

**HB**

**323**

<TARGET><BILL>HB 323</BILL><SUBJECT>HB  
323</SUBJECT><COMM>HL&C30</COMM></TARGET>

# REPRESENTATIVE COLLEEN SULLIVAN-LEONARD

ALASKA STATE LEGISLATURE HOUSE DISTRICT 7

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**TO:** Representative Sam Kito/Labor & Commerce Committee

**FROM:** Representative Colleen Sullivan-Leonard

**DATE:** February 2, 2018

**RE:** Hearing Request – HB 323 “An Act extending the termination date of the Board of Pharmacy; and providing for an effective date.”


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I respectfully request that HB323 be scheduled at your earliest possible convenience.

Pursuant to A.S. §08.03.010(c)(16), this Board is scheduled to sunset on June 30th, 2018. HB323 seeks to extend the termination date for the Board of Pharmacy from June 20, 2018 to June 30, 2022.

I ask for your support of this legislation. Please contact my staff, Angela Stephl, if you have any questions.

Sincerely,

  
Representative Colleen Sullivan-Leonard

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## Sponsor Statement

### **HB 323: "An Act extending the termination date of the Board of Pharmacy; and providing for an effective date."**

House Bill 323 extends the termination date for the Board of Pharmacy to June 30, 2022. Pursuant to A.S. §08.03.010(c)(16), this Board is scheduled to sunset on June 30th, 2018 if the legislature does not pass legislation extending it.

Legislative Audit reviewed the Board's operations and determined that it is in the best interest of the state to extend this Board considering recent statutory changes that expand the Board's responsibilities in relation to the controlled substance prescription database. Therefore, recommendation is made to extend this Board for 4 years or through June 30, 2022.

The Board of Pharmacy is composed of 7 members; 5 licensed pharmacists actively engaged in the practice of pharmacy in the State for a period of 3 years immediately preceding their appointments and 2 members of the public.

The Board also regulates admission into the practice of pharmacy, establishes and enforces compliance with professional standards and adopts regulations. It also establishes and maintains a controlled substance prescription database, and establishes standards for the independent administration by a pharmacist of vaccines, related emergency medications and opioid overdose drugs.

The Board also oversees licensing for pharmacists, pharmacy interns, pharmacy technicians, pharmacies, wholesale drug distributors located inside the state, licenses drug rooms located inside institutional facilities and also registers pharmacies located outside of the State if a pharmacy ships, mails or delivers prescription drugs to consumers of that state.

These regulations control various aspects of the field, including but not limited to controlling and regulating the practice of pharmacy in Alaska. A.S. §08.80.005 mandates that effective control and regulation is necessary to promote, preserve and protect the public's health, safety and welfare.

Thank you for your support of this litigation.

# REPRESENTATIVE COLLEEN SULLIVAN-LEONARD

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## SECTIONAL ANALYSIS

**HB323** – “An Act extending the termination date of the Board of Pharmacy; and providing for an effective date.”

\* \* \* \* \*

Please note that a sectional summary of a bill should not be considered an authoritative interpretation of the bill and the bill itself is the best statement of its contents.

**Bill Sec. 1.** Amends A.S. §08.03.010( c)(16) to extend the duration of the Board of Pharmacy from June 30 2018 to June 30, 2022.

**Bill Sec. 2.** Puts forth an immediate effective date pursuant to AS §01.10.070( c).

# Report Highlights

## Why DLA Performed This Audit

The purpose of the audit was to determine if there is a need for the board's continued existence and whether its termination date should be extended. The board is set to sunset June 30, 2018, and will have one year from that date to conclude its administrative operations.

## What DLA Recommends

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

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

August 7, 2017

Audit Control Number 08-20104-17

## REPORT CONCLUSIONS

The audit concluded the board operated in the public interest by effectively licensing pharmacists, pharmacy interns, pharmacy technicians, in-state pharmacies, drug rooms, and wholesale distributors. Board meetings were conducted in accordance with applicable laws and the board was active in amending regulations to improve the industry.

In accordance with AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2018. In recognition of recent statutory changes that expands the board's responsibilities in relation to the controlled substance prescription database, we recommend that the legislature extend the board's termination only four years to June 30, 2022.

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# 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 27, 2017

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

August 7, 2017

Audit Control Number  
08-20104-17

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, 2018. We recommend that the legislature extend the board's termination date to June 30, 2022.

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

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AAC	Alaska Administrative Code
ACN	Audit Control Number
AS	Alaska Statute
board	Board of Pharmacy
CISA	Certified Information Systems Auditor
CPA	Certified Public Accountant
DCBPL	Division of Corporations, Business, and Professional Licensing
DCCED	Department of Commerce, Community, and Economic Development
DHSS	Department of Health and Social Services
DLA	Division of Legislative Audit
DPS	Department of Public Safety
FY	Fiscal Year
RSA	Reimbursable Service Agreement
SB	Senate Bill

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# ORGANIZATION AND FUNCTION

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## Board of Pharmacy

The Board of Pharmacy (board) was established for the purpose of controlling and regulating the practice of pharmacy in Alaska. Alaska Statute 08.80.005 states that 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 their appointment. The remaining two positions are to be filled by individuals from the general public. Statute prohibits public members from having a direct financial interest in the health care industry.

In general, 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, and establish standards for the independent administration by a pharmacist of vaccines, related emergency medications, and opioid overdose drugs.

The board licenses pharmacists, pharmacy interns, and pharmacy technicians. The board also licenses pharmacies and wholesale drug distributors located inside the state. Additionally, licenses are issued for drug rooms located within an institutional facility.

## Exhibit 1

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### Board of Pharmacy Members as of March 31, 2017

Leif Holm, Chair  
*Licensed Pharmacist*

Lana Bell  
*Licensed Pharmacist*

Anne Gruening  
*Public Member*

James Henderson  
*Licensed Pharmacist*

Richard Holt  
*Licensed Pharmacist*

Phil Sanders  
*Licensed Pharmacist*

Vacant  
*Public Member*

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

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

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. The division 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.

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

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# BACKGROUND INFORMATION

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## Controlled Substance Prescription Database

Senate Bill 196,<sup>1</sup> passed in 2008, requires the Board of Pharmacy (board) to establish and maintain a controlled substance prescription database as provided in AS 17.30.200. 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 database electronically collects information from in-state and out-of-state pharmacies as well as other dispensers of controlled substance prescriptions. The database allows pharmacists and practitioners to review prescription history prior to prescribing or dispensing a controlled substance. The database is also to be used to:

- monitor prescribing practices and patterns of prescribing or dispensing;
- identify practitioners who prescribe controlled substances in an unprofessional or unlawful manner;
- identify individuals who may be abusing controlled substances; and
- identify individuals who present forgeries or otherwise false or altered prescriptions to a pharmacy.

Per statute, the Department of Commerce, Community, and Economic Development (DCCED) shall assist the board and provide the necessary staff and equipment to implement the database. However, no State funding for the database or staff positions was authorized as part of the original bill.

To implement and manage the database, DCCED Division of Corporations, Business, and Professional Licensing (DCBPL) management expanded the duties of the board's primary

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<sup>1</sup>Alaska Statute 08.80.030(11).

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**Various challenges limited the effectiveness of the controlled substance prescription database.**

investigator. Federal funds were used to procure the database software. Procuring and implementing the database took over two years from the time the federal grant was awarded in July 2009. Exhibit 2 on page 6 provides a timeline of database activities and funding from April 2008 through June 2017. Appendix A reports whether the database statutes in effect as of March 31, 2017, have been implemented.

After implementation of the original legislation, it became apparent that important authority was omitted from the original 2008 law which prevented the database from meeting its intent. Deficiencies included:

- **Completeness of Information** – The law did not provide the ability to identify all dispensers that must submit information. Consequently, DCBPL staff claimed they could not monitor completeness or identify which specific dispensers were not submitting the required information. Regulations required monthly reporting of information; however, monthly reporting was not effective for monitoring prescription practices.
- **Use of Information** – There was no requirement that a dispenser or practitioner check the database prior to dispensing, prescribing, or administering medication. Further, according to DCBPL staff, information in the database was not analyzed by the board and forwarded to practitioners or pharmacists because the Department of Law advised that the law did not allow the agency or board to provide unsolicited reports.

As abuse of prescription drugs escalated, legislation was passed to improve the effectiveness of the database and address some of the deficiencies listed above. Appendix B summarizes recent legislation. Most of the significant changes listed below were effective July 2017 or July 2018:

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- **Completeness of Information** – Pharmacists who dispense and practitioners who prescribe, administer, or dispense controlled substances are required to register with the database.<sup>2</sup> Additionally, the board must notify the applicable occupational boards when practitioners register with the database, thereby allowing a check for completeness and the ability to identify noncompliance. Failure to register is grounds for disciplinary action. Dispensers were required to report weekly and this requirement was subsequently changed to report daily.
  - **Use of Information** – Access to the database was expanded to include dispensers, dispenser delegates, and other persons or entities with a valid business need. The board was authorized to provide unsolicited notification 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. Unsolicited reports may also be issued to a practitioner’s licensing board. Further, new performance measures must be reported to the legislature annually including measures regarding the impact of the database. Dispensers and practitioners are now required to check the database prior to dispensing, prescribing, or administering medication, with specific exclusions.<sup>3</sup>

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<sup>2</sup>It should be noted that tribal health consortiums and federal military health care facilities are not subject to the state law that requires submission into the controlled substance prescription database. This will limit the database’s effectiveness at identifying misuse, abuse, and diversion of controlled substances within these demographic centers.

<sup>3</sup>Alaska Statute 17.30.200(u) excludes practitioners or pharmacists that prescribe or dispense controlled substances to a patient at a health care facility or correctional facility. Also excluded are controlled substances dispensed to a patient for an outpatient supply of 24 hours or less at a hospital inpatient pharmacy or emergency department.

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**Exhibit 2****Controlled Substance Prescription Database Timeline  
April 2008 through June 2017**

- April 2008** Senate Bill 196 required the board to establish the controlled substance prescription database.
- October 2008** Federal grant received for \$49,400 to assist with implementation plans.
- January 2009** As required by statute, the board notified the legislature that initial federal funds were depleted.
- July 2009** State was awarded approximately \$400,000 in federal funds to implement the controlled substance prescription database including training and outreach.
- August 2010** DCCED entered into a contract to provide electronic data collection of controlled substance prescription information from dispensers, provide database management, and provide secure web services.
- December 2011** Regulations for the database became effective. Regulations require dispensers to report monthly.
- January 2012** Database goes live.
- February 2013** As required by statute, the board notified the legislature that federal funds were ending.
- August 2013** DCCED entered into a Reimbursable Service Agreement (RSA) with Department of Health and Social Services (DHSS) for \$85,000 in federal funds for continued database oversight and management.
- October 2014** DCCED and DHSS entered into another RSA for \$85,000 in continued federal funding for database oversight and management.
- January 2016** Database transitioned to a new vendor.
- February 2016** DCCED and DHSS entered into an RSA for \$125,000 in continued federal funds for database oversight and management.
- April 2016** Senate Bill 74 amended statutory requirements for required registration, weekly reporting, expanded access to the database information, and mandated additional performance measures. New statutes were added to include additional registration requirements, unsolicited reports, and registration fees. Funding for a dedicated position was included in the bill. Most amendments and additions were effective July 2017.
- February 2017** DCCED entered into an RSA with DHSS for \$125,000 in federal funds for database oversight and management.
- March 2017** DCCED entered into an RSA with DHSS for \$42,000 in federal funds for outreach and education to all authorized users.
- June 2017** House Bill 159 required daily reporting with specific exclusions (effective July 2018).

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Source: DCCED, DCBPL, and legislative documents.

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# REPORT CONCLUSIONS

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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 as Appendix C of this report. Under the State's "sunset" law, these factors are to be considered in assessing whether an entity has demonstrated a public policy need for continuing operations.

The audit concluded the board operated in the public interest by effectively licensing pharmacists, pharmacy interns, pharmacy technicians, in-state pharmacies, drug rooms, and wholesale distributors. Board meetings were conducted in accordance with applicable laws, and the board was active in amending regulations to improve the industry.

In accordance with AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2018. In recognition of recent statutory changes that expands the board's responsibilities in relation to the controlled substance prescription database, we recommend that the legislature extend the board's termination four years to June 30, 2022.

Detailed report conclusions are as follows.

**The board operated in the public interest and does not duplicate the efforts of other entities.**

Board meetings held from FY 15 through March 2017 were conducted in an effective manner. The audit found that the board held 16 meetings. This exceeded the minimum number required by statute; however, the board's workload supported the number held. Board meetings were public noticed timely, each meeting allowed time for public comment, and a quorum was consistently met. The audit also determined that the board does not duplicate the efforts of another governmental or private sector agency.

A review of board investigative activity identified that 71 cases were open or opened between July 2014 and March 2017. All but 10 cases were closed during the audit period. The audit found

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20 of the cases were open for over 180 days. Testing of a judgmental sample of 13 cases open for over 180 days found six cases had unjustified periods of inactivity ranging from 51 to 184 days. (Recommendation 1)

The audit found the board actively issued and amended regulations to serve the public's interest. Specifically, the board revised two regulations to help increase entry into the occupation by eliminating restrictive licensing requirements. Furthermore, the board issued regulations to implement SB 71 passed in 2015, and SB 23 passed in 2016. New regulations established standards for the independent administration of vaccines and related emergency medication as well as the independent dispensing of opioid overdose drugs.

**The board licensed individuals and facilities according to statutes and regulations; however, improvements are needed.**

Except for the errors noted below, the audit found the board operated in the public's interest by licensing pharmacists, pharmacy interns, pharmacy technicians, in-state pharmacies, drug rooms, and wholesale distributors in accordance with state laws and regulations. The board also registered out-of-state pharmacies that ship, mail, or deliver prescription drugs to individual patients in the state in accordance with state laws and regulations.

A random sample of 25 individual<sup>4</sup> and 25 facility licenses issued during the audit period were tested, and all but four were found to be issued in accordance with statutes and regulations. Documentation was not retained to support the educational requirement for one of 25 (4 percent) individual licenses reviewed. Three of 25 (12 percent) facility licenses reviewed were also missing supporting documentation. One facility licensee did not submit a required self-inspection report. One licensee did not have the required background report. One licensee reported a "yes" answer to a professional fitness question,<sup>5</sup> but no follow up was conducted by Division of Corporations, Business, and Professional Licensing (DCBPL) licensing staff to request the explanatory information necessary to verify qualifications. These

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<sup>4</sup>Individual license types include: pharmacists, pharmacy interns, and pharmacy technicians.

<sup>5</sup>The licensee reported a citation was issued against their out-of-state professional license.

errors indicate improvements are needed in processing and retaining applications. (Recommendation 2)

As shown in Exhibit 3, from FY 13 through FY 16, the board issued 3,405 new licenses. As of March 31, 2017, there were a total of 3,747 licensees, representing a 33 percent increase when compared to the 2009 sunset audit.<sup>6</sup>

**Exhibit 3**

Board of Pharmacy Licensing and Registration Activity FY 13 through March 31, 2017					
	New Issued (Exclusive of Renewals)				Total Active as of March 31, 2017
	FY 13	FY 14	FY 15	FY 16	
<b>Individual Licenses:</b>					
Pharmacist	67	68	100	69	1,057
Pharmacy Intern	179	199	200	203	471
Pharmacy Technician	412	353	500	410	1,443
<b>Facility Licenses:</b>					
Pharmacy (In-State)	7	12	9	23	138
Registered Out-of-State Pharmacy	109	161	166	136	573
Drug Room	4	3	3	4	40
Wholesale Drug Distributer	4	-	1	3	25
<b>Totals</b>	<u>782</u>	<u>796</u>	<u>979</u>	<u>848</u>	<u>3,747</u>

Source: Compiled from DCBPL licensing database.

<sup>6</sup>The number of total licenses reported in the 2009 sunset audit (ACN 08-20065-10) was 2,807.

**Exhibit 4**

**Board of Pharmacy  
Schedule of Revenues and Expenditures  
FY 13 through FY 17  
(Unaudited)**

	FY 13	FY 14	FY 15	FY 16	FY 17
<b>Revenues</b>					
Licensing Revenue	\$159,341	\$673,100	\$269,646	\$802,230	\$208,755
Other Sources	-	1,701	-	-	3,256
<b>Total Revenues</b>	<u>159,341</u>	<u>674,801</u>	<u>269,646</u>	<u>802,230</u>	<u>212,011</u>
<b>Direct Expenditures</b>					
Personal Services	158,574	182,280	164,266	225,050	215,674
Travel	18,850	24,054	24,548	16,676	11,119
Services	11,798	24,633	9,149	14,812	41,331
Commodities	365	69	90	111	519
<b>Total Direct Expenditures</b>	<u>189,587</u>	<u>231,036</u>	<u>198,053</u>	<u>256,649</u>	<u>268,643</u>
<b>Indirect Expenditures</b>	<u>228,785</u>	<u>197,912</u>	<u>145,863</u>	<u>192,296</u>	<u>222,916</u>
<b>Total Expenses</b>	<u>418,372</u>	<u>428,948</u>	<u>343,916</u>	<u>448,945</u>	<u>491,559</u>
<b>Annual Surplus (Deficit)</b>	<u>(259,031)</u>	<u>245,853</u>	<u>(74,270)</u>	<u>353,285</u>	<u>(279,548)</u>
<b>Beginning Cumulative Surplus (Deficit)</b>	288,927	29,896	275,749	201,479	554,764
<b>Ending Cumulative Surplus (Deficit)</b>	<u>\$29,896</u>	<u>\$275,749</u>	<u>\$201,479</u>	<u>\$554,764</u>	<u>\$275,216</u>

Source: DCCED management.

**DCBPL management, in consultation with the board, adjusted fees to cover the cost of board 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 4, the board had a surplus of \$275,216 at the end of FY 17.

The board’s 2009 sunset audit identified a growing surplus and recommended that DCBPL management consider reducing fees. Licensing fees were reduced in 2010 and the surplus declined to \$29,896 in FY 13. DCBPL management increased fees for the FY 14 through FY 17 licensing periods to cover anticipated costs. Exhibit 5 presents a schedule of fees from FY 13 through March 31, 2017. According to DCBPL management, a fee analysis is scheduled for the end of 2017.

**Exhibit 5**

Board of Pharmacy License and Registration Fees FY 13 through March 31, 2017					
Fee Type	FY 13	FY 14	FY 15	FY 16	July 1, 2016 - March 31, 2017
Application fee for initial license	\$50	\$60	\$60	\$60	\$60
Pharmacist	200	240	240	240	240
Pharmacy intern	25	30	30	30	30
Pharmacy technician	50	60	60	60	60
Temporary pharmacist	50	60	60	60	60
Pharmacy	200	240	240	240	240
Registered pharmacy located outside of the state	500	600	600	600	600
Remote pharmacy	200	240	240	240	240
Drug room	200	240	240	240	240
Wholesale drug distributor	300	500	500	500	500
Emergency permit to practice pharmacy	90	110	110	110	110

Source: DCBPL Regulations.

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**Recent statutory changes empower the board to help combat the abuse of controlled substances.**

As discussed in this audit's Background Information section, the original 2008 controlled substance prescription database legislation omitted certain authority, which limited the database's effectiveness. The database effectiveness also suffered from a lack of funding.

Statutory changes effective 2017 and 2018 should improve the database. Furthermore, funding for one position was provided in FY 18. With these changes, the board now has the ability to monitor the completeness of information; information must be submitted daily, and the board is authorized to provide unsolicited reports of prescribing habits and notifications of abuse and possible diversion.

As the statutes were only recently changed, the audit was unable to evaluate the degree the board utilized its new authority to analyze controlled substance prescription information to identify potential abuse. According to DCBPL management, the board's role is to provide a database that contains prescription data not to proactively analyze the data to meet public health objectives. Department of Commerce, Community, and Economic Development management indicated that additional resources are needed if the legislature intends for the board to analyze data and become proactive in helping enforce prescription drug laws.

Given the opioid abuse crisis facing Alaska and legislative intent to help combat drug abuse through the administration and analysis of the controlled substance prescription database, the board's duties are expected to significantly change in the future. As such, a shorter term of extension is warranted to evaluate the degree to which the board is operating in the public's interest in its administration of the prescription drug database.

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## FINDINGS AND RECOMMENDATIONS

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The prior 2009 sunset audit made three recommendations:

- The Board of Pharmacy (board) should approve collaborative protocols<sup>7</sup> in accordance with regulation.
- Department of Commerce, Community, and Economic Development's professional licensing administrative officer should improve administrative support.
- The Board of Pharmacy and staff within the Officer of the Governor should work together to increase the pool of qualified applicants available for board appointments to ensure full representation.

The prior audit recommendation to improve the collaborative protocols has been addressed. Division of Corporations, Business, and Professional Licensing (DCBPL) management implemented a checklist to ensure collaborative protocols complied with regulations. Additionally, legislation effective August 2015 allows pharmacists to independently administer vaccines without collaborative protocols.

The prior audit recommendation to improve administrative support reported problems with accurate reporting of licensing statistics in annual reports, public noticing board meetings, and accounting of expenditures. These specific prior deficiencies have been addressed by implementing checklists and changing administrative staff. Testing showed meetings were public noticed timely during the audit period.

The prior recommendation concerning board appointments has been addressed, as there were no significant board vacancies during the audit period.

Two new recommendations were made as part of this audit.

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<sup>7</sup>Collaborative protocols are cooperative practice agreements in which practitioners authorize pharmacists to administer or dispense drugs in accordance with a written protocol.

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**Recommendation 1:**

**DCBPL's chief investigator should work with the director to improve the timeliness of investigations.**

The audit identified and reviewed 13 of 20 cases opened for over 180 days between July 2014 and March 2017. Six of the 13 (46 percent) cases were found to have unjustified periods of inactivity ranging from 51 to 184 days.

According to AS 08.01.050(a)(19), DCBPL is responsible for investigating and monitoring occupational licensing activity. Investigations and complaints that sit idle for extended periods may pose a risk to public safety.

According to the chief investigator, periods of inactivity were due to competing priorities, specifically oversight of the controlled substance prescription database.

We recommend DCBPL's chief investigator work with the director to improve the timeliness of investigations.

**Recommendation 2:**

**DCBPL's director should improve procedures to ensure required licensure documentation is appropriately obtained and retained.**

DCBPL administrative staff assisting the board with license applications did not ensure licensing documents were obtained, retained, or adequately tracked or monitored.

Three of 25 facility applications tested as part of the audit did not include the required regulatory documentation.

- A self-inspection report for one renewed license was missing. Regulation (12 AAC 52.300(b)(3)) requires an applicant for renewal of a pharmacy, wholesale drug distributor, or drug room license submit a completed self-inspection of the premises on a form provided by the department. According to DCBPL management, 2016 was the first year the division offered online license renewal for Board of Pharmacy licensees and tracking whether applicants submitted the required documentation was not adequately performed in all cases.

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- The background check report for one wholesale drug distributor applicant was not obtained until the auditors requested the report. Regulation (12 AAC 52.610(6)) requires wholesale drug distributor applicants to submit a completed fingerprint card of the facility manager for evaluation and a background check by the Department of Public Safety (DPS). According to DCBPL management, based on advice from the Department of Law, the division issues licenses to applicants without the results of a background check from DPS with the intent that later discovery of a disqualifying background check may result in further investigation or disciplinary action.
  - A facility reported that a citation was issued on a pharmacist's out-of-state license, yet documentation to explain the citation was not obtained by DCBPL licensing staff. Regulation (12 AAC 52.991) states:

*a licensee shall report in writing to the board any disciplinary decision or conviction of a felony or conviction of another crime that affects the applicant's or licensee's ability to practice competently and safely, issued against the licensee no later than 30 days after the date of the disciplinary decision or conviction.*

Furthermore, testing of 25 individual licenses tested found that one pharmacy intern's license application file did not include support of the educational requirement. Regulation (12 AAC 52.120(b)(3)) states a pharmacist intern license will be issued to an applicant who has:

*(A) completed the first year of a professional pharmacy curriculum in a college or pharmacy accredited by the Accreditation Council for Pharmacy Education or (B) graduated from a college or pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy.*

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According to AS 08.01.050(a)(3), (9), and (14), DCBPL is responsible for overseeing the licensing activity for the board. DCBPL management stated the errors were a result of a lack of quality control procedures due to insufficient resources. Ensuring individual applicants and facilities are qualified minimizes the risk to public safety.

We recommend DCBPL's director improve procedures to ensure required licensure documentation is appropriately obtained and retained.

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# OBJECTIVES, SCOPE, AND METHODOLOGY

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In accordance with Title 24 and 44 of the Alaska Statutes, we have reviewed the activities of the Board of Pharmacy (board) 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, 2018, and will have one year from that date to conclude its administrative operations.

## Objectives

The three central, interrelated objectives of our report are:

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

## Scope

The assessment of operations and performance of the board 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. We reviewed the board's activities from FY 15 through March 31, 2017. Financial information is presented, unaudited, from FY 13 through FY 17.

## Methodology

During the course of our audit we reviewed and evaluated the following:

- The prior sunset audit report (ACN 08-20065-10) 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 meeting minutes and annual reports 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.
  - The State's online public notice system to verify the board meetings were adequately public noticed.
  - Various State and news-related websites to identify complaints against the board or other board related concerns.
  - Expenditures, revenues, and fee levels for the board to determine whether fee levels covered the costs of operations.
  - Investigation data of the board for cases open six months or longer from FY 15 through March 31, 2017. A judgmental sample of 13 of 20 cases open for over 180 days was reviewed for unjustified periods of inactivity.
  - Eight collaborative practice applications active as of March 31, 2017, were reviewed for regulatory compliance.
  - Internal controls over the licensing database and investigative case management system were assessed to determine if controls were properly designed and implemented.
  - Website of the Alaska Pharmacy Association to evaluate possible duplication of efforts.

To identify and evaluate board activities, we conducted interviews with Division of Corporations, Business, and Professional Licensing (DCBPL) staff and board members. Specific topics of inquiry included board operations, regulations, duplication of

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effort, fee levels, and complaints against the board.

Random samples of 25 individual licenses and 25 facility licenses were selected from 2,971 and 776 licenses, respectively, that were active as of March 31, 2017. License applications were assessed for statutory and regulatory compliance. The sample size was based on low control and inherent risk and low/moderate audit risk. The sample items included initial and renewal licensees. Testing results were projected to the population.

To evaluate if the board served the public's interest in its management and oversight of the controlled substance prescription database, questionnaires were sent to all board members and DCBPL management; legislative bills, statutes, and regulations were reviewed; vendor contracts, annual reports, reimbursable service agreements, and database user guides were reviewed; observations were conducted of the information in the database; and DCBPL staff and board members were interviewed.

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## APPENDICES SUMMARY

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**Appendix A** provides the status of each statute effective as of March 31, 2017, that authorizes the implementation of the controlled substance prescription database.

**Appendix B** summarizes the changes to the controlled substance prescription database statutes.

**Appendix C** provides the sunset criteria. In developing our conclusion regarding whether the Board of Pharmacy's termination date should be extended, its operations were evaluated using the 11 factors set out in AS 44.66.050(c).

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# APPENDIX A

**Controlled Substance Prescription Database Statutes  
Implementation Status  
(Alaska Statute 17.30.200)  
Statutes Effective as of March 31, 2017**

Statute Section	Status
<p>(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 IA, IIA, IIIA, IVA, or VA controlled substance under state law or a schedule I, II, III, IV, or V controlled substance under federal law dispensed in the state to a person other than those administered to a patient at a health care facility. The Department of Commerce, Community, and Economic Development shall assist the board and provide necessary staff and equipment to implement this section.</p> <p>[Effective April 2008]</p>	<p>The board procured a database, which became operational in 2012.</p>
<p>(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule IA, IIA, IIIA, IVA, or VA controlled substance under state law or a schedule I, II, III, IV, or V 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 IA, IIA, IIIA, IVA, or VA controlled substance under state law or a schedule I, II, III, IV, or V controlled substance under federal law other than those administered to a patient at a health care facility, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database:</p> <ol style="list-style-type: none"> <li>(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;</li> <li>(2) the date of the prescription;</li> <li>(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;</li> <li>(4) the name, address, and date of birth of the person for whom the prescription was written;</li> <li>(5) the name and national drug code of the controlled substance;</li> <li>(6) the quantity and strength of the controlled substance dispensed;</li> </ol>	<p>This law did not provide a mechanism to identify all the pharmacists or practitioners subject to the database reporting requirement. The law under section (o) now requires registration with the database effective July 2017.</p> <p>The name of the controlled substance and the name of the pharmacists is not a required data field in the database. Division of Corporations, Business, and Professional Licensing (DCBPL) management reported that a decision was made to require a license number and the national drug code versus the names to help eliminate misidentification and misspellings.</p>

# APPENDIX A

## (Continued)

**Controlled Substance Prescription Database Statutes  
Implementation Status  
(Alaska Statute 17.30.200)  
Statutes Effective as of March 31, 2017**

Statute Section	Status
<p>(7) the name of the drug outlet dispensing the controlled substance; and</p> <p>(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.</p> <p>[Effective April 2008]</p>	
<p>(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</p> <ul style="list-style-type: none"> <li>(1) prescribing practices and patterns of prescribing and dispensing controlled substances;</li> <li>(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;</li> <li>(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</li> <li>(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.</li> </ul> <p>[Effective April 2008]</p>	<p>The board has maintained a database. However, the data has not been analyzed for identifying prescribing and dispensing practices and patterns. The board and DCBPL staff believed that publishing unsolicited reports was illegal. Statutory change effective July 2017 addressed this issue. However, Department of Commerce, Community, and Economic Development (DCCED) management reported that if the legislative intent is to analyze the data to meet the public health objectives as well as be proactive in prescription drug enforcement additional resources are needed.</p>
<p>(d) The database and the information contained within the database are confidential, are not public records, and are not subject to public disclosure. 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:</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(2) authorized board personnel or contractors as required for operational and review purposes;</li> </ul>	<p>DCBPL did not require the vendor obtain a third party verification of system controls of the database. DCBPL amended the vendor contract in November 2017 to include a clause requiring a third party verification of database system controls.</p>

# APPENDIX A

## (Continued)

Controlled Substance Prescription Database Statutes  
Implementation Status  
(Alaska Statute 17.30.200)  
Statutes Effective as of March 31, 2017

Statute Section	Status
<p>(3) a licensed practitioner having authority to prescribe controlled substances, 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;</p> <p>(4) a licensed or registered pharmacist having authority to dispense controlled substances, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance;</p> <p>(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant, subpoena, or order issued by a court establishing probable cause for the access and use of the information; and</p> <p>(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.</p> <p>[Effective April 2008]</p>	
<p>(e) The failure of a pharmacist-in-charge, pharmacist, or practitioner to 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 or for another licensing board to take disciplinary action against a practitioner.</p> <p>[Effective April 2008]</p>	<p>No disciplinary action taken due to lack of required registration. Effective July 2017, registration is required for all pharmacists who dispense or practitioners who prescribe, administer, or dispense.</p>
<p>(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</p>	<p>The department received a memorandum from the Department of Veterans Affairs dated May 17, 2017, authorizing transmission of Veterans Health Administration prescription drug</p>

# APPENDIX A

## (Continued)

**Controlled Substance Prescription Database Statutes  
Implementation Status  
(Alaska Statute 17.30.200)  
Statutes Effective as of March 31, 2017**

Statute Section	Status
<p>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.</p> <p>[Effective April 2008]</p>	<p>data to state's controlled substance prescription database. No other agreements have been entered into.</p> <p>It should be noted that tribal health consortiums and federal military health care facilities are not subject to the state law that requires submission into the controlled substance prescription database.</p>
<p>(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.</p> <p>[Effective April 2008]</p>	<p>The board provided notification in 2009 and 2013 to the legislature when federal grant funds were ending.</p>
<p>(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. Nothing in this section requires or obligates a dispenser or practitioner to access or check the database before dispensing, prescribing, or administering a medication, or providing medical care to a person. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.</p> <p>[Effective April 2008]</p>	<p>Department management is not aware of any litigation regarding the database.</p>
<p>(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.</p> <p>[Effective April 2008]</p>	<p>The board and DCCED management is not aware of any illegal or improper access.</p>
<p>(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.</p> <p>[Effective April 2008]</p>	<p>The board and DCCED management is not aware of any illegal or improper access.</p>

# APPENDIX A

## (Continued)

Controlled Substance Prescription Database Statutes  
Implementation Status  
(Alaska Statute 17.30.200)  
Statutes Effective as of March 31, 2017

Statute Section	Status
<p>(k) In the regulations adopted under this section, the board shall provide</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(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.</li> </ul> <p>[Effective April 2008]</p>	<p>The board established regulations for challenging information in the database; however, no regulations were established to purge data after two years from the prescription dispensed date. Per DCBPL management, database information over two years is not accessible.</p>
<p>(l) A person</p> <ul style="list-style-type: none"> <li>(1) with authority to access the database under (d) of this section who knowingly <ul style="list-style-type: none"> <li>(A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;</li> <li>(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;</li> <li>(C) allows another person who is not authorized to access the database to access the database commits a class C felony;</li> </ul> </li> <li>(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.</li> </ul> <p>[Effective April 2008]</p>	<p>The board and DCCED management is not aware of any illegal or improper access.</p>
<p>(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to</p> <ul style="list-style-type: none"> <li>(1) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;</li> </ul>	<p>The performance measure examples in the law were not reported.</p>

# APPENDIX A

## (Continued)

Controlled Substance Prescription Database Statutes  
Implementation Status  
(Alaska Statute 17.30.200)  
Statutes Effective as of March 31, 2017

Statute Section	Status
<p>(2) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;</p> <p>(3) increase coordination among prescription drug monitoring program partners; and</p> <p>(4) involve stakeholders in the planning process.</p> <p>[Effective April 2008]</p>	
<p>(s) The Department of Commerce, Community, and Economic Development shall</p> <p>(1) assist the board and provide necessary staff and equipment to implement this section; and</p> <p>(2) establish fees for registration with the database by a pharmacist or practitioner required to register under (o) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall</p> <p>(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</p> <p>(B) consult with the board to establish the fees under this paragraph.</p> <p>[Effective September 1, 2016]</p>	<p>The department, through DCBPL, provides staff and equipment to support the database. Per DCBPL management, the establishment of registration fees will be evaluated pending receipt of grant funds through a reimbursable service agreement with Department of Health and Social Services. Note that section (o) of the statute requires registration effective July 2017.</p>

# APPENDIX B

## Controlled Substance Prescription Database Statutory Changes

AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
<p>(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 IA, IIA, IIIA, IVA, or VA controlled substance under state law or a schedule I, II, III, IV, or V controlled substance under federal law dispensed in the state to a person other than those administered to a patient at a health care facility. The Department of Commerce, Community, and Economic Development shall assist the board and provide necessary staff and equipment to implement this section.</p>	<p><b>[Effective July 17, 2017]</b> (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 those administered to a patient at a health care facility.</p>	<p><b>[Effective July 17, 2017]</b> (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 (u) of this section.</p>
<p>(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule IA, IIA, IIIA, IVA, or VA controlled substance under state law or a schedule I, II, III, IV, or V 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 IA, IIA, IIIA, IVA, or VA controlled substance under state law or a schedule I, II, III, IV, or V controlled substance under federal law other than those administered to a patient at a health care facility, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database:</p> <p>(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement</p>	<p><b>[Effective July 17, 2017]</b> (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 administered to a patient at a health care facility, 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 weekly basis:</p> <p>Subsections (1) through (8) were not revised.</p>	<p><b>[Effective July 17, 2017]</b> (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 (u) 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 weekly basis:</p>

# APPENDIX B

## (Continued)

### Controlled Substance Prescription Database Statutory Changes

AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
<p>Administration registration number or other appropriate identifier;</p> <p>(2) the date of the prescription;</p> <p>(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;</p> <p>(4) the name, address, and date of birth of the person for whom the prescription was written;</p> <p>(5) the name and national drug code of the controlled substance;</p> <p>(6) the quantity and strength of the controlled substance dispensed;</p> <p>(7) the name of the drug outlet dispensing the controlled substance; and</p> <p>(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.</p>		<p>Subsections (1) through (8) were not revised.</p> <p><b>[Effective July 1, 2018]</b></p> <p>(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 (u) 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:</p> <p>Subsections (1) through (8) were not revised.</p>
<p>(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</p> <p>(1) prescribing practices and patterns of prescribing and dispensing controlled substances;</p>		

# APPENDIX B

## (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
<p>(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;</p> <p>(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</p> <p>(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.</p>		
<p>(d) The database and the information contained within the database are confidential, are not public records, and are not subject to public disclosure. 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:</p> <p>(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;</p> <p>(2) authorized board personnel or contractors as required for operational and review purposes;</p>	<p><b>[Effective July 17, 2017]</b></p> <p>(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:</p> <p>(Subsections (1) and (2) were not revised.)</p>	<p><b>[Effective July 17, 2017]</b></p> <p>Subsections (d) (1) through (4) and (6) through (11) were not revised.</p> <p>Revised subsection:</p> <p>(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant or order issued by a court establishing probable cause for the access and use of the information;</p>

# APPENDIX B

## (Continued)

### Controlled Substance Prescription Database Statutory Changes

AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
<p>(3) a licensed practitioner having authority to prescribe controlled substances, 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;</p> <p>(4) a licensed or registered pharmacist having authority to dispense controlled substances, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance;</p> <p>(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant, subpoena, or order issued by a court establishing probable cause for the access and use of the information; and</p> <p>(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.</p>	<p>(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 agency or employee must be licensed or registered under AS 08;</p> <p>(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;</p> <p>(5) state and local law enforcement authorities may receive printouts of information contained in the database under a search warrant or order issued by a court establishing probable</p>	

# APPENDIX B

## (Continued)

### Controlled Substance Prescription Database Statutory Changes

AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
	<p>cause for the access and use of the information;</p> <p>(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;</p> <p>(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;</p> <p>(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;</p>	

# APPENDIX B

## (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
	<p>(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death;</p> <p>(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 purposes 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 the patient, prescriber, and dispenser are located and specialty of the prescriber; and</p> <p>(11) a practitioner, pharmacist, or clinical staff employed by the 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.</p>	
<p>(e) The failure of a pharmacist-in-charge, pharmacist, or practitioner to 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</p>	<p><b>[Effective July 17, 2017]</b>            (e) The failure of a pharmacist-in-charge, pharmacist, or practitioner to register or submit information to the database as required under this section is grounds for the</p>	<p><b>[Effective July 17, 2017]</b>            (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</p>

# APPENDIX B (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
pharmacy or pharmacist or for another licensing board to take disciplinary action against a practitioner.	board to take disciplinary action against the license or registration of the pharmacy or pharmacist or for another licensing board to take disciplinary action against a practitioner.	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.
(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.		

# APPENDIX B

## (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
(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. Nothing in this section requires or obligates a dispenser or practitioner to access or check the database before dispensing, prescribing, or administering a medication, or providing medical care to a person. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.	<b>[Effective July 17, 2017]</b> (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.	<b>[Effective July 17, 2017]</b> Subsections (k) (1) through (2) were not revised.  New subsections added: (3) a procedure and timeframe 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 administering a schedule II or III controlled	

# APPENDIX B

## (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
	<p>substance under federal law to the patient; the regulation must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering</p> <p>(A) a controlled substance to a person who is receiving treatment</p> <p>(i) in an inpatient setting;</p> <p>(ii) at the schedule of an emergency or in an ambulance; in this subparagraph, an "ambulance" has the meaning given in AS 18.08.200;</p> <p>(iii) in an emergency room;</p> <p>(iv) immediately before, during or with in the first 48 hours after surgery or a medical procedure;</p> <p>(v) in a hospice or nursing home that has an in-house pharmacy; or</p> <p>(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.</p>	
<p>(l) A person</p> <p>(1) with authority to access the database under (d) of this section who knowingly</p> <p>(A) accesses information in the database beyond the scope of the person's</p>		

# APPENDIX B

## (Continued)

### Controlled Substance Prescription Database Statutory Changes

AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
<p>authority commits a class A misdemeanor;</p> <p>(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;</p> <p>(C) allows another person who is not authorized to access the database to access the database commits a class C felony;</p> <p>(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.</p>		
<p>(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to</p> <p>(1) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;</p> <p>(2) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;</p> <p>(3) increase coordination among prescription drug monitoring program partners; and</p> <p>(4) involve stakeholders in the planning process.</p>	<p><b>[Effective July 17, 2017]</b></p> <p>(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures</p> <p>(1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to</p> <p>(A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;</p> <p>(B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;</p>	

# APPENDIX B

## (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
	(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 prescriptions of controlled substances resulting from the use of the database.	
(n) 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) "pharmacist-in-charge" has the meaning given in AS 08.80.480.		<b>[Effective July 26, 2017]</b> Subsections (n) (1) through (4) were not revised.  New subsection added:  (5) "opioid" includes the opium and opiate substance and opium and opiate derivatives listed in AS 11.71.140 and AS 11.71.160.
	<b>[Effective July 17, 2017]</b> (o) 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.	
	<b>[Effective July 17, 2017]</b> (p) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of	<b>[Effective July 17, 2017]</b> (p) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of

# APPENDIX B (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
	Dental Examiners, and the Board of Examiners in Optometry when a practitioner registers with the database under (o) of this section.	Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (o) of this section.
	<b>[Effective July 17, 2017]</b> (q) The board is authorized to provide unsolicited notification to a pharmacist 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.	<b>[Effective July 17, 2017]</b> (q) 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.
	<b>[Effective July 17, 2017]</b> (r) The board shall update the database on at least a weekly basis with the information submitted to the board under (b) of this section.	<b>[Effective July 1, 2018]</b> (r) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.

# APPENDIX B

## (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
	<p><b>[Effective September 1, 2016]</b>            (s) The Department of Commerce, Community, and Economic Development shall</p> <p>(1) assist the board and provide necessary staff and equipment to implement this section; and</p> <p>(2) establish fees for registration with the database by a pharmacist or practitioner required to register under (o) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall</p> <p>(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</p> <p>(B) consult with the board to establish the fees under this subsection.</p>	
		<p><b>[Effective July 17, 2017]</b>            (t) Notwithstanding (q) 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</p>

# APPENDIX B

## (Continued)

Controlled Substance Prescription Database Statutory Changes		
AS 17.30.200 Senate Bill 196 Effective April 2008	Sections of AS 17.30.200 Revised by Senate Bill 74	Sections of AS 17.30.200 Revised by House Bill 159
		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.
		<b>[Effective July 17, 2017]</b> (u) 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.

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## APPENDIX C

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### **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;

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- (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, budgeting, 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 Office of the Governor

STATE CAPITOL  
P.O. Box 110001  
Juneau, AK 99811-0001  
907-465-3500  
Fax: 907-465-3532



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gov.alaska.gov  
Governor@alaska.gov

Governor Bill Walker  
STATE OF ALASKA

December 19, 2017

Kris Curtis, CPA, CISA  
Legislative Auditor  
P.O. Box 113300  
Juneau, AK 99811-3300

RECEIVED  
DEC 22 2017  
LEGISLATIVE AUDIT

Dear Kris Curtis:

Thank you for the opportunity to respond to the Legislative Budget and Audit Committee regarding the preliminary audit reports for the Board of Pharmacy under the Department of Commerce, Community and Economic Development.

The audit did not address any concerns relevant to the Office of Boards and Commissions.

We agree that the board is functioning in the best interest of the public. They continue to protect the public health, safety and welfare by controlling registration and disciplinary sanctions of pharmacists, and providing for the regulation of controlled substances. We believe the board's termination date should be extended until June 30, 2022.

Sincerely,

A handwritten signature in black ink, appearing to read "Shirley Marquardt".

Shirley Marquardt  
Director  
Boards and Commissions

SM/li

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



THE STATE  
of **ALASKA**  
GOVERNOR BILL WALKER

Department of Commerce, Community,  
and Economic Development  
OFFICE OF THE COMMISSIONER

P.O. Box 110800  
Juneau, AK 99811-0800  
Main: 907.465.2500  
Fax: 907.465.5442

January 5, 2018

RECEIVED

JAN 05 2018

LEGISLATIVE AUDIT

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

RE: Confidential Preliminary Audit Report, Department of Commerce, Community, and Economic Development, Board of Pharmacy, August 7, 2017

Dear Ms. Curtis:

Thank you for the opportunity to comment on the Preliminary Audit Report regarding the Board of Pharmacy. The department has the following response to the information and recommendations presented in the letter:

Recommendation No. 1 – DCBPL's chief investigator should work with the director to improve the timeliness of investigations.

A Standard Operating Procedure (SOP) was recently adopted to require investigative staff to enter case notes explaining any gaps between meaningful investigative activities greater than sixty days. While there are times when investigations cannot progress due to factors outside the investigator's control (i.e. board member or expert review, litigation and/or opposing counsel response to settlement offers), we will make strong effort to explain why the action is not moving forward in order to make the record reflective of those challenges.

Lastly, each member of staff is held accountable for the timeliness of their investigative actions. Employees who fail to meet the unit goals are actively coached and closely supervised. We feel that timeliness of investigations is important to protecting public safety, to addressing consumer concerns, and to decreasing stress on those licensees who may find themselves the subject of a specious or unfounded allegation. The division constantly seeks to improve processes to resolve allegations completely and quickly.

The department agrees with this recommendation.

Recommendation No. 2 – DCBPL's director should improve procedures to ensure required licensure documentation is appropriately obtained and retained.

In its effort to continuously monitor and improve quality controls, the department agrees that additional checks are needed to ensure the administrative record is complete. With over 13,000 new

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Division of Legislative Audit  
January 5, 2018  
Page 2

professional licenses issued by the agency in FY2017, additional supervisory resources are needed to ensure that all license files are reviewed to meet this standard.

The division will continue to provide training to staff to ensure they are aware of their roles and responsibilities in preserving an accurate and complete administrative record.

The department agrees with this recommendation.

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 907-465-2500.

Sincerely,



Mike Navarre  
Commissioner

cc: Janey McCullough, Director, Division of Corporations, Business and Professional Licensing  
Micaela Fowler, Legislative Liaison, DCCED

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# Agency Response from the Board of Pharmacy

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01/04/2018

RE: 2017 Sunset Audit

In Response to the completed sunset audit, as Board Chair, I feel this report accurately reflects the efforts our and where we are with respect to current legislation and operations. Regarding the Recommendations included in the report:

Recommendation 1: Agree.

I agree with more cooperation the investigations should move more swiftly, and with the addition of staff to the BOP that will help with the PDMP implementation, our current investigator, whose time has been divided, will have more of such to devote to these investigations. The Board will be able to monitor this through investigation reports during meetings and will be able to determine if we are falling behind on investigations or if they are moving slowly.

Recommendation 2: Agree

I agree that these documentations should be easily retrievable, and all should be available, they are necessary to monitor licensees appropriately and thus required. With the addition of staff, duties will be more properly delegated, and the issue of missing documentation should be minimized. This will be tested through future audits, of which will be sooner than most according to this report due to a significant change in duty regarding the PDMP and the health crisis our state is facing.

Lastly, I understand for the desire to shorten our Boards future audit period to help monitor compliance of current legislation due to Alaska's current opioid crisis, however, it does disappoint me and make known to me a lack of faith, however small or great, in our Board's ability to do so, of which I feel is an unfair evaluation.



Leif J. Holm, PharmD  
Chair  
Board of Pharmacy

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