1, 2020 - January 31, 2021
Revenues				
Federal Funds	\$ 259,500	\$ 243,475	\$ 502,918	\$ 55,464
Registration Fees		90,765	26,150	32,730
Total Revenues	<u>259,500</u>	<u>334,240</u>	<u>529,068</u>	<u>88,194</u>
Expenditures				
Personal Services	84,351	139,363	225,358	94,999
Travel	6,042	10,829	796	-
Services	169,107	99,337	324,382	16,718
Commodities	-	-	676	-
Total Expenditures	<u>\$ 259,500</u>	<u>\$ 249,529</u>	<u>\$ 551,212</u>	<u>\$ 111,717</u>

Source: DCCED management.

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REPORT CONCLUSIONS

In developing our conclusion regarding whether the Board of Pharmacy’s (board) termination date should be extended, its operations were evaluated using the 11 factors set out in AS 44.66.050(c), which are included in this report as Appendix B. Under the State’s “sunset” law, the 11 factors are to be considered in assessing whether an entity has demonstrated a public policy need for continuing operations.

Overall, the audit concluded that the board served the public’s interest by effectively conducting its meetings and actively amending regulations; however, improvements over the board’s licensing function are needed. Further, the audit concluded that Division of Corporations, Business and Professional Licensing (DCBPL) staff investigated complaints unrelated to the controlled substance prescription database (CSPD) in a timely manner and activity worked toward implementing new CSPD requirements.

At the time of the audit, occupational boards were not effectively monitoring or enforcing CSPD requirements. Additionally, DCBPL licensing staff were not consistently entering the existence of a Drug Enforcement Administration (DEA) registration number into DCBPL’s licensing database, which prevented the licensing database from being used to monitor compliance with CSPD registration requirements.

In accordance with AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2022. We recommend that the legislature extend the board’s termination date six years, to June 30, 2028, which is less than the eight-year maximum allowed in statute. The reduced extension reflects the need for more timely oversight of the board’s evolving role in combating the public health opioid crisis.

Detailed report conclusions are as follows.

The board conducted its meetings effectively and did not duplicate the efforts of another entity.

A review of nine of 22 board meetings held from FY 18 through January 2021 found that all nine meetings were public noticed timely, allowed time for public comment, and a quorum was consistently met. The 22 board meetings exceeded the minimum number required by statute; however, the board’s workload supported the number held.

As the only entity authorized to license and regulate the pharmacy profession, the board did not duplicate the efforts of another agency.

Investigations were conducted in a timely manner.

Auditors’ review of investigative activity concluded that board investigations unrelated to the CSPD were conducted in a timely manner. A total of 115 non-CSPD board related cases were open as of July 2017 or opened from July 2017 through January 2021. Fifty cases remained open as of January 2021. Of the 115 cases, 23 were open for more than 180 days. Auditors reviewed 12 of the 23 cases and found all were actively investigated. The timeliness of CSPD investigations is addressed on page 19.

Licenses were not consistently issued in compliance with state law.

As shown in Exhibit 4, there were 4,280 active board licenses as of January 2021, representing a 14 percent increase when compared to the 2017 sunset audit.⁴ The increase was due to the addition of three out-of-state license types: wholesale drug distributor, outsourcing facility, and third-party logistics provider.

Auditors tested 50 licenses issued during the audit period (25 individual licenses and 25 facility licenses), including both initial licenses and renewals. Testing found licenses were issued in compliance with statutes and regulations, except five license files were missing information required by regulation and three licensing files did not demonstrate adequate review of applicants’ professional fitness. (See Recommendation 1)

⁴ The number of total licenses reported in the 2017 sunset audit (ACN 08-20104-17) was 3,747.

Exhibit 4

Board of Pharmacy Licensing and Registration Activity FY 18 through January 31, 2021				
	New Licenses Issued (Exclusive of Renewals)			Total Active as of January 31, 2021
	FY 18	FY 19	FY 20	
Individual Licenses:				
Pharmacist	81	91	67	1,047
Pharmacy Intern	217	252	291	481
Pharmacy Technician	314	355	270	1,174
Facility Licenses:				
Pharmacy (In-State)	11	16	6	132
Registered Out-of-State Pharmacy	198	161	149	627
Drug Room	4	4	4	40
Wholesale Drug Distributor (In-State)	1	6	1	16
Wholesale Drug Distributor (Out-of-State)			408	570
Outsourcing Facility			17	31
Third-Party Logistics Provider			116	162
Totals	826	885	1,329	4,280

Source: Compiled from DCBPL licensing database.

Board fees covered the cost of operations.

Primarily, the board receives its revenue from licensure, registration, and renewal fees. Renewals are conducted on a biennial basis, creating a two-year cycle in board revenues. As shown in Exhibit 6 on page 15, the board had a surplus of \$794,789 at the end of January 31, 2021. The large surplus was due to an increase in license revenues associated with the addition of three license types. DCBPL management and board members discussed license fee reductions

during the February 2021 board meeting. Fees were not reduced in recognition that the planned addition of a new licensing examiner position would increase future expenditures. There was also concern that establishment of a disciplinary matrix for CSPD noncompliance would lead to more investigations and increase related expenditures. Exhibit 5 presents a schedule of board fees from FY 18 through FY 21.

Exhibit 5

Board of Pharmacy License, Registration, and Permit Fees FY 18 through FY 21			
	FY 18	FY 19	FY 20 - FY 21
Nonrefundable application fee for initial license	60	60	100
Pharmacist	240	240	200
Pharmacy intern	30	30	30
Pharmacy technician	60	60	50
Temporary pharmacist	60	60	50
Pharmacy	240	240	200
Registered pharmacy located out of the state	600	600	600
Remote pharmacy	240	240	200
Drug room	240	240	200
Wholesale drug distributor (in-state)	500	500	500
Wholesale drug distributor (out-of-state)	0	0	600
Outsourcing provider	0	0	600
Third-party logistics provider	0	0	600
Emergency permit to practice pharmacy	110	110	100

Source: DCBPL regulations.

Exhibit 6**Board of Pharmacy
Schedule of Revenues and Expenditures
FY 18 through January 31, 2021
(Unaudited)**

	FY 18	FY 19	FY 20	July 1, 2020 - January 31, 2021
Revenues				
Licensing Fees	\$ 801,317	\$ 213,770	\$ 631,105	\$ 932,837
Other Sources	210	962	-	-
Total Revenues	<u>801,527</u>	<u>214,732</u>	<u>631,105</u>	<u>932,837</u>
Direct Expenditures				
Personal Services	273,406	264,742	257,072	192,448
Travel	13,704	8,299	3,901	-
Services	21,960	31,243	48,783	16,094
Commodities	-	26	521	-
Total Direct Expenditures	<u>309,070</u>	<u>304,310</u>	<u>310,277</u>	<u>208,542</u>
Indirect Expenditures*	<u>259,680</u>	<u>263,571</u>	<u>256,442</u>	<u>148,736</u>
Total Expenditures	<u>568,750</u>	<u>567,881</u>	<u>566,719</u>	<u>357,278</u>
Annual Surplus (Deficit)	232,777	(353,149)	64,386	575,559
Beginning Cumulative Surplus	<u>275,216</u>	<u>507,993</u>	<u>154,844</u>	<u>219,230</u>
Ending Cumulative Surplus	<u>\$ 507,993</u>	<u>\$ 154,844</u>	<u>\$ 219,230</u>	<u>\$ 794,789</u>

* Indirect expenditures are estimated as of January 31, 2021, using the board's prior year indirect expenditures allocated for seven months.
Source: DCCED management.

The board actively amended regulations.

During the audit period, the board completed six regulation projects. The projects implemented statutory changes, addressed outdated verbiage, and made changes to help respond to the COVID-19 pandemic. When reviewing the new regulations, auditors noted that regulations governing license renewals (12 AAC 52.300) were not amended to include two new out-of-state license types: third-party logistics providers and outsourcing facilities. (See Recommendation 2)

Changes to statutes and regulations improved the CSPD.

During the audit period, administration of the CSPD significantly changed in terms of legal authority and organizational structure. The changes were intended to make the CSPD more effective at preventing the misuse, abuse, and diversion of controlled substances. As discussed in the Background Information section of this letter, significant changes included requirements to:

- **Register** - licensees of the six occupational boards that prescribe or dispense controlled substances were required to register with the CSPD;
- **Report** - data regarding prescriptions and dispensed substances were required to be reported daily to the CSPD; and
- **Review** - practitioners were required to check the database prior to dispensing, prescribing, or administering medication, with specific exclusions.

The audit concluded that changes to statutes and regulations materially addressed previously identified deficiencies, making the CSPD more capable of combating the opioid crisis. Further, the audit found the addition of a dedicated program coordinator helped provide the resources necessary to effectively administer the CSPD.

Occupational boards were slow to implement CSPD enhancements.

Implementing the new CSPD laws required the coordination of six occupational boards. The Prescription Drug Monitoring Program (PDMP) is housed within the Board of Pharmacy; however, each applicable licensing board is responsible for monitoring and

enforcing the requirements for their respective licensees. As of January 2021, each applicable board was at a different stage in implementing new CSPD laws and none of the boards were fully monitoring or enforcing CSPD requirements. Audit findings related to the CSPD are listed below:

1. Requirements for registering, reporting, and reviewing the CSPD were not actively monitored.

At the time of the audit, monitoring procedures for registering and reporting were evolving and only the Board of Pharmacy was actively monitoring both requirements. Exhibit 7 summarizes the degree each applicable occupational board monitored CSPD registration and reporting requirements.

Additionally, the boards did not monitor the degree each licensee reviewed the CSPD prior to dispensing, prescribing, or administering controlled substances. According to the PDMP coordinator, that information is tracked within the CSPD and could be monitored

Exhibit 7

Board Monitoring of CSPD Registration and Reporting Requirements Status as of December 31, 2020 (Unaudited)		
Board Type	Registration	Reporting
Dentistry	Not monitoring	Planned to start in 2021
Medical	Not monitoring	Planned to start in 2021
Nursing	Not monitoring	Monitoring since 2020
Optometry	Not monitoring	Not applicable – no optometrist dispensing as of 2020
Pharmacy	Monitoring since 2019	Monitoring since 2018
Veterinary	Not monitoring	Monitoring since 2020

Source: Alaska Prescription Drug Monitoring Program - 2021 Legislative Report.

by the licensing boards, if boards chose to do so. The PDMP coordinator reported to relevant boards the percent of prescribers that reviewed the CSPD on a quarterly basis beginning the second quarter of 2020. According to a 2021 legislative report of the Alaska PDMP, a majority of prescribers did not review the CSPD.⁵ (See Recommendation 3) The extent providers reviewed the CSPD is shown in Exhibit 8.

Exhibit 8

Controlled Substance Prescription Database Extent Prescribers Reviewed Database FY 18 through FY 20 (Unaudited)			
	FY 18	FY 19	FY 20
Percent of Prescribers Reviewing	35.63%	34.85%	43.88%

Source: Alaska Prescription Drug Monitoring Program – 2021 Legislative Report.

2. Compliance with CSPD registration requirements could not be determined due to DCBPL’s incomplete licensing database.

In an effort to evaluate compliance with CSPD registration requirements, auditors compared DCBPL’s licensing database to the CSPD. A high rate of unmatched licensees was found. Auditors tested a sample of the unmatched licensees and identified that board licensing staff were not consistently entering the existence of a DEA registration number into the licensing database and licensees that retired or did not renew their license were not consistently removed

⁵ According to the 2021 PDMP Legislative Report, the database may not capture review by prescribers that work in multiple health care positions (for example, a prescriber who works in a position that is exempt from the review requirements and in a position that is not exempt).

from the CSPD.⁶ Consequently, DCBPL's licensing database and the CSPD did not adequately identify licensees that were subject to the CSPD requirements and could not be used to accurately monitor compliance with CSPD registration requirements. (See Recommendation 4)

3. CSPD requirements for registering, reporting, and reviewing were not actively enforced.

Even though DCBPL's licensing database limited the ability to accurately identify all licensees that were noncompliant with the CSPD registration requirements, potentially noncompliant licensees were identified by board staff using available data and over 750 licensees were referred to DCBPL's investigative section for further review. DCBPL's chief investigator stated that insufficient staff resources and insufficient information provided by occupational board licensing staff and/or the PDMP coordinator limited the ability to investigate. DCBPL's chief investigator believes standard procedures are needed to ensure all board licensing staff obtain and verify specific information prior to referring a licensee to the investigative section. Standard procedures were drafted during May 2020, but had not been finalized as of May 2021. (See Recommendations 3 and 5)

Enforcement was further limited by inadequate disciplinary matrices. Board disciplinary matrices needed to help guide the resolution of CSPD related cases were not available for all boards during the audit period. Exhibit 9 summarizes the status of the disciplinary matrices as of January 31, 2021. Several board matrices covered a failure to register, but not a failure to review CSPD information or a failure to report controlled substances to the CSPD. The Board of Examiners in Optometry disciplinary matrix did not address the CSPD.

⁶ A license integration project designed to identify and remove expired licensees from the CSPD was unsuccessfully launched in August 2020 and deactivated in September 2020. According to DCBPL management, another license integration project is planned for 2021.

Exhibit 9

Disciplinary Matrices Addressing CSPD Requirements Status as of January 31, 2021

Board Type	Effective Date	CSPD Requirements Covered
Dentistry	Proposed (not final)	Registration and review
Medical	May 2019	Registration only
Nursing	August 2018 (allowed 120 day grace period)	Registration only
Optometry	None	None
Pharmacy	November 2020	Registration only
Veterinary	February 2020	Registration, review, and reporting

Source: DCCED documents.

Statutes authorize the Board of Pharmacy to provide unsolicited notifications to a pharmacist or practitioner if a patient has received one or more prescriptions for controlled substances inconsistent with generally recognized standards of safe practice. The term “generally recognized standards of safe practice” must be defined by the respective boards. At the time of the audit, the standards had not been fully defined. Only two of the applicable boards set prescription limitations in regulation. The State Medical Board set a limitation of 50 morphine milligram equivalents (MME) for initial opioid prescriptions only and the Board of Dental Examiners set a limitation of 60 MME. (See Recommendation 3)

The Board of Pharmacy may, but is not required to, send patient-specific utilization notifications to pharmacists and practitioners. Instead of sending patient-specific notifications, the PDMP coordinator provided summary data to applicable occupational boards as part of standard board reports and to practitioners as part of prescriber report cards. The following three metrics, referred to as “clinical alerts,” were provided:

1. Number of patients treated with over 90 and 120 MME;⁷
2. Number of patients treated with dangerous combinations;⁸ and
3. Number of patients who received controlled substances from five prescribers, at five pharmacies, over a three month period.

The process of sending board reports evolved during the audit period. Not all boards were sent reports on a routine basis and not all board reports included the three metrics. Exhibit 10 identifies the number of board reports issued during the audit period and the number of reports that included one or more of the three clinical alert metrics.

Exhibit 10

Controlled Substance Prescription Database Number of Board Reports FY 18 through January 31, 2021		
Board Type	Board Reports	Reports with Clinical Alert Metrics
Dentistry	8	2
Medical	6	3
Nursing	4	3
Optometry	2	0
Pharmacy	9	8
Veterinary	8	1

Source: Compiled from PDMP board reports.

⁷ The Centers for Disease Control and Prevention (CDC) recommend that primary care clinicians reassess evidence of the benefits and risk to the individual when increasing dosage to greater or equal to 50 MME and avoid increasing to greater or equal to 90 MME per day.

⁸ CDC recommends avoiding concurrent benzodiazepine and opioid prescription.

Beginning FY 18, CSPD information, referred to as Prescriber Report Cards, was provided to prescribing practitioners. The report cards were intended to give practitioners the ability to review their prescribing activity and compare the activity to other practitioners within the same occupation and within a specific specialty. Quarterly report cards included:

- the three clinical alerts;
- the prescriber’s current prescribing controlled substance volumes and duration, including comparison to peers;
- the top three prescribed controlled substances; and
- the number of patients searched in the CSPD.

Exhibit 11 illustrates the number of practitioners who received a prescriber report card by occupational board.

Exhibit 11

Number of Prescriber Report Cards FY 18 through January 31, 2021				
Board Type	FY 18	FY 19	FY 20	July 1, 2020 - January 31, 2021
Dentistry	793	1,482	1,451	1,014
Medical	2,948	5,742	6,874	5,421
Nursing	790	1,546	1,871	1,567
Optometry	10	13	21	10
Veterinary	293	555	630	549

Source: DCBPL management.

Occupational boards recognized the need to coordinate and standardize.

The need for division-wide procedures and coordination between applicable boards became apparent as the program evolved. In September 2020 a PDMP Board Chair group was created and began to meet biweekly. Participants included the chairperson of each of the six applicable occupational boards and DCBPL staff. The meetings provided a venue for discussing CSPD related matters and for disseminating information.

The board was unable to report certain performance measures.

Effective July 2017, the Board of Pharmacy was required to annually report performance measures to the legislature. Specifically, the board was required to report on CSPD security and reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the CSPD. The board reported its performance measures annually as part of a PDMP report to the legislature. Auditors confirmed that the 2021 PDMP legislative report addressed security over the CSPD; however, due to inherent limitations of the CSPD, the board did not report the reduction of inappropriate use or prescription.

The board explained in the 2021 legislative report that it was not possible to quantify the reduction of inappropriate use or prescription of controlled substances because the CSPD does not contain or relate prosecutorial data regarding diversion cases and is not informed when an individual, whether a patient or provider, has avoided inappropriate use or prescribing. Further, the board reported that there may be other factors that can be attributed to any reduction of inappropriate controlled substance use or prescribing, including provider education, which is independent of the database. Additionally, the CSPD does not log when a practitioner or pharmacist has considered, but ultimately declined, prescribing, administering, or dispensing a controlled substance.

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FINDINGS AND RECOMMENDATIONS

The prior 2017 sunset audit of the Board of Pharmacy (board) made two recommendations:

- The Division of Corporations, Business and Professional Licensing’s (DCBPL) chief investigator should work with the director to improve the timeliness of investigations.
- DCBPL’s director should improve procedures to ensure required licensure documentation is appropriately obtained and retained.

The prior audit recommendation to improve the timeliness of investigations has been addressed. Review of 12 investigations unrelated to the controlled substance prescription database (CSPD) open during the audit period identified no unjustified periods of inactivity.

The prior audit recommendation to improve procedures to ensure required licensure documentation is appropriately obtained and retained has not been addressed and is reiterated below as Recommendation 1.

Four new recommendations were made as part of this audit.

Recommendation No. 1:

The board chair and DCBPL’s director should improve procedures and training to ensure applicants meet requirements prior to licensure.

Three of 25 individual applications tested (12 percent) were missing affidavits of moral character. Regulation 12 AAC 52.120(b)(8) requires an applicant provide two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant’s good moral character. Auditors noted that the DCBPL checklist used to ensure applications were complete was missing the requirement for affidavits of moral character, which contributed to the deficiency.

Five of 25 facility license applications tested (20 percent) did not include all the required regulatory documentation. Specifically:

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- One third-party logistics provider did not include résumés of the officers responsible for the facility with its initial license application. Regulation 12 AAC 52.697(b)(3) states the board will issue a third-party logistics provider license to an applicant who provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility.
 - One out-of-state wholesale drug distributor’s application did not include a résumé of the officer responsible for the facility and a background check report was not retained in the applicant’s licensing file. Regulation 12 AAC 52.610(b)(3) states the board will issue a wholesale drug distributor license to an applicant who provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility. Regulation 12 AAC 52.610(b)(6) requires wholesale drug distributor applicants submit a completed fingerprint card for the facility manager to allow a background check by the Department of Public Safety.
 - One out-of-state wholesale drug distributor, one out-of-state pharmacy, and one in-state pharmacy were issued licenses when the applicants answered yes to a professional fitness question and the applicants’ licensing files lacked documentation of approval by a supervisor prior to issuance. Alaska Statute 08.80.261(a) states that the board may deny a license if the board finds the applicant has been convicted of a crime or acted in a way that does not conform to minimum professional standards. To help evaluate an applicant’s professional fitness, the application asks a series of questions. Division policy (DOL-28) requires the licensing supervisor review and approve applications that contain “yes” answers to professional fitness questions. Two of the three licenses were issued without follow-up due to human error. DCBPL management stated that the fitness questions were reviewed by a supervisor for the third license; however, no evidence was included in the file to demonstrate the review and there was no evidence that additional information was obtained upon which to base the review.

According to DCBPL management, turnover in the licensing examiner position, a lack of training, and human error contributed

to the facility license errors noted above. Issuing licenses without ensuring that applicants meet statutory and regulatory requirements increases the risk to public safety.

We recommend the board chair and the division director improve procedures and training to ensure applicants meet requirements prior to licensure.

Recommendation No. 2:

The board should adopt regulations for renewing outsourcing facilities and third-party logistics provider licenses.

License renewal regulations were not amended to include the new licensure types: outsourcing facilities and third-party logistics providers. According to the board chair, regulations for outsourcing facility and third-party logistics provider licensure renewal have not been adopted due to the COVID-19 pandemic and other competing priorities.

Per AS 08.80.030(b)(4), the board has the power to adopt regulations necessary to carry out its purposes. Lack of regulations over license renewal may result in licensing unqualified applicants, which may increase the risk to public safety.

We recommend the board adopt regulations for renewing licenses for outsourcing facilities and third-party logistics providers.

Recommendation No. 3:

Applicable occupational boards and DCBPL's director should continue to coordinate efforts to improve the monitoring and enforcement of CSPD requirements.

Enforcement of CSPD requirements was hampered by a lack of standard investigative referral procedures and incomplete disciplinary matrices. The audit also found that generally recognized standards of safe practice for controlled substances were not thoroughly defined by the applicable occupational boards.

Per AS 17.30.200(e)

The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of

the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner's licensing board to take disciplinary action against the practitioner.

Per AS 17.30.200(p)

*The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with **generally recognized standards of safe practice** [emphasis added].*

The need for standardized investigative referral procedures was not identified until a large number of licensees were referred to the investigative unit without adequate support. Many of the referrals came from the Prescription Drug Monitoring Program coordinator position without review by the applicable occupational boards. According to DCBPL management, board licensing staff generally did not have a thorough understanding of the information needed by the investigative section.

The incomplete disciplinary matrices and undefined standards of safe practice reflect the competing priorities of the various boards. Furthermore, resources were limited due to the COVID-19 pandemic.

The lack of standard procedures, disciplinary matrices, and investigative resources resulted in most CSPD referrals not being investigated. Ineffective enforcement increases the risk of noncompliant licensees, which increases the risk to public safety. Further, undefined generally recognized standards of safe practice hamper the board's ability to monitor prescribing activity and provide unsolicited notifications to pharmacists, practitioners, and applicable licensing boards, which increases the risk to public safety.

In September 2020 the applicable board chairs formed an advisory group to help foster teamwork, strategize ways to improve compliance amongst licensees, and address database challenges. We recommend the board chairs and the DCBPL director continue to coordinate efforts to improve the monitoring and enforcement of CSPD requirements, including the establishment of standard investigative referral procedures, CSPD related standards of safe practice, and disciplinary matrices that cover all CSPD requirements.

Recommendation No. 4: Occupational board licensing staff did not identify the existence of a DEA registration number within the DCBPL licensing database in a consistent manner.

The Department of Commerce, Community, and Economic Development’s (DCCED) commissioner should allocate sufficient resources to ensure licensees holding a Drug Enforcement Administration (DEA) registration number are consistently recorded in DCBPL’s licensing database.

DCBPL management provided written instructions and training to board licensing staff regarding how to record the existence of a DEA registration number in the licensing database; however, DCBPL licensing staff did not consistently follow the guidance. According to DCBPL management, regular turnover of the boards’ licensing examiner and supervisor positions led to inadequate training and oversight, which contributed to the finding.

Insufficient information within the licensing database limits the ability to monitor licensees’ compliance with the CSPD registration requirements. Incomplete information within the CSPD limits its ability to reduce the misuse, abuse, and diversion of controlled substances.

We recommend DCCED’s commissioner allocate sufficient resources to ensure licensees holding a DEA registration number are consistently recorded in DCBPL’s licensing database.

Recommendation No. 5:
**DCCED’s commissioner
should allocate
sufficient resources
to ensure the CSPD
requirements are
enforced.**

Over 750 licensees potentially noncompliant with CSPD registration, review, and reporting requirements were identified by DCBPL staff; however, few cases were investigated. Investigations were not conducted due to insufficient licensing examiner and investigator resources. Additionally, most of the referrals to the investigative section did not include the information necessary to proceed.

Per AS 17.30.200(e)

The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner’s licensing board to take disciplinary action against the practitioner.

Noncompliance with CSPD registration, reporting, and review requirements limits the ability to reduce the misuse, abuse, and diversion of controlled substances.

We recommend DCCED’s commissioner allocate sufficient resources to ensure the CSPD requirements are enforced.

OBJECTIVES, SCOPE, AND METHODOLOGY

In accordance with Title 24 and Title 44 of the Alaska Statutes, the activities of the Board of Pharmacy (board) were reviewed to determine if there is a demonstrated public need for its continued existence.

As required by AS 44.66.050(a), this report shall be considered by the committee of reference during the legislative oversight process in determining whether the board should be reestablished. Currently, under AS 08.03.010(c)(16), the board will terminate on June 30, 2022, and will have one year from that date to conclude its administrative operations.

Objectives

The three central, interrelated objectives of the audit are to:

1. Determine if the termination date of the board should be extended;
2. Determine if the board is operating in the public's interest; and
3. Determine the status of recommendations made in the prior sunset audit.

Scope

The assessment of board operations and performance was based on criteria set out in AS 44.66.050(c). Criteria set out in this statute relates to the determination of a demonstrated public need for the board. The board's activities were reviewed from July 1, 2017, through January 31, 2021. Financial information is presented, unaudited, from July 1, 2017, through January 31, 2021.

Methodology

During the course of the audit the following were evaluated:

- The prior sunset audit report (ACN 08-20104-17) to identify issues affecting the board and to identify prior sunset audit recommendations.

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- Applicable statutes and regulations to identify board functions and responsibilities, determine whether statutory or regulatory changes enhanced or impeded board activities, and help ascertain if the board operated in the public interest.
 - Legislative bills to identify new board functions and responsibilities.
 - Board expenditures, revenues, and fee levels to determine whether fee levels covered the costs of operations.
 - Controlled substance prescription database (CSPD) expenditures and revenues to evaluate operating costs and funding sources.
 - The State's Online Public Notices System to verify board meetings were public noticed in compliance with state law.
 - Various state and news related websites to identify complaints against the board or other board related concerns.
 - Various websites to identify potential duplication of board activities.
 - Board licensing data from July 1, 2017, through January 31, 2021, to identify the number of newly issued licenses by type and total active as of January 31, 2021.
 - Prescription Drug Monitoring Program (PDMP) legislative reports to gain an understanding of the CSPD.
 - PDMP coordinator reports provided to relevant occupational boards to gain an understanding of the information reported to the boards and evaluate the extent unsolicited notifications were presented in the reports.
 - CSPD vendor contracts to identify scope of work.
 - Various occupational board license application forms to evaluate whether the CSPD information was required as part of the application process.

-
- Listing of CSPD noncompliant licensees to determine the timing and extent of referrals to the Division of Corporations, Business and Professional Licensing (DCBPL) investigative section and the status of referrals.
 - Various occupational board disciplinary matrices to determine the extent the matrices covered CSPD requirements.
 - DCBPL standard operating procedures specific to the investigative referral process to gain an understanding of the process.
 - Prescriber report card data to determine the extent data was obtained and reported to prescribers.

Internal controls over the licensing database and investigations case management system were assessed to determine if controls were properly designed and implemented. Additionally, to identify and evaluate board activities, interviews were conducted with state agency staff and board members. Specific topics of inquiry included board operations, statutory duties, regulations, duplication of effort, fee levels, and complaints against the board.

The audit utilized the following samples:

- A random samples of 25 individual licenses and 25 facility licenses were selected from 2,702 and 1,578 licenses, respectively, that were active as of January 31, 2021. License applications were assessed for statutory and regulatory compliance. The sample size was based on low/moderate control risk, inherent risk, and audit risk. The sample included initial and renewal licensees. Testing results were projected to the population.
- A sample of nine of 22 board meetings held from FY 18 through January 31, 2021, was reviewed to gain an understanding of board proceedings and activities, the nature and extent of public input, whether a quorum was maintained, and whether board vacancies impeded operations. Six meetings were randomly selected and three were judgmentally selected. Test results were projected to the population.

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- A random sample of 12 of 23 cases open for over 180 days during July 1, 2017, through January 31, 2021, was reviewed to identify unjustified periods of inactivity. The results were projected to the population.
 - Samples were selected from each applicable occupational board's unmatched licensees based on a data match between DCBPL's licensing database and the CSPD to identify reasons why a licensee appears in one database but not the other.⁹ The following samples were reviewed: 45 licensees were randomly selected from 1,312 unmatched State Medical Board licensees; 25 licensees were randomly selected from 405 unmatched Board of Pharmacy licensees; 20 licensees were randomly selected from 200 unmatched Board of Nursing licensees; 10 licensees were randomly selected from 100 unmatched Board of Dental Examiners licensees; and all 28 unmatched Board of Veterinary Examiners licensees were reviewed. Results were projected to the population.

⁹ Applicable occupational boards are listed on page 6. Although the Board of Examiners in Optometry is an applicable board, its licensees were excluded from the data match because a separate sunset audit was conducted in 2021 that reviewed the Board of Examiners in Optometry's compliance with the CSPD.

APPENDICES

SUMMARY

Appendix A provides the controlled substance prescription database statutes effective as of January 31, 2021.

Appendix B provides the sunset criteria used in developing the conclusion regarding whether the Board of Pharmacy termination date should be extended.

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Controlled Substance Prescription Database Statutes

Alaska Statute 17.30.200. Controlled substance prescription database.

(a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule II, III, or IV controlled substance under federal law dispensed in the state to a person other than under the circumstances described in (t) of this section.

(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule II, III, or IV controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule II, III, or IV controlled substance under federal law other than those dispensed or administered under the circumstances described in (t) of this section, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database on at least a daily basis:

- (1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;
- (2) the date of the prescription;
- (3) the date the prescription was filled and the method of payment; this paragraph does not authorize the board to include individual credit card or other account numbers in the database;
- (4) the name, address, and date of birth of the person for whom the prescription was written;
- (5) the name and national drug code of the controlled substance;
- (6) the quantity and strength of the controlled substance dispensed;
- (7) the name of the drug outlet dispensing the controlled substance; and
- (8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

(c) The board shall maintain the database in an electronic file or by other means established by the board to facilitate use of the database for identification of

- (1) prescribing practices and patterns of prescribing and dispensing controlled substances;
- (2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;

APPENDIX A

(Continued)

- (3) individuals who receive prescriptions for controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance; and
 - (4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.
- (d) The database and the information contained within the database are confidential, are not public records, are not subject to public disclosure, and may not be shared with the federal government. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. The board may allow access to the database only to the following persons, and in accordance with the limitations provided and regulations of the board:
- (1) personnel of the board regarding inquiries concerning licensees or registrants of the board or personnel of another board or agency concerning a practitioner under a search warrant, subpoena, or order issued by an administrative law judge or a court;
 - (2) authorized board personnel or contractors as required for operational and review purposes;
 - (3) a licensed practitioner having authority to prescribe controlled substances or an agent or employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance; the agent or employee must be licensed or registered under AS 08;
 - (4) a licensed or registered pharmacist having authority to dispense controlled substances or an agent or employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance; the agent or employee must be licensed or registered under AS 08;
 - (5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant

APPENDIX A

(Continued)

or order issued by a court establishing probable cause for the access and use of the information;

(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed \$10;

(7) a licensed pharmacist employed by the Department of Health and Social Services who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;

(8) a licensed pharmacist, licensed practitioner, or authorized employee of the Department of Health and Social Services responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the information relates specifically to utilization review of prescription drugs provided to recipients of medical assistance;

(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death;

(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not disclose the identity of a patient, prescriber, dispenser, or dispenser location, for the purpose of identifying and monitoring public health issues in the state; however, the information provided under this paragraph may include the region of the state in which a patient, prescriber, and dispenser are located and the specialty of the prescriber; and

(11) a practitioner, pharmacist, or clinical staff employed by an Alaska tribal health organization, including commissioned corps officers of the United States Public Health Service employed under a memorandum of agreement; in this paragraph, "Alaska tribal health organization" has the meaning given to "tribal health program" in 25 U.S.C. 1603.

(e) The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of

APPENDIX A

(Continued)

the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner's licensing board to take disciplinary action against the practitioner.

(f) The board may enter into agreements with (1) dispensers in this state that are not regulated by the state to submit information to and access information in the database, and (2) practitioners in this state to access information in the database, subject to this section and the regulations of the board. The board shall prohibit a dispenser that is not regulated by the state from accessing the database if the dispenser has accessed information in the database contrary to the limitations of this section, discloses information in the database contrary to the limitations of this section, or allows unauthorized persons access to the database.

(g) The board shall promptly notify the president of the senate and the speaker of the house of representatives if, at any time after September 7, 2008, the federal government fails to pay all or part of the costs of the controlled substance prescription database.

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

(i) A person who has reason to believe that prescription information from the database has been illegally or improperly accessed shall notify an appropriate law enforcement agency.

(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.

(k) In the regulations adopted under this section, the board shall provide

- (1) that prescription information in the database shall be purged from the database after two years have elapsed from the date the prescription was dispensed;
- (2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;
- (3) a procedure and time frame for registration with the database;
- (4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or

APPENDIX A

(Continued)

administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering

(A) a controlled substance to a person who is receiving treatment

(i) in an inpatient setting;

(ii) at the scene of an emergency or in an ambulance; in this subparagraph, "ambulance" has the meaning given in AS 18.08.200;

(iii) in an emergency room;

(iv) immediately before, during, or within the first 48 hours after surgery or a medical procedure;

(v) in a hospice or nursing home that has an in-house pharmacy; or

(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.

(l) A person

(1) with authority to access the database under (d) of this section who knowingly

(A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;

(B) accesses information in the database and recklessly discloses that information to a person not entitled to access or to receive the information commits a class C felony;

(C) allows another person who is not authorized to access the database to access the database commits a class C felony;

(2) without authority to access the database under (d) of this section who knowingly accesses the database or knowingly receives information that the person is not authorized to receive under (d) of this section from another person commits a class C felony.

(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures

(1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to

(A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;

APPENDIX A

(Continued)

- (B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;
- (C) increase coordination among prescription drug monitoring program partners;
- (D) involve stakeholders in the planning process;
- (2) shall include information related to the
 - (A) security of the database; and
 - (B) reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the database.
- (n) A pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law shall register with the database by a procedure and in a format established by the board.
- (o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (n) of this section.
- (p) The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice. An unsolicited notification to a practitioner's licensing board under this section
 - (1) must be provided to the practitioner;
 - (2) is confidential;
 - (3) may not disclose information that is confidential under this section;
 - (4) may be in a summary form sufficient to provide notice of the basis for the unsolicited notification.
- (q) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.
- (r) The Department of Commerce, Community, and Economic Development shall
 - (1) assist the board and provide necessary staff and equipment to implement this section; and
 - (2) establish fees for registration with the database by a pharmacist or practitioner required to register under (n) of this section so that the total amount of fees collected by the department equals the total operational

APPENDIX A

(Continued)

costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall

- (A) set the fees for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and
- (B) consult with the board to establish the fees under this paragraph.

(s) Notwithstanding (p) of this section, the board may issue to a practitioner periodic unsolicited reports that detail and compare the practitioner's opioid prescribing practice with other practitioners of the same occupation and similar specialty. A report issued under this subsection is confidential and the board shall issue the report only to a practitioner. The board may adopt regulations to implement this subsection. The regulations may address the types of controlled substances to be included in an unsolicited report, the quantities dispensed, the medication strength, and other factors determined by the board.

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if a controlled substance is

- (1) administered to a patient at
 - (A) a health care facility; or
 - (B) a correctional facility;
- (2) dispensed to a patient for an outpatient supply of 24 hours or less at a hospital
 - (A) inpatient pharmacy; or
 - (B) emergency department.

(u) In this section,

- (1) "board" means the Board of Pharmacy;
- (2) "database" means the controlled substance prescription database established in this section;
- (3) "knowingly" has the meaning given in AS 11.81.900;
- (4) "opioid" includes the opium and opiate substances and opium and opiate derivatives listed in AS 11.71.140 and 11.71.160;
- (5) "pharmacist-in-charge" has the meaning given in AS 08.80.480.

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APPENDIX B

Analysis of Public Need Criteria AS 44.66.050(c)

A determination as to whether a board or commission has demonstrated a public need for its continued existence must take into consideration the following factors:

1. the extent to which the board or commission has operated in the public interest;
2. the extent to which the operation of the board or commission has been impeded or enhanced by existing statutes, procedures, and practices that it has adopted, and any other matter, including budgetary, resource, and personnel matters;
3. the extent to which the board or commission has recommended statutory changes that are generally of benefit to the public interest;
4. the extent to which the board or commission has encouraged interested persons to report to it concerning the effect of its regulations and decisions on the effectiveness of service, economy of service, and availability of service that it has provided;
5. the extent to which the board or commission has encouraged public participation in the making of its regulations and decisions;
6. the efficiency with which public inquiries or complaints regarding the activities of the board or commission filed with it, with the department to which a board or commission is administratively assigned, or with the office of victims' rights or the office of the ombudsman have been processed and resolved;
7. the extent to which a board or commission that regulates entry into an occupation or profession has presented qualified applicants to serve the public;

APPENDIX B (Continued)

8. the extent to which state personnel practices, including affirmative action requirements, have been complied with by the board or commission to its own activities and the area of activity or interest;
9. the extent to which statutory, regulatory, budgetary, or other changes are necessary to enable the board or commission to better serve the interests of the public and to comply with the factors enumerated in this subsection;
10. the extent to which the board or commission has effectively attained its objectives and purposes and the efficiency with which the board or commission has operated; and
11. the extent to which the board or commission duplicates the activities of another governmental agency or the private sector.

Agency Response from the Department of Commerce, Community, and Economic Development



THE STATE
of **ALASKA**
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

OFFICE OF THE COMMISSIONER
Anchorage Office

550 West Seventh Avenue, Suite 1535
Anchorage, Alaska 99501
Main: 907.269.8100
Fax: 907.269.8125

RECEIVED

JAN 05 2022

LEGISLATIVE AUDIT

January 5, 2022

Kris Curtis
Division of Legislative Audit
P.O. Box 113300
Juneau, AK 99811

RE: Preliminary Audit Report, Department of Commerce, Community, and Economic Development,
Board of Pharmacy Sunset Review

Dear Ms. Curtis:

Thank you for the opportunity to comment on the Preliminary Audit Report regarding the Board of Pharmacy (board). The department concurs with the conclusions that the board is generally operating in the public interest in accordance with statutes and regulations and has the following comments on the report:

Report Conclusions

Conclusion 1: The board conducted its meetings effectively and did not duplicate the efforts of another entity.

The department agrees with this conclusion.

Conclusion 2: Investigations were conducted in a timely manner.

The department agrees with this conclusion.

Conclusion 3: Licenses were not consistently issued in compliance with state law.

The department agrees with this conclusion. The executive administrator of the Board of Pharmacy will continue to provide training and oversight of professional licensing staff to improve consistency. The board has recently proposed changes to regulations in applicant requirements that will provide clarity and increase compliance.

Conclusion 4: Board fees covered the cost of operations.

The department agrees with this conclusion.

Conclusion 5: The board actively amended regulations.

Since this conclusion is directed toward board governance, the department does not have a response.

Conclusion 6: Changes to statutes and regulations improved CSPD's capabilities.

Since this conclusion is directed toward board governance, the department does not have a response.

Conclusion 7: Occupational boards were slow to implement CSPD enhancements.

The division has made significant improvements in establishing administrative and investigative priorities for the Prescription Drug Monitoring Program (which includes the CSPD), which has already improved the allocation of resources. The entry of DEA information into the database across six licensing programs has been consistent in recent years and, with the addition of administrative help for the program, now features a quality assurance check. The division continues to work with the database contractor to provide enhancements within the funding of the program grant.

The department does not have a response to the board governance elements of this conclusion.

Conclusion 8: CSPD notifications were sent to pharmacists, practitioners and licensing boards.

Since this conclusion is directed toward board governance, the department does not have a response. See recommendation #3

Conclusion 9: Occupational boards recognized the need to coordinate and standardize.

Division staff has improved coordination of processes across the programs that use CSPD/PDMP by holding regularly scheduled meetings, discussing procedures and any changes for capturing and analyzing data. This coordination extends to regularly scheduled meetings of PDMP board chairs.

The department does not have a response to the board governance elements of this conclusion.

Conclusion 10: The board was unable to report certain performance measures.

Since this conclusion is directed toward board governance, the department does not have a response.

Report Recommendations

Recommendation No.1:

The board chair and the division director should improve procedures and training to ensure applicants meet requirements prior to license issuance.

The department agrees that continuous improvement in procedures and training by the division will improve licensure requirements. This summer, the division director implemented division-wide monthly training for all professional licensing staff. The executive administrator for the Board of Pharmacy has implemented additional procedures for checking the correctness of file documentation. Adding a licensing examiner position has also reduced the per-person processing volume, which will reduce the error rate.

Recommendation No. 2:

The board should adopt regulations for outsourcing facilities and third-party logistic provider licensure renewal.

Since this recommendation is directed to the board, the department has no response on their behalf.

Recommendation No. 3:

Applicable occupational boards and the DCBPL director should continue coordination efforts to improve the monitoring and enforcement of CSPD requirements.

The department agrees with this recommendation, and the division has implemented processes for improving CSPD/PDMP coordination between licensing and enforcement efforts. Investigator and professional licensing staff training, new priority policies, and clarified investigative procedures have already improved outcomes.

The division is currently facilitating regularly scheduled meetings with the chairs of the boards that are required to register for the CSPD/PDMP. This is an ongoing effort to better communicate the need for board involvement in monitoring their program's requirements as it pertains to CSPD/PDMP, such as setting guidelines for safe standards of practice and disciplinary matrices. Quarterly reports are also provided by the

CSPD/PDMP coordinator to each of the applicable licensing boards for a review of usage of the CSPD by their licensees.

The department disagrees that licensing program staff should provide referral information to investigators: Per statute, they do not have access to licensee compliance reporting or user activity. These duties are currently appropriately assigned to the CSPD/PDMP coordinator or the executive administrator for the Board of Pharmacy.

Recommendation No. 4:

The DCCED commissioner should allocate sufficient resources to ensure licensees holding a DEA registration number are consistently recorded in DCBPL's licensing database.

The department has approved two additional grant-funded positions to support the administrative duties of this program. Training for professional licensing staff continues to be a priority, and it is resulting in consistency in entry of DEA information. The division expects to launch a more streamlined method of CSPD/PDMP entry into the system. The director anticipates implementing a license integration enhancement in early 2022, which will automate certain steps for the applicant and for staff.

Recommendation No. 5:

The DCCED commissioner should allocate sufficient resources to ensure CSPD requirements are effectively enforced.

The department approved a new investigator position specifically assigned to oversee enforcement of CSPD/PDMP matters. This assignment will contribute to a more coordinated effort in monitoring compliance and enforcement.

Again, thank you for the opportunity for the DCCED to provide input on this matter. Should you have any questions about the contents of this letter, please do not hesitate to contact me at 907-269-8125.

Sincerely,



Julie Anderson
Commissioner

cc: Sara Chambers, Director, Division of Corporations, Business and Professional Licensing
Glenn Hoskinson, Legislative Liaison, DCCED

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Agency Response from the Board of Pharmacy

January 1, 2022

Kris Curtis
Legislative Auditor
Division of Legislative Audit

RECEIVED

JAN 03 2022

LEGISLATIVE AUDIT

Dear Auditor Curtis,

In regards to the report conclusions, it is my conclusion the audit process has accurately reflected the actions, intentions and limitations of the Board of Pharmacy during my time serving with the board.

In regards to the recommendations:

1.) Agree. Certain elements of the licensing process have been under review during my time serving on the board. One of those elements is a reduction of superfluous paperwork and unnecessary burdens for limited licensing staff. The moral character section is one of those elements. Although still a requirement, it is an area the board has already submitted requests to change. That does not, however, address the issues with staffing/training in general. Steps should be taken to retain and train staff in all licensing areas to ensure these processes are able to be accomplished with minimal error or items missed.

2.) This recommendation has already been accomplished at the board level. The board at its September 2021 meeting passed language changes to licensing renewal (12 AAC 52.300) to add outsourcing facility and third-party logistics providers. This has been forwarded on to the regulations specialist for processing.

3.) Agree. The board chairs continue to meet bi-weekly. This has served each board well and we continue to work towards standardizing our approach as well as discussing best approaches to utilizing the database for highest efficiency and efficacy. Since this recommendation involves boards outside of our own it is hard to determine the length of time required to fully implement change in this area.

4 & 5.) Agree. Resources continue to be a challenge across the division. One of the areas that is felt most keenly is in the management of the Controlled Drug Database. Currently there is one person who manages the database. By contrast, many states employ or create an entire department dedicated to their controlled drug database. It is certainly a great tool but having access to the data is only half the battle. Being able to use the data consistently to identify issues, promote better prescribing practices, and investigate those who are falling outside the established guidelines takes people and processes. Both of these are in short supply. The board of pharmacy will continue to promote use of the CSPD across our licensees as well as continue to request resources be dedicated to this important tool to combat opiate use in our state.

Finally, the conclusions and recommendations you have put forth are an accurate reflection of the current state of the Board. I fully support the request to extend to June 30th, 2028.

Sincerely



Justin Ruffridge PharmD

Chair, Board of Pharmacy

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Legislative Auditor's Additional Comments

ALASKA STATE LEGISLATURE LEGISLATIVE BUDGET AND AUDIT COMMITTEE Division of Legislative Audit



P.O. Box 113300
Juneau, AK 99811-3300
(907) 465-3830
FAX (907) 465-2347
legaudit@akleg.gov

January 6, 2022

Members of the Legislative Budget
and Audit Committee:

I have reviewed the responses to the Board of Pharmacy audit report. Nothing contained in the responses causes me to revise or reconsider the report conclusions or recommendations. However, I offer the following rebuttal to a statement made by the commissioner of the Department of Commerce, Community, and Economic Development (DCCED) in response to Recommendation No. 3:

The department disagrees that licensing program staff should provide referral information to investigators: Per statute, they do not have access to licensee compliance reporting or user activity. These duties are currently appropriately assigned to the [controlled substance prescription database (CSPD)]/[Prescription Drug Monitoring Program (PDMP)] coordinator or the executive administrator for the Board of Pharmacy.

During fieldwork, auditors were told by DCCED staff that referrals to investigations regarding the CSPD should be made by the respective licensing boards as it was the boards' responsibility to enforce compliance with the database requirements. DCCED's investigations unit *draft* standard operating procedures for database related referrals states, "Once it is determined that further investigation is necessary, the [respective board's] executive administrator or licensing supervisor will refer the alleged PDMP violation to the Investigations Unit via email to the Chief Investigator and the Senior Investigator." Regardless, effective communication between license staff and the CSPD/PDMP coordinator is essential to ensure the appropriate information is obtained that would enable licensing staff to evaluate compliance. We reaffirm the recommendation and encourage the commissioner to take action to ensure procedures are in place to allow for effective referrals to the Division of Corporations, Business and Professional Licensing investigative section for noncompliance.

Additionally, I acknowledge that Recommendation No. 4 on page 29 of the report failed to identify criteria to support the finding. The finding should have included a reference to AS 17.30.200(n), which requires a pharmacist who dispenses or a practitioner who prescribes,

Members of the Legislative Budget
and Audit Committee

- 2 -

January 6, 2022

administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law to register with the database. Criteria is also codified in board specific statutes, including: Board of Pharmacy AS 08.80.030(b)(14); State Medical Board AS 08.64.101(7); Board of Nursing AS 08.68.100(a)(11); Board of Dental Examiners AS 08.36.070(a)(10); Board of Examiners of Optometry AS 08.72.060(c)(3); and Board of Veterinary Examiners AS 08.98.050(a)(10).

Sincerely,



Kris Curtis, CPA, CISA
Legislative Auditor