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Nevada State Board of Pharmacy

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January 30, 2020

Warren Lowman
Administrator
Division of Internal Audits
Governor's Finance Office
209 East Musser Street, Room 302
Carson City, NV 89701

Re: Audit No. 20-05 - Board of Pharmacy Licensing Process

Dear Mr. Lowman:

This correspondence constitutes the Nevada State Board of Pharmacy (BOP) response and implementation plan to the audit of the BOP Licensing Process, Audit Report No. 20-05 (Audit).

RECOMMENDATION NO. 1 - Establish Management Oversight of Background Check Cycle

RESPONSE: The BOP shall, by regulation or internal policy as necessary, ensure enhanced oversight of the criminal background check cycle consistent with the audit recommendations, including establishing criteria under which the Executive Secretary can reject an application or use a civil name check, and developing a full-cycle tracking log for wholesaler license applications requiring background checks. The BOP will commence the statutory administrative rulemaking process within the 6-month time frame specified in NRS 353A.090.

RECOMMENDATION NO. 2 - Enforce Fingerprinting Authority More Stringently

RESPONSE: The BOP shall by regulation, consistent with the audit recommendations, define persons that "exercise significant influence over the operation" as used in NRS 639.500(2) and (4), and require applicants to submit a list of officers from their domicile business registration agency. The BOP will commence the statutory administrative rulemaking process within the 6-month time frame specified in NRS 353A.090.

RECOMMENDATION NO. 3 - Modify Fingerprinting Protocol for License Renewals

RESPONSE: The BOP shall by regulation, consistent with the audit recommendations, only require criminal background checks for initial wholesaler licensure and not for license renewal, and shall review all current reporting requirements for wholesalers set forth in regulation for revision as necessary. The BOP will commence the statutory administrative rulemaking process within the 6-month time frame specified in NRS 353A.090.

Warren Lowman
January 30, 2020
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RECOMMENDATION NO. 4 - Require Fingerprint Background Check for Other License Types

RESPONSE: The BOP notes that there are compelling policy justifications for requiring criminal background checks for other license categories and that this would require legislative action, which cannot occur prior to the 2021 Nevada Legislative Session.

RECOMMENDATION NO. 5 - Account for Fingerprint Fees Separately

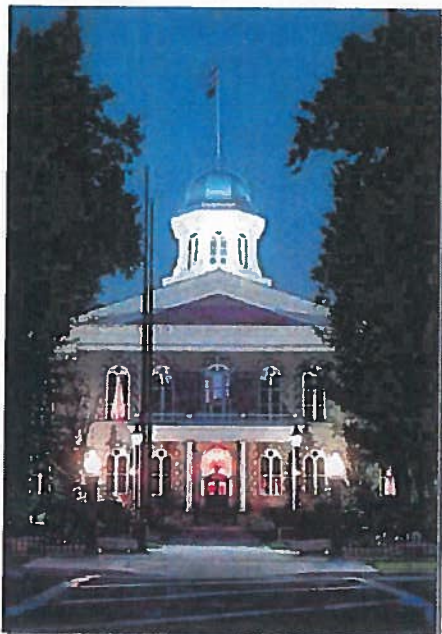
RESPONSE: Consistent with the audit recommendation, the BOP now maintains a separate account for fingerprint fees.

If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,



Brett Kandt
General Counsel
Nevada State Board of Pharmacy



State of Nevada
Governor's Finance Office
Division of Internal Audits

Audit Report

**Board of Pharmacy
Licensing Process**

DIA Report No. 20-05
February 26, 2020

EXECUTIVE SUMMARY

Board of Pharmacy Licensing Process

Introduction..... page 1

Objective: Improve the Wholesale Background Check Process

Establish Management Oversight of Background Check Cycle..... page 2

Establishing management oversight of the background check cycle will allow the Board of Pharmacy (board) to quickly identify problematic background check requests. Although the board has developed tracking logs to enhance oversight of the background check process, the current logs do not track the full cycle including fees, invoices for background checks performed, and corresponding payment of invoices. The board can quickly identify and resolve problematic background checks if it segregates wholesale applications requiring fingerprint background checks onto a separate tracking log with full-cycle information and require a review of the process by the Executive Secretary or Deputy Executive Secretary on a monthly basis. In addition, to clarify procedures where a fingerprint card has been rejected twice, establishing criteria under which the Executive Secretary may reject an application or use a civil name check as an alternative would provide management oversight in a transparent and consistent manner.

Enforce Fingerprint Authority More Stringently..... page 9

Enforcing fingerprint authority more stringently will allow the board to thoroughly vet persons on each application for a wholesale pharmaceutical license. Currently, the board does not explicitly define "persons of influence" nor does it exercise its authority to fingerprint individuals they deem to have significant influence in the wholesale distribution process. Additionally, the board does not require all applicants to provide an official list of officers from the domicile business registration agency to verify the accuracy of the application information. Establishing criteria to define "persons of influence" and requiring applicants to provide an official list of officers would promote public safety by more thoroughly vetting wholesale license applicants.

Modify Fingerprint Protocol for License Renewals..... page 12

Modifying fingerprint protocols for license renewals would help reduce the biennial workload for the board. Current practice is dictated by statute and requires all licensees to provide fingerprints with renewal on a biennial basis. This practice is inconsistent with that of other Nevada boards. Statute also requires applicants to provide an updated list of stakeholders on an annual basis. This list should be used by the board to require fingerprints of those individuals deemed to have significant influence over the operation. Not requiring fingerprints during the renewal phase would help reduce the workload for the board while allowing them to use their resources more effectively.

Objective: Improve the Overall Licensing Process

Require Fingerprint Background Check for Other License Types..... page 15

Requiring fingerprint background checks for other license types will help the board enhance public health, safety, and welfare. Currently, the board only requires fingerprints from wholesalers among its 17 different license types. Other states licensing pharmacists, pharmacist technicians, and MDEGs (medical devices, equipment, and gases) require fingerprints during the licensure process. Additionally, other Nevada boards regulating healthcare professionals have taken a more widespread approach to fingerprinting applicants.

Account for Fingerprint Fees Separately.....page 18

Accounting for fees separately will provide greater transparency and more accurate fiscal information to the board. The amount of fees collected for fingerprint processing since the inception of the statutory requirement could not be determined through financial records and had to be queried through the board's case management system. The board is in the process of reimbursing dormant fees along with other disciplinary fees, which were comingled in the past. Additionally, the board will seek reimbursement from wholesale licensees for whom fingerprints were processed at the board's expense during the temporary moratorium.

Appendix A page 20 Scope and Methodology, Background, Acknowledgments

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Appendix C..... page 24 Timetable for Implementing Audit Recommendations

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INTRODUCTION

At the request of the Executive Branch Audit Committee, the Division of Internal Audits conducted an audit of the Board of Pharmacy. Our audit focused on improving the wholesale background check process and improving the overall licensing process. The audit's scope and methodology, background, and acknowledgements are included in Appendix A.

Our audit objectives were to develop recommendations to:

- ✓ Improve the wholesale background check process; and
- ✓ Improve the overall licensing process.

Board of Pharmacy Response and Implementation Plan

We provided draft copies of this report to the board for review and comment. The board's comments have been considered in the preparation of this report and are included in Appendix B. In its response, the board accepted all our recommendations. Appendix C includes a timetable to implement the recommendations.

NRS 353A.090 requires within six months after the final report is issued to the Executive Branch Audit Committee, the Administrator of the Division of Internal Audits shall evaluate the steps that the board has taken to implement the recommendations and shall determine whether the steps are achieving the desired results. The administrator shall report the six-month follow-up results to the committee and board officials.

The following report (DIA Report No. 20-05) contains our *findings, conclusions, and recommendations*.

Respectfully,



Warren Lowman
Administrator

Improve Wholesale Background Check Process

The Board of Pharmacy can improve the wholesale background check process by:

- Establishing management oversight of the background check cycle;
- Enforcing fingerprinting authority more stringently; and
- Modifying fingerprinting protocol for license renewals.

Improving the wholesale background check process will protect public safety by identifying disqualifying behavior before issuing or renewing pharmaceutical licenses.

Establish Management Oversight of Background Check Cycle

The Board of Pharmacy should establish management oversight of the background check cycle. Lack of management oversight over the background check cycle contributed to the board's failure to implement fingerprint requirements for wholesale license applicants since 2005. Although the board developed tracking logs to enhance oversight of the background check process with guidance from the Department of Public Safety (DPS), the current logs do not track the full cycle including fees, invoices for background checks performed, and corresponding payment of invoices. Establishing management oversight of the background check cycle will ensure stalled background checks and process bottlenecks are recognized and resolved in a timely manner.

Statute Requires Fingerprint Background Checks

NRS 639.500 establishes fingerprint requirements for wholesale license applicants in response to reports of counterfeit drugs in the wholesale market in the early 2000's. The statute states:

"In addition to the requirements for an application set forth in NRS 639.100 each applicant for a license to engage in wholesale distribution shall submit with an application a complete set of fingerprints and written permission authorizing the [b]oard to forward the fingerprints to the Central Repository for Nevada Records of Criminal History (repository) for submission to the Federal Bureau of Investigation for its report."

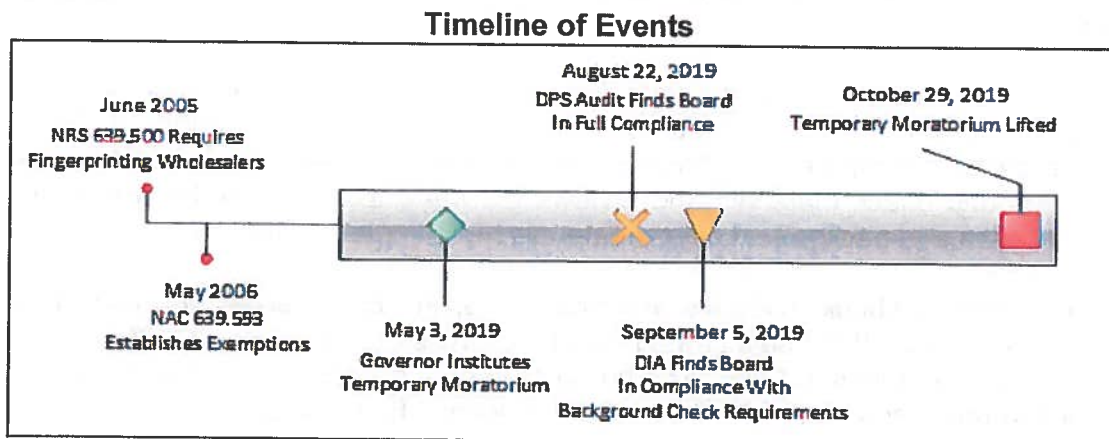
The board subsequently adopted regulations that created exemptions from the fingerprint requirement if the wholesale pharmaceutical license applicant is:

- Publicly traded and regulated by the Securities and Exchange Act of 1934;
- Owned by a corporation whose securities are publicly traded and regulated by the Act;
- Accredited by the National Association of Boards of Pharmacy under the Verified-Accredited Wholesale Distributors (VAWD) program;¹
- A manufacturer of prescription drugs; and/or
- A facility that distributes prescription drugs manufactured by a single manufacturer.²

Governor Imposed Wholesale Pharmaceutical License Moratorium

On May 3, 2019 Governor Sisolak issued a moratorium on wholesale license applications after becoming aware of the board's failure to implement background checks in accordance with NRS 639.500. The Governor directed DPS to investigate and the moratorium was to remain in effect until DPS informed that processes were implemented to ensure compliance with statutory requirements. On August 22, 2019 the repository found the board to be in full compliance with FBI and state policies and re-enrolled the board to submit fingerprints. On October 29, 2019 Governor Sisolak lifted the moratorium. See Exhibit I for the timeline of events.

Exhibit I



Source: Nevada Board of Pharmacy.

At the time of the moratorium, there were 1,138 active wholesale pharmaceutical licensees, from which \$53,000 in fingerprint fees had been collected since 2006. When lifting the moratorium, Governor Sisolak ordered that dormant fees be

¹ VAWD was established as a national program in 2004 to help protect the public from the threat of counterfeit drugs.

² NAC 639.593(7).

returned and fingerprint background checks be performed for existing licensees that were not exempt from the fingerprint requirement.

Board Developed Background Check Process

With guidance from DPS, board staff developed internal written procedures to achieve compliance with FBI and State policies. Specifically, the board developed a background check process to:

- Document and identify the purpose of fees collected;
- Segregate wholesale license applications for review by the background check specialist;
- Identify and segregate wholesale license applications exempt from the fingerprint requirements and those requiring fingerprint background checks;
- Track the progress of background check requests; and
- At the request of the board, segregate applicants by exemption category; and fingerprints required with and without potentially disqualifying events on board meeting agendas.

Updated Wholesale Background Check Process Increases Transparency

The updated background check process will increase transparency by documenting each step of the wholesale application. The board has segregated duties as a control mechanism to ensure that no steps are overlooked during the process.

The Administrative Assistant logs wholesaler application fees and ensures fingerprint cards are delivered to a safe located in the Background Check Specialist's (BCS) office. The BCS receives, processes, and maintains all background check materials and reviews the materials to verify the wholesaler application and background check materials are completed properly.

If background check materials are incomplete, the BCS sends the applicant a rejection notice. If the background check materials are complete, the BCS sends the fingerprint cards to DPS. The board created a new "Fingerprint and Criminal Background Report Log for Wholesaler Applicants" to document the following:

- Name of applicant who submitted the wholesale application;
- Name of individuals on the application who submitted background check materials;
- Date the application was received;
- Whether the application was completed properly;
- Whether background check materials were completely properly (if applicable);

- Date fingerprint cards were submitted to DPS for processing (if applicable);
- Date the rejection notice was sent to the applicant (if applicable) and reason or the date the BCS communicated with the applicant;
- Date fingerprint cards were rejected by DPS;
- Reason fingerprints were rejected;
- Date the rejection notice and instructions for executing and submitting a second fingerprint card was sent to the applicant;
- Date Criminal History Record Information (CHRI) was received;
- Whether there was a disqualifying event;
- Date Notice to Contact Board of Pharmacy was sent (if applicable);
- Date criminal background history report was destroyed (if applicable); and
- Name of person who destroyed the criminal background report (if applicable).

Fingerprint cards rejected by DPS are returned to the board. The Administrative Assistant delivers the sealed envelope to a safe located in the BCS's office. The BCS is responsible for mailing a rejection notice and providing instruction for submitting a second fingerprint card. If the second fingerprint card submitted by the applicant is rejected by DPS, the BCS will request a non-fingerprint-based background check with the approval of the Executive Secretary.³

Executive Secretary Discretion Lacks Criteria

On September 5, 2019 the Division of Internal Audits (DIA) issued a memorandum to the Governor that, in part, expressed concern regarding the Executive Secretary's discretion related to the handling of disqualifying events and rejected fingerprint cards. The memorandum noted it appeared the Executive Secretary had discretion to determine which potentially disqualifying events must appear before the board. Despite this apparent discretion, no such appearances were noted in board minutes dating back to 2006. NRS 639.210 assigns authority to determine disqualifying events solely to the board. Since the moratorium, the board modified background check procedures to require any subject of a report indicating a criminal conviction to appear before the board with a representative of the applicant. At the January 2020 meeting, subjects from seven wholesale pharmaceutical applications with potentially disqualifying events appeared before the board.⁴

DIA's memorandum expressed concern that an alternative background check method (civil name check) may not comply with the intent of the statute. Based upon advice from DPS, the board believes that civil name checks are an acceptable method of background check in cases where fingerprints are rejected

³ Per DPS, a non-fingerprint-based check of criminal files may be processed by the repository or the Federal Bureau of Investigation (FBI).

⁴ Wholesalers appearing pursuant to NRS 639.500.

twice.⁵ A letter provided to board staff from DPS outlined the process by which civil name checks may be requested. Although the Executive Secretary may choose to reject an application without pursuing a civil name check, board staff represented that prior to the moratorium fingerprints had never been rejected twice. However, the board has incorporated the DPS civil name check process into its background check fingerprint procedures. Since the moratorium was lifted and fingerprint processing resumed, 11 individuals have required a civil name check due to the rejection of two fingerprint cards.

The procedure established by the board to address civil name checks in cases where fingerprints have been rejected twice by the repository does not provide criteria for the Executive Secretary to reject an application or pursue a civil name check. Establishing criteria will provide transparency and consistency in discretion exercised by the Executive Secretary.

Limited Access Protects Confidentiality of Criminal History

The board receives a DPS background check report containing Criminal History Record Information (CHRI) valid for six months. Only the Executive Secretary, Deputy Secretary, or General Counsel are allowed to discuss the results with the subject of the report.

The BCS receives, reviews, processes, and maintains all reports. Reports with no disqualifying event, by definition, contain no criminal history and are not retained. Reports must be destroyed per the Records Retention Schedule.⁷ If all required reports for an applicant are received with a "no disqualifying event" designation, the wholesaler application is processed.

Reports with a disqualifying event, by definition, contain criminal history as defined in NRS 179A.070 and require limited access to protect confidentiality. The BCS sends a Notice to Contact the Board of Pharmacy, notifies the Executive Secretary of receipt of the report pursuant to NRS 639.500, and will not process the application until authorized by the Executive Secretary, Deputy Secretary, or General Counsel. Reports are retained and destroyed upon final disposition of the wholesaler application per the Records Retention Schedule.⁸

⁵ This check is conducted by the DPS repository and is based on name, date of birth, numeric descriptors, and/or social security number provided at the time of the original submission of fingerprints.

⁷ Board Authorized Records Retention and Disposition Schedule mandates that complaint and discipline files shall be destroyed in accordance with NAC 239.722.

⁸ Destroyed means disposal by shredding, burning, or bonded recycling in a secure manner.

More Transparency Created on Board Agendas

As an effort to increase transparency, the board revised its agendas to provide greater levels of detail. The January 2020 board agenda segregates applications that require a background check from those exempt from a background check. Exempt applications are categorized by exemption type pursuant to NAC 639.593. Applications requiring a background check and containing a disqualifying event require the wholesaler to appear before the board. The board may convene in a closed session to consider the character, alleged misconduct, professional competence, or physical or mental health of these applicants.⁹

Tracking Log Does Not Track Fees Collected and Invoicing

The tracking log could be improved by separating all wholesale applications requiring fingerprint background checks into a separate worksheet. Currently, all applications are tracked together on the same worksheet, making it difficult to discern application status. Also, the tracking log does not indicate whether fingerprint fees were received or invoices from the repository have been received or paid. Segregating wholesale applications requiring fingerprint background checks onto a separate worksheet with full-cycle information would allow problem background check requests to be quickly identified and resolved.

Tracking Log Not Reviewed by Management

The background check process lacks management oversight. The tracking log for wholesale license applications is rightfully directed through the background check specialist for a determination of exemption eligibility and tracking of background checks, if appropriate. However, tracking logs are not being reviewed by management. Routine management oversight should be embedded in an established procedural manual. A full-cycle background check tracking log would facilitate a review by the Executive Secretary or Deputy Executive Secretary on a monthly basis to ensure that wholesale background checks are performed as statutorily required.

⁹ NRS 241.030(1)(a). /

Conclusion

The board should establish management oversight of the background check cycle to ensure stalled background checks and process bottlenecks are recognized and resolved in a timely manner. This includes establishing criteria under which the Executive Secretary can reject an application or use a civil name check. Developing a full-cycle tracking log for wholesale license applications requiring background checks would facilitate a review of in-process applications. Establishing routine management oversight of the process in a procedural manual would ensure quick identification of problematic background check requests.

Recommendation

1. Establish management oversight of background check cycle.

Enforce Fingerprint Authority More Stringently

The Board of Pharmacy should enforce its fingerprint authority for wholesale applicants more stringently by thoroughly vetting persons on each application. The board should explicitly define persons of influence and require all applicants to provide an official list of officers from the domicile business registration agency to verify the accuracy of the information provided by the applicant.¹⁰ These measures will further promote public safety by identifying disqualifying behavior before issuing wholesale pharmaceutical licenses.

No Criteria for Persons of Significant Influence

NRS 639.500(2) authorizes background checks on those applicants the board deems to have "significant influence over the operation." In our review of pre-moratorium and post-moratorium files, we noted those required to submit background checks had done so, but no attempt was made to determine if others had significant influence. In some instances, individuals listed on the application with titles such as Director of Operations or Vice President of Operations were not fingerprinted despite such potentially influential positions. Further, according to staff, no criteria had been established to determine what roles would potentially be considered to have significant influence.

Following the Civil Name Check Audit in 2018 by Department of Public Safety (DPS), the board developed policies and procedures in collaboration with the repository to help guide its civil background check and fingerprint process.¹¹ Per wholesaler application and licensing procedures, the applicant has to provide the following information depending on the type of ownership:

- If the applicant is a publicly-traded corporation, it must provide a list of officers and directors.
- If the applicant is a privately-held corporation and not Verified-Accredited Wholesale Distributors (VAWD) or registered as a manufacturer by the FDA, it must provide a list of officers and directors.
- If the applicant is a partnership or sole proprietorship and not a VAWD or registered as a manufacturer by the FDA, it must provide detailed ownership information as requested in the application.

Additional licensing requirements are specified in NRS 639.500(2) stating:

"The applicant shall submit with the application a list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant. The

¹⁰ The Secretary of State's office functions as the business registration agency in most states.

¹¹ The board adapted existing policies and procedures used by the Board of Nursing to process fingerprints through the repository.

[b]oard may require any person on the applicant's list to submit a complete set of fingerprints to the [b]oard if the [b]oard determined that the person has the power to exercise significant influence over the operation of the applicant as a licensed wholesaler."

The wholesale licensing process produces a comprehensive list of individuals who are potential candidates for fingerprinting. The statute gives the board the authority to exercise discretion as to who should submit to fingerprint background checks. However, a person of significant influence isn't explicitly defined by the board. While certain officers of the applicant are required to disclose criminal history and submit to fingerprint background checks, others who exercise significant influence are excluded.

Sampled Applications Showed Shortcomings in Fingerprinting

Since the moratorium, the board had not approved any wholesale licenses that required background checks. The December 2019 meeting marked the first time wholesale applications requiring fingerprints were presented to the board. A total of 62 licenses were presented to the board for approval, none of which had a disqualifying event. Exhibit II shows the breakdown of applications:

Exhibit II

Wholesale Applications December 2019 Meeting

Applications Pending Approval	Exempt Pursuant NAC 639.593(7)	Fingerprint Required Pursuant NRS 639.500
62	44	18

Source: Nevada Board of Pharmacy.

In our examination of the 62 applications, we found that the board exercised due diligence in determining exemptions based on regulation. The appropriate VAWD, SEC, and FDA documentation was provided in each application packet.

To ensure fingerprint background checks were conducted for non-exempt applications, we cross-referenced fingerprint fee payments to the list of officers provided by each applicant. In three instances we found applicants had provided a list of employees who handled drugs daily but were not fingerprinted. On another application, we found only the president was fingerprinted but not the vice president.

While statute gives the board authority to fingerprint anyone it deems to have significant influence, it does not exercise this authority. Statute was established to enhance public health, welfare, and safety, and the board can continue to do so by taking a proactive approach and performing a more thorough fingerprint process. Individuals who handle drugs daily or have a position of influence within the operation should be identified on every application and be required to submit

fingerprints to ensure public safety during the distribution of wholesale pharmaceuticals.

No Official List to Verify Officers

Per wholesale application and licensing procedures, "All out-of-state applicants must also provide documentation that the applicant is licensed and in good standing in the state in which the applicant has its principal place of business." Our review of applications confirmed that certificates of good standing were provided as required. However, applicants are not required to provide an official list of officers from their domicile business registration agency. Current procedures allow applicants to submit their own list of officers and the lists are not verified for accuracy. An official list from the domicile business registration agency would further allow the board to verify the accuracy of the officers listed on the application.

Conclusion

The board has taken measures to rectify the fingerprint background check process. Enforcing fingerprinting criteria more stringently by explicitly defining persons of influence and requiring applicants to submit a list of officers from their domicile business registration agency would promote public safety by more thoroughly vetting wholesale license applicants.

Recommendation

2. Enforce fingerprint authority more stringently.

Modify Fingerprint Protocols for License Renewals

The Board of Pharmacy should modify fingerprint protocols for wholesale license renewals. Modifying fingerprint protocol would reduce the biennial workload for staff while adopting similar practices used by other boards. Enforcing and reviewing an annual updated list by licensees would screen new officers and persons of influence.

Board Identified and Segregated Applicants

After the moratorium, the board identified and segregated active licensees at the time of the moratorium who required fingerprints but were not processed and those who were exempt per NRS 639.500.¹²

In compliance with NRS 639.505, the board adopted procedures for administrative action against licensees requiring background checks who did not comply with the annual requirement for updated fingerprints. The following procedures are effective at the next license renewal cycle:

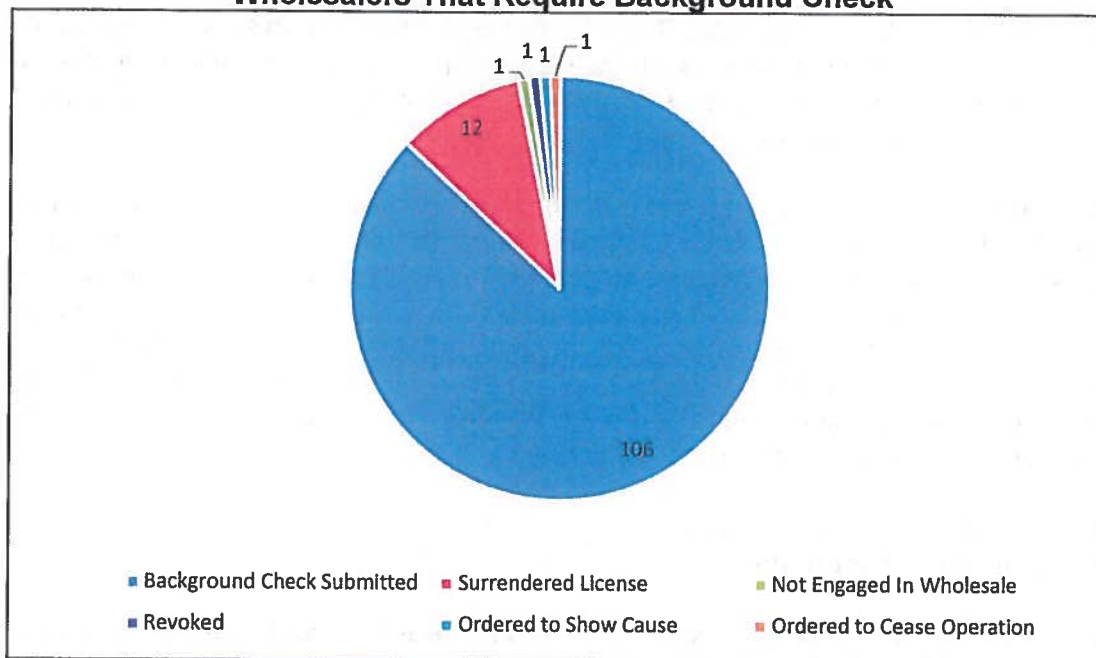
- Staff serves written notice via mail to any wholesaler who fails to timely comply with NRS 639.505;
- Executive Secretary files and serves administrative charges pursuant to NRS 233B.127(3) against any wholesaler who doesn't comply;
- Board holds hearing pursuant to NRS 639.247 for any wholesaler licensee for failure to comply with NRS 639.505 and requires that an applicant comply within 20 days or be subject to order to show cause;
- Executive Secretary issues order to show cause pursuant to NAC 639.965 directing any wholesaler licensee to appear before the board; and
- Board holds a show cause hearing pursuant to NAC 639.965 for any wholesaler licensee and revokes or suspends license pursuant to NRS 639.255 and NAC 639.976.

Exhibit III shows a breakdown of the 122 wholesalers that required a fingerprint background check. The board requested new fingerprints from currently licensed wholesalers. During this process some of the wholesalers did not respond or comply with board requests. Of the 122 fingerprint background checks requested:

- 106 wholesalers submitted fingerprints and waivers;
- 12 surrendered their licenses;
- 1 license was revoked;
- 1 licensee was determined to not be engaged in wholesale distribution under NRS 639.0155(3)(a) and did not require a wholesale license; and
- 2 licensees had not complied.¹³

¹² At the time of the moratorium there were 1,138 wholesale licensees.

¹³ One was issued an order to show cause, and one was ordered to cease operation.

Exhibit III**Wholesalers That Require Background Check**

Source: Nevada Board of Pharmacy.

Requiring Fingerprints Biennially May Be Cumbersome

Wholesale license renewals are conducted biennially pursuant to NRS 639.180 and are subject to the additional requirements specified in NRS 639.505. Statute states, "A certificate, license, or permit issued by the Board pursuant to this chapter expires on October 31 of each even-numbered year."¹⁴ The most recent biennial renewal date was October 31, 2018. Since the moratorium, the board has not yet approved wholesale renewals due by October 31, 2020. Nevada regulation requires that each wholesaler applying for a renewal of a license to engage in wholesale distribution of prescription drugs submit a complete set of fingerprints with written permission to authorize the board to forward prints to the repository.¹⁵ This will require the reprocessing of hundreds of duplicate fingerprints that were processed during the initial application and may be cumbersome.

Statute Requires Wholesalers to Submit Updated List of Stakeholders Annually

Per NRS 639.505, "On an annual basis, each licensed wholesaler shall submit to the [b]oard an updated list of each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the wholesaler who is employed by or otherwise contracts with the wholesaler for

¹⁴ NRS 639.180(1).

¹⁵ NAC 639.593(6).

the provision of services in connection with the operation of the licensee as a wholesaler.” If a person identified on an updated list of the wholesaler is employed after the board issues a license, that person may be required to submit fingerprints if the board determines the person has the power to exercise significant influence over the operation of the licensee as a wholesaler. Fingerprints are to be submitted within 30 days after being requested.

An updated annual list has not been enforced for wholesale licensees. The board asserts that applicants notify staff of personnel changes when necessary; however, no formal lists have been routinely submitted as proscribed in statute. Ensuring the submission of this documentation would be beneficial to the board as it ensures all new members of significant influence are fingerprinted. Additionally, enforcing the annual list update could offset the number of fingerprints that need to be processed if fingerprints are only required for changes on the applicant’s annual list of officers and persons of influence.

Other Boards Do Not Require Fingerprinting Biennially

We surveyed three other Nevada boards that regulate healthcare professions: Board of Medical Examiners, Board of Dental Examiners, and Board of Nursing. We found that almost all license types issued by these boards are renewed biennially.

While renewal standards are consistent with that of the Board of Pharmacy, these boards only require fingerprinting for initial licensure and not renewals.¹⁶ Adopting similar practices would reduce the workload for board staff and allow them to use resources more effectively.

Conclusion

Statute requires that each licensed wholesaler submit an updated list of employees annually. This list should be used by the board to determine which individuals have significant influence over the operation and require fingerprints. The board should consider adopting similar practices utilized by other boards by only requiring fingerprinting for initial licensure. Not requiring fingerprints during the renewal phase would help reduce the workload for the board while allowing them to use their resources more effectively.

Recommendation

3. Modify fingerprint protocol for license renewals.

¹⁶ Boards may require fingerprinting where formal disciplinary action is initiated against a licensee.

Improve Overall Licensing Process

The Board of Pharmacy can improve the overall licensing process by:

- Requiring fingerprint background checks for other license types; and
- Accounting for fingerprint fees separately.

Require Fingerprint Background Check for Other License Types

The Board of Pharmacy should require fingerprint background checks for other license types, such as pharmacists, pharmacy technicians, and MDEGs (medical devices, equipment, or gases). To protect the public, the board should license medical professionals and healthcare providers only after conducting a preliminary fingerprint check. Requiring fingerprint background checks will not only enhance public health, safety, and welfare but will help the board become consistent with the professional standards adopted by other Nevada healthcare boards.

Fingerprints Required Only for Wholesalers

The board only requires fingerprints from wholesalers among its 17 different license types, including pharmacists and prescribing individuals, per NRS 639.500. The board forwards fingerprints to the Central Repository for Nevada Records of Criminal History for submission to the FBI for a background investigation. Appendix D shows a chart of license categories along with the number of active licenses.

In our review of the licensing procedures for pharmacists, pharmacy technicians, and MDEGs, we found that all applicants are required to disclose information regarding mental illness, substance abuse, and any history of criminal or administrative actions brought against the applicant with evidence of the outcome. However, aside from self-reporting, there is no process to verify criminal history with FBI records.

Other States Fingerprint Pharmacy and Prescribing Professionals

We surveyed other states to determine what license types were required to submit fingerprints. The following states require fingerprint background checks for pharmacy and prescribing professionals:

Arizona: pharmacists, pharmacy technician trainee, pharmacy technicians, interns;

Oregon: pharmacists, pharmacy technicians, certified pharmacy technicians, and pharmacy interns;

Utah: pharmacists, pharmacy technicians, prescribing nurses; and

Washington: pharmacists, interns, and pharmacy assistants.

Pharmacists and pharmacy technicians make up a large portion of active licenses issued by the Nevada Board of Pharmacy; however, none are subject to background checks as required by other states.

Other Nevada Boards Fingerprint Healthcare Professionals

We surveyed other Nevada boards that regulate healthcare professionals. Boards showed an aggressive approach to fingerprinting.

Board of Medical Examiners: all licensure category applicants are fingerprinted as part of the application process (NRS 630.167);

Board of Dental Examiners: every applicant applying for a license to practice dentistry or dental hygiene must submit a complete set of fingerprints (NRS 631.220);

Board of Nursing: an applicant for a license must submit to the board a complete set of fingerprints (NRS 632.344); and

Physical Therapy Board: application for a licensure as a physical therapist or a physical therapist assistant must submit to the board a complete set of fingerprints (NRS 640.090).

Other Nevada boards regulating healthcare professionals have taken a more widespread approach to fingerprinting applicants. The Board of Pharmacy statute limits fingerprint background checks to pharmaceutical wholesalers and neglects a large portion of pharmaceutical professionals dealing directly with the public.

Conclusion

The board should do its due diligence to confirm individuals do not have a criminal history or any disciplinary action that would exclude them from obtaining a license. Currently only wholesalers are subject to background checks. Professional standards developed by other states and boards suggest that the board request fingerprints from other licensures. Requiring fingerprint background checks for other license types would enhance public health, safety, and welfare.

Recommendation

4. Require fingerprint background checks for other license types.

Account for Fingerprint Fees Separately

The Board of Pharmacy should account for fingerprint fees separately. Accounting for fees separately will provide greater transparency and more accurate fiscal information to the board.

The amount of fees collected for fingerprint processing could not be determined through financial records and had to be queried through the board's case management system.

Board in Process of Returning Dormant Fees

The board has been collecting fees for background checks since 2006 without processing the associated fingerprint cards. These fees have remained dormant because fingerprint cards have not been processed. The failure to process fingerprint cards was first identified in August 2012 and again in August 2018 following the Civil Name Check Audits conducted by the Records, Communication, and Compliance Division (repository). In response to the most recent audit of the fingerprint process on August 22, 2019, DPS instructed the board to stop using the bank account to deposit fingerprint fees until it was audited and received direction from the Governor's Office.

The money from background check fees is currently in a non-interest-bearing account.¹⁸ These funds were moved from an interest-bearing account when the board was told to open a new account in August 2018. The board agrees with DPS' recommendation to return all fees and has reconciled fees with applicants who submitted them. A total of \$53,000 in dormant fees are being returned.

Board to Apply Interest to All Fees

The board is in the process of determining a method for calculating interest for reimbursements. Fees from different accounts were commingled prior to being moved to a non-interest-bearing account. The board believes that the best approach moving forward would be to apply interest to each refund amount. Fees for applicants that the board cannot locate will be transferred to the State Treasurer's Unclaimed Property Account in accordance with NRS 120A.500.

¹⁸ NRS 639.081 requires that all money coming in the possession of the Board must be kept or deposited in banks, credit unions, savings and loan associations or savings banks in the State of Nevada, or invested in United States treasury bills or notes.

Board Paid for Fingerprints

Following the issuance of the moratorium in May 2019, the board determined which licensees' fingerprints it had not processed and were still valid. At the direction of DPS the board processed these fingerprints at board expense using their operating budget, not fees, in the interest of expediency. Moreover, the board also paid to process fingerprints from those licensees for which new fingerprint cards were necessary. The board will seek reimbursement of the \$12,400 in fingerprint costs after refunds are completed.

Disciplinary Fingerprint Fees Commingled with Other Fees

Per NRS 622.360, "If a regulatory body initiates disciplinary proceedings against a licensee pursuant to this title, the regulatory body may require the licensee to submit to the regulatory body a complete set of fingerprints and written permission authorizing the regulatory body to forward the fingerprints to the Central Repository of Nevada Records of Criminal History for submission to the Federal Bureau of Investigation for its report." The board collected \$2,200 in disciplinary fingerprint fees. These fees were not related to wholesalers but were deposited in the same account as wholesale fingerprint fees and other operating funds. These fees also need to be returned because the fingerprints were not processed.

Conclusion

The amount of fees collected for fingerprint processing since the inception of the statutory requirement was not readily determinable. The fingerprint fees should, at a minimum, be accounted for separately because NRS 639.081 does not require a separate account for fingerprint fees or specify whether such account would be interest or non-interest bearing. Accounting for fees separately will allow users to distinguish between fees types and promote greater transparency in the future.

Recommendation

5. Account for fingerprint fees separately.

Appendix A

Scope and Methodology, Background, Acknowledgements

Scope and Methodology

We began the audit in June 2019. In the course of our work, we interviewed management and discussed processes inherent to the Board of Pharmacy. We researched division records, policies and procedures, professional publications, applicable Nevada Revised Statutes (NRS), Nevada Administrative Code (NAC), and other state and federal guidelines. Additionally, we reviewed applicable federal and independent reports and audits. We concluded fieldwork in December 2019.

We conducted our audit in conformance with the *International Standards for the Professional Practice of Internal Auditing*.

Background

The Nevada Board of Pharmacy is governed by NRS 639, which sets forth the general provisions of the board. The board concentrates on four areas of the practice of pharmacy to protect the public: proper credentialing and inspection of licenses; adoption of regulations as necessary to further legislative intent; providing timely access to accurate information in Nevada's Prescription Monitoring Database; and investigation of complaints filed by the public on activities within the board. The board currently has 40,000 licenses in 17 different license types including wholesalers, pharmacists, and proscribing individuals.

On May 3, 2019 a temporary moratorium was instituted on the award of any wholesale pharmacy licenses or renewal of such licenses. This action was the result of allegations that the board had failed to provide statutorily required fingerprints to the Records, Communication, and Compliance Division (repository). On August 22, 2019 the repository conducted an audit on the board's Civil Name Check process to ensure that adequate policies and procedures, controls, safeguards, documentation, and practices were in place which complied with federal and state guidelines. The board was found to be in full compliance with FBI and state policies.

As a complementary review of the board's practices, the Division of Internal Audits was instructed to conduct an emergency audit of the board in August. DIA found that the board was in full compliance with the law and requested that the Governor lift the temporary moratorium on eligible wholesale license applicants, return

dormant fingerprint card fees to applicants, and continue their review of the pharmacy board. All suggestions were accepted by the Governor, who lifted the moratorium on October 29, 2019.

Acknowledgments

We express appreciation to the Board of Pharmacy management and staff for their cooperation and assistance throughout the audit.

Contributors to this report included:

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Appendix B

Board of Pharmacy Response and Implementation Plan



Nevada State Board of Pharmacy

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January 30, 2020

Warren Lowman
Administrator
Division of Internal Audits
Governor's Finance Office
209 East Musser Street, Room 302
Carson City, NV 89701

Re: Audit No. 20-05 - Board of Pharmacy Licensing Process

Dear Mr. Lowman:

This correspondence constitutes the Nevada State Board of Pharmacy (BOP) response and implementation plan to the audit of the BOP Licensing Process, Audit Report No. 20-05 (Audit).

RECOMMENDATION NO. 1 - Establish Management Oversight of Background Check Cycle

RESPONSE: The BOP shall, by regulation or internal policy as necessary, ensure enhanced oversight of the criminal background check cycle consistent with the audit recommendations, including establishing criteria under which the Executive Secretary can reject an application or use a civil name check, and developing a full-cycle tracking log for wholesaler license applications requiring background checks. The BOP will commence the statutory administrative rulemaking process within the 6-month time frame specified in NRS 353A.090.

RECOMMENDATION NO. 2 - Enforce Fingerprinting Authority More Stringently

RESPONSE: The BOP shall by regulation, consistent with the audit recommendations, define persons that "exercise significant influence over the operation" as used in NRS 639.500(2) and (4), and require applicants to submit a list of officers from their domicile business registration agency. The BOP will commence the statutory administrative rulemaking process within the 6-month time frame specified in NRS 353A.090.

RECOMMENDATION NO. 3 - Modify Fingerprinting Protocol for License Renewals

RESPONSE: The BOP shall by regulation, consistent with the audit recommendations, only require criminal background checks for initial wholesaler licensure and not for license renewal, and shall review all current reporting requirements for wholesalers set forth in regulation for revision as necessary. The BOP will commence the statutory administrative rulemaking process within the 6-month time frame specified in NRS 353A.090.

Warren Lowman
January 30, 2020
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RECOMMENDATION NO. 4 - Require Fingerprint Background Check for Other License Types

RESPONSE: The BOP notes that there are compelling policy justifications for requiring criminal background checks for other license categories and that this would require legislative action, which cannot occur prior to the 2021 Nevada Legislative Session.

RECOMMENDATION NO. 5 - Account for Fingerprint Fees Separately

RESPONSE: Consistent with the audit recommendation, the BOP now maintains a separate account for fingerprint fees.

If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandi@plwrmacv.nv.gov.

Best regards,



Brett Kandi
General Counsel
Nevada State Board of Pharmacy

Appendix C

Timetable for Implementing Audit Recommendations

In consultation with the Board of Pharmacy (board), the Division of Internal Audits categorized the recommendations contained within this report into two separate implementation time frames (i.e., *Category 1* – less than six months; *Category 2* – more than six months). The board should begin taking steps to implement all recommendations as soon as possible. The boards target completion dates are incorporated from Appendix B.

Category 1: Recommendations with an anticipated implementation period less than six months.

<u>Recommendation</u>	<u>Time Frame</u>
1. Establish management oversight of background check cycle. (page 2)	Aug 2020
2. Enforce fingerprint authority more stringently. (page 9)	Aug 2020
3. Modify fingerprint protocol for license renewals. (page 12)	Aug 2020
4. Account for fingerprint fees separately. (page 18)	Aug 2020

Category 2: Recommendations with an anticipated implementation period exceeding six months.

<u>Recommendations</u>	<u>Time Frame</u>
5. Require fingerprint background checks for other license types. (page 15)	Aug 2021

The Division of Internal Audits shall evaluate the action taken by the board concerning the report recommendations within six months from the issuance of this report. The Division of Internal Audits must report the results of its evaluation to the Executive Branch Audit Committee and the board.

Appendix D

Nevada State Board of Pharmacy Licenses

LICENSE CATEGORY	NUMBER OF ACTIVE LICENSES
APRN [NRS 639.1375: Prescribe NAC 639.850 and .854/Dispensing NAC 639.870 and .879*]	213 (prescribe)
Controlled Substance [NRS 453.226]	13011
Dispensing Practitioner [NRS 639.0727, NAC 639.742]	333
Dispensing Technician [NRS 639.0727, NAC 639.7425]	265
Dispensing Technician Trainee [NRS 639.0727, NAC 639.7425]	90
Dispensing Veterinarian [NRS 639.070, NAC 639.7423]	62
Intern Pharmacist [NRS 639.137, NAC 639.262]	646
Manufacturer [NRS 639.100, NRS 639.233]	2
Medical Devices, Equipment, Gas [NRS 639.233, NAC 639.6942]	699
Outsourcing Facility [NRS 639.100, NAC 639.6915 (manufacturer) and .6916 (pharmacy)]	17
Pharmaceutical Technician [NRS 639.1371, NAC 639.240]	4959
Pharmaceutical Technician Trainee [NRS 639.1371, NAC 639.240]	1331
Pharmacist [NRS 639.127, NAC 639.205]	8145
Pharmacy [NRS 639.230 and .231; NAC 639.214 and .215]	1654
Physician Assistant [NRS 639.1373: Prescribe NAC 639.272/Dispensing NAC 639.272*]	53 (prescribe)
Veterinary Drug Supplier [NRS 639.2345]	31
Warehouse [NRS 639.070, NAC 639.631]	7
Wholesaler [NRS 639.100, NRS 639.233, NAC 639.593]	1138

*APRNs and Physician Assistants are licensed to dispense as Dispensing Practitioners

Appendix E

Nevada State Board of Pharmacy Action Plan

**NEVADA STATE BOARD OF PHARMACY (BOP) ACTION PLAN IN RESPONSE TO GOVERNOR'S 5-3-19 DIRECTIVE REGARDING
WHOLESALE BACKGROUND CHECKS REQUIRED BY NRS 639.500**

Action	Completion Date
Hold processing of all pending wholesaler license applications per Governor's 5-3-19 directive	5/6/19
Meet with DPS to formulate action plan	5/6/19
Locate and transfer all fingerprint cards in BOP possession to DPS	5/6/19
Identify number of wholesalers currently licensed, number currently licensed subject to NRS 639.500, number of wholesaler license applications pending, and number of pending applications subjects to NRS 639.500	5/7/19
Identify, segregate and account for all Background Check Fees previously collected and not remitted to DPS and identify each applicant/payee	5/8/19
Establish separate bank account for all newly-submitted all Background Check Fees	5/9/19
AT DPS HQ perform review of all fingerprint cards not previously submitted to DPS and determine number of submitted cards now out-of-date and segregate; submit all fingerprint cards not out-of-date for background check reports [no additional fees assessed/DPS invoices paid out of BOP operating account]	5/9/19
Implement temporary policies and procedures and record retention schedule for fingerprint card submissions and background check report processing	5/9/19
Correct Background Check Fee on BOP website from \$45.00 to \$36.75	5/9/19
Implement use of DPS Fingerprint Background Waiver Form	5/9/19
Revise all other relevant BOP website information, instruction sheets, and forms as necessary	5/9/19
Execute Background Check User Agreement with DPS	5/9/19
Meet with DPS for status report, training of all personnel authorized to handle fingerprint card submissions and background check reports, and approval of BOP actions to date	5/9/19
Submit BOP Authorized Personnel List to DPS	5/10/19
Obtain DPS approval to return wholesaler applications submitted with overpayment of Background Check Fee and request resubmittal with correct fee	5/10/19
Designate Background Check Specialist to receive, review and process fingerprint card submissions and background check reports and designate secure facility for same	5/14/19

Appendix E (Continued)

Obtain DPS authorization to place pending wholesaler license applications that do not require background checks on BOP 6-6-19 meeting agenda for review and action	5/15/19
Resume processing wholesaler license applications per DPS authorization	5/15/19
Notify current wholesaler licensees who require background checks to submit fingerprint cards	5/24/19
Implement revised policies and procedures for fingerprint card submissions and background check report processing	5/28/19
Pending wholesaler license applications that do not require background checks approved by BOP	6/06/19
Submit updated BOP Authorized Personnel List to DPS	6/12/19
Commence submitting fingerprint cards from current wholesaler licensees to DPS [no additional fees assessed/DPS invoices paid out of BOP operating account]	6/13/19
Commence submitting fingerprint cards from new wholesaler licensee applicants to DPS	6/13/19
Obtain DPS approval to 1) refund overpayment of Background Check Fees previously accepted directly to applicants; 2) correct and process Fingerprint Background Waiver Forms submitted by applicants that reference an incorrect state agency; and 3) accept and process Fingerprint Background Waiver Forms submitted with a stamped signature	6/14/2019
Refund pending wholesaler license applications submitted with incorrect fee	6/14/19
Increase Background Check Fee from \$36.75 to \$40.25 in conformance with DPS all-agency directive and revise Fingerprint Submission Instructions and BOP website as necessary	7/1/19
Contact current wholesaler licensees regarding background checks with disqualifying events that failed to self-disclose on application	7/8/19
Provide DPS updated information on 1) number of current wholesaler licensees subject to NRS 639.500 with subsequent background checks performed; 2) number of current wholesaler licensees whose subsequent background checks revealed disqualifying event; 3) accounting of fingerprints fees collected; 4) timeline for completing all background checks for current wholesaler licensees subject to NRS 639.500	7/19/19
Second notification to any current wholesaler licensees who have not responded 5-24-19 BOP request to submit fingerprint cards for background checks	7/23/19
Reinstitute moratorium of processing of all pending wholesaler license applications until further directed	7/26/19
Notice appearances on BOP 9-4-19 meeting agenda for any current wholesaler licensees whose subsequent background checks reveal undisclosed disqualifying event resulting in conviction	8/14/19
Review background checks for current wholesaler licensees returned with disqualifying events and reconcile self-disclosures on previously-submitted applications	8/30/19
Notice revocation hearings for any current wholesaler licensees who have not responded 7-23-19 BOP request to submit fingerprint cards for background checks	8/30/19
Direction from Governor on disposition of previously collected Background Check Fees not submitted to DPS/no background check performed	PENDING
Resume processing wholesaler license applications per Governor's authorization	PENDING