

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov



March 13, 2023

Candace Shields, Secretary
Louisiana Senate
Committee on Commerce, Consumer Protection, & International Affairs
PO Box 94183
Baton Rouge, LA 70804
Via E-mail: scom@legis.la.gov

Electronic Mail - Delivery Receipt Requested

Re: Act 483 (2022 Regular Session) Reporting Requirement

Dear Ms. Shields,

Pursuant to Act 483 of the 2022 Regular Session of the Louisiana Legislature, please accept this correspondence as the Louisiana Board of Pharmacy's report for the information requested.

The attached contains a typed summary, no longer than one page for each credential issued by the Board of Pharmacy, identifying requirements for obtaining a full licensure status or practice.

If you have any questions, please do not hesitate contacting me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

Joe Fontenot
Executive Director

cc: House Committee on Commerce @ stevens@legis.la.gov





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New Louisiana Pharmacy Permit for In-State Pharmacy and New Louisiana Controlled Dangerous Substance License for Pharmacies Requirements

Applications and Fees:

- Application for New Louisiana Pharmacy Permit \$525.00
- Application for New Louisiana Controlled Dangerous Substance License \$25.00

Required Attachments:

- **Authority to Conduct Business** A W9 or FEIN letter is required for the legal entity identified as the direct owner. The board will also verify that the legal entity is registered with the Louisiana Secretary of State.
- **Indirect Ownership** List of indirect ownership with identifying information as outlined in the application.
- **Prior Actions** If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation
 - o Certified copies of documents from relevant court or government agency
- **PIC Delegation** Corporate resolution granting the PIC authority to complete the application.
- Ownership Transfers Owner of the existing pharmacy permit shall confirm the pending sale to the applicant as well as the anticipated transfer. The new owner shall confirm the sale with a copy of the Bill of Sale or similar legal document.
- **Nuclear Pharmacy** Legible copy of the Radioactive Materials (RAM) license issued by the La. Dept. of Environmental Quality, identifying the qualified nuclear pharmacists for that site.
- **Charitable Pharmacy** Legible copy of the IRS letter granting the applicant the appropriate taxexempt status.
- **Tele-pharmacy Dispensing** Identify the central pharmacy, its permit number, and its pharmacist-in-charge.

Board Review: A review of prior actions and criminal history is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time.

Issuance: When the compliance officer has verified compliance with the minimum standards, the compliance officer shall ascertain whether the applicant is prepared to open for business immediately or in the alternative requests an additional period of time before opening for business. In the event the applicant intends to open for business immediately, the permit and CDS license shall be issued in active status with a notation it is valid for practice.





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New Louisiana Pharmacy Permit for Nonresident Pharmacy

Application: The Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy.

Fee: \$525.00 to be paid with the submission of the online application.

Required Attachments:

- Authority to Conduct Business A W9 or FEIN letter is required for the legal entity identified as the direct owner.
- **Indirect Ownership** List of indirect ownership with identifying information as outlined in the application.
- **Prior Actions** If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation
 - o Certified copies of documents from relevant court or government agency
- PIC Delegation Corporate resolution granting the PIC authority to complete the application.
- Ownership Transfers Owner of the existing pharmacy permit shall confirm the pending sale to
 the applicant as well as the anticipated transfer. The new owner shall confirm the sale with a
 copy of the Bill of Sale or similar legal document.
- **Resident Permit Verification** Verification of license status from resident board licensing agency. Must include permit number, address, issuance, expiration, and if the permit has ever been disciplined.
- Inspection An inspection report dated within the last 24 months completed by the resident licensing agency. Pharmacies engaging in compounding activities and with intentions of providing these compounds to Louisiana residents, must provide an inspection report outlining compliance with USP Chapter 797 for sterile preparations and USP Chapter 795 for nonsterile preparations. Acceptable inspections include: Universal Inspection from NABP or an ACHC inspection.

Board Review:

- The Chief Pharmacist Compliance Officer will review all compounding inspections.
- A review of prior actions and criminal history, reported by the applicant, is completed when all
 documents have been received and payment processed.

Issuance: In the event that there are no matters preventing the immediate issuance, the board will issue the credential within fourteen business days.





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New Louisiana Therapeutic Marijuana Pharmacy Satellite Permit Requirements and

New Louisiana Controlled Dangerous Substance License for Pharmacies Requirements

Application and Fees:

- New Louisiana Therapeutic Marijuana Pharmacy Satellite Permit \$525.00
- New Louisiana Controlled Dangerous Substance License for Pharmacies \$25.00

Eligible Applicants: After three thousand five hundred active, qualified patients are identified in the Prescription Monitoring Program in a region, the Louisiana Board of Pharmacy shall allow the therapeutic marijuana pharmacy licensee in that region to open one additional therapeutic marijuana pharmacy location as a satellite location in that region.

Fee: \$525.00

Required Attachments:

- Services A detailed description of any other services or products being offered.
- **Diversion Controls** A detailed description of the applicants plans to maintain adequate controls against diversion, theft, and loss.
- Authorized Business Documents and information sufficient to verify that the applicant is authorized to conduct business in Louisiana and that all applicable state and local ordinances will be met.
- **Blueprint** A complete blueprint of the proposed therapeutic marijuana pharmacy satellite location is required.

Criminal Background Check: All owners, the pharmacist-in-charge, and the owner's managing officer must complete a criminal background check (CBC). The board will supply the applicant with materials necessary to perform a CBC with the Louisiana State Police (LSP) and the Federal Bureau of Investigation (FBI). LSP and FBI may take 2-8 weeks to process the CBC depending on the method of submission the applicant selects. The CBC will be waived for individuals that have completed this requirement with the Board within the two years preceding the submission of the application.

Board Review: A review of prior actions and criminal history is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time.

Issuance: When the compliance officer has verified compliance with the minimum standards, the compliance officer shall ascertain whether the applicant is prepared to open for business immediately or in the alternative requests an additional period of time before opening for business. In the event the applicant intends to open for business immediately, the permit and CDS license shall be issued in active status with a notation it is valid for practice. The CDS license will be valid for only Schedule 1 and include a notation that it is limited to therapeutic marijuana only.



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New Pharmacy Benefit Manager Permit Requirements

Application: Application for New Pharmacy Benefit Manager Permit

Fee: \$1,000.00 for two-year permit

Required Attachments:

- W9 or FEIN letter is required for the legal entity identified as the direct owner.
- A copy of the verification from the Louisiana Secretary of State when located within the state.
- A copy of the verification from the resident Secretary of State and articles of incorporation.
- Verification that the entity is registered with the La. Dept. of Insurance as a third-party administrator.
- Identification of indirect ownership and managing officers as outlined in the application. With copies of social security cards and FEIN letters.
- Identification of prior ownership structures if ownership changes have occurred with the past 5 years.
- 10K or equivalent filings.
- Contingency plans for operations.
- Identification of any pharmacies under the same ownership.
- Grievance procedures.
- If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation.
 - Certified copies of documents from relevant court or government agency.

Board Review: A review of prior actions and criminal history, reported by the applicant, is completed when all documents have been received and payment processed.

Issuance: In the event that there are no matters preventing the immediate issuance, the board will issue the credential within fourteen business days.





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New Emergency Drug Kit Permit Requirements

Application: Application for New Emergency Drug Kit

Fee: \$50.00

Required Attachments: La. Dept. of Health License for the hosting facility.

Board Review:

- Board staff will verify that one of the following eligibility requirements have been met:
 - o Hosting facility is one of the following as evidenced by the La. Dept. of Health License:
 - A long-term care facility
 - An institutional facility without an institutional pharmacy
 - Other board-approved site, other than a hospital.





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New Durable Medical Equipment Provider Permit Requirements

Application: Application for New Durable Medical Equipment Provider Permit.

Fee: \$200.00

Required Attachments:

- Authority to Conduct Business A W9 or FEIN letter is required for the legal entity identified
 as the direct owner. This entity must be registered with the Louisiana Secretary of State if
 located in the state.
- **Indirect Ownership** List of indirect ownership with identifying information as outlined in the application.
- Owners Managing Officer Information required to identify the Owner's Managing Officer as outlined in the application.

Board Review: A review of prior actions and criminal history, reported by the applicant, is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time. An inspection is not required for nonresident applicants.

Issuance: When the compliance officer has verified compliance with the minimum standards, the license will be issued.





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New Controlled Dangerous Substance Licenses for Facilities Requirements

Application: Application for New Louisiana Controlled Dangerous Substance (CDS) License for Facilities.

Fee:

- CDS-CRX Correctional Center \$0.00
- CDS-DIS Distributor \$50.00
- CDS-HOS Hospital \$50.00
- CDS-HOX Hospital \$0.00
- CDS-HTG Hemp Facility \$20.00
- CDS-MFR Manufacturer \$100.00
- CDS-ROF Registered Outsourcing Facility \$100.00
- CDS-SAC Substance Abuse Clinic \$50.00
- CDS-SAX Substance Abuse Clinic \$0.00
- CDS-TPL Third Party Logistics Provider \$50.00
- CDS-WMC Withdraw Management Clinic \$50.00

Required Attachments:

- Primary License. The primary license(s) must be active at the physical address provided on the application and without any restrictions that would prevent the procuring or possession of controlled dangerous substances.
- Authority to Conduct Business A W9 or FEIN letter is required for the legal entity identified as the direct owner. This entity must be registered with the Louisiana Secretary of State when facility is physically located in the state.
- **Indirect Ownership** List of indirect ownership with identifying information as outlined in application.

Board Review: A review of prior actions and criminal history, reported by the applicant, is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time.

Issuance: When the compliance officer has verified compliance with the minimum standards, the license will be issued.





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New Controlled Dangerous Substance Licenses for Practitioners Requirements

Application: Application for New Louisiana Controlled Dangerous Substance (CDS) License for Practitioners.

Fee:

- APRN, DDS, DPM, INT, MD, MDT, MP, OD, PA, RNT \$45.00
- DVM \$20.00

Required Attachments

- · Social security card
- Legible copy of the professional license issued by the Louisiana primary licensing board.
- APRNs and ODs must include a legible copy of their Limited Prescriptive and Distributive Authority for Controlled Substance letter from their professional licensing agency.

Board Review: Board staff will verify that the applicant has met the following requirements:

- Holds an active primary license without any restrictions that would prevent the prescribing, procuring, or possession of controlled dangerous substances.
- The applicant has provided a Louisiana practice address. Out of state addresses will be accepted for those practicing by telemedicine and/or at a federal facility.
- A review of prior actions and criminal history, reported by the applicant, is completed when all documents have been received and payment processed.

Issuance: In the event that there are no matters preventing the immediate issuance, the board will issue the credential within business days. CDS-INT will be issued to limited status. CDS-APN, CDS-OD, and CDS-PA will be issued in active status with only the schedules authorized by the primary licensing board.





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New Controlled Dangerous Substance License for Drug Detection / Canine Handler Requirements

Application: Application for New Louisiana Controlled Dangerous Substance (CDS) License for Selected Persons or Organizations.

Fee: \$30.00

Required Attachments

- **Explanation of Need** A letter summarizing the business activities and the need for controlled dangerous substances is required.
- Prior Actions If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation.
 - o Certified copies of documents from relevant court or government agency.

Criminal Background Check: Upon receipt of the properly completed application, the Board will provide the applicant with materials necessary to perform a criminal history record check with the Louisiana State Police and the Federal Bureau of Investigation. Louisiana State Police and FBI may take 2-8 weeks to process the criminal background check depending on the method of submission the applicant selects.

Board Review: A review of prior actions and criminal history is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time.

Issuance: The credential will be issued at the conclusion of a successful inspection.





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New Controlled Dangerous Substance for Animal Euthanasia Technician License Requirements

Application: Application for New Louisiana Controlled Dangerous Substance (CDS) License for Selected Persons or Organizations.

Fee: \$20.00 to be paid with the submission of the online application.

Required Attachments

- Social security card.
- Copy of the professional license issued by Louisiana Board of Veterinary Medicine.
- An affirmative reply to any application question regarding prior history will require
 - Personal letter of explanation.
 - o Certified copies of documents from relevant court or government agency.

Board Review: A review of prior actions and criminal history, reported by the applicant, is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time.

Issuance: The credential will be issued at the conclusion of a successful inspection.





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New Controlled Dangerous Substance Licenses for Laboratories Requirements

Application: Application for New Louisiana Controlled Dangerous Substance (CDS) License for Selected Person and Organizations.

Fee: \$20.00

Board Review:

- The facility must be certified with the Clinical Laboratory Improvements Amendments (CLIA). Board staff will verify that certification upon receipt of the application.
- A review of prior actions and criminal history, reported by the applicant, is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time. An inspection is not required for nonresident applicants.

Issuance: When the compliance officer has verified compliance with the minimum standards, the license will be issued.





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Controlled Dangerous Substance for Researchers Requirements

Application: Application for New Louisiana Controlled Dangerous Substance (CDS) License for Selected Persons or Organizations.

Fee: \$30.00

Required Attachments

- Social Security Card A legible copy of the social security card is required.
- **Letter of Verification** A letter of verification summarizing the research and the need for controlled dangerous substance from the organization authorizing the research is required.
- **IRB Approval** When human test subjects are used, a copy of the approval from the Internal Review Board is required.
- **Prior Actions** If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation.
 - Certified copies of documents from relevant court or government agency.

Criminal Background Check: Upon receipt of the properly completed application, the Board will provide the applicant with materials necessary to perform a criminal history record check with the Louisiana State Police and the Federal Bureau of Investigation. Louisiana State Police and FBI may take 2-8 weeks to process the criminal background check depending on the method of submission the applicant selects. The CBC is waived for researchers employed by the State of Louisiana.

Board Review: A review of prior actions and criminal history is completed when all documents have been received and payment processed.

Inspection: In the event that there are no matters preventing the issuance, the applicant shall be instructed to contact the pharmacist compliance officer for that part of the state to arrange a site inspection at a mutually agreeable time.

Issuance: The credential will be issued at the conclusion of a successful inspection.



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New Louisiana Pharmacist License Requirements

Application: Application for New Louisiana Pharmacist License.

Age Requirement: 21

Fee: Examination / Score transfer - \$300.00 or License transfer - \$450.00.

Required Attachments:

- **Proof of Identity** Birth certificate, passport, or naturalization papers. Social Security Card. Legal documents for any name changes that have occurred.
- Photo. Passport style (head and shoulders only) photograph of the applicant.
- **Verifications** List of all professional credentials ever held. For each license listed, verification of licensure in another jurisdiction is required.
- **Prior Actions** If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation.
 - o Certified copies of documents from relevant court or government agency.
- **Electronic Business Request** Statement attesting that it is the applicants wish to conduct electronic business with the Board. This statement can be written or typed but must be signed by the applicant.
- Foreign Pharmacy Graduate Experience hours earned in Louisiana with a valid intern
 registration or hours of experience earned in other jurisdictions using the form supplied by the
 Board.

Criminal Background Check: The board will supply the applicant with materials necessary to perform a criminal background check (CBC) with the Louisiana State Police (LSP) and the Federal Bureau of Investigation (FBI). LSP and FBI may take 2-8 weeks to process the CBC depending on the method of submission the applicant selects. The CBC will be waived for applicants that have previously completed the requirement through this agency.

Board Review:

- **License Transfer** Application through the National Association of Boards of Pharmacy (NABP). This application will serve as evidence that the education and experience requirements have been met.
- Education The Board will verify educational requirements have been met through NABP.
 - A professional pharmacy degree awarded by a school or college of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE) is required.
 - Foreign pharmacy graduate shall hold a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate.
- **Experience** The Board will grant credit of the required 1,740 hours upon verification that the applicant has graduated from an ACPE-accredited school of pharmacy.
- **Examination** Successful completion of the North American Pharmacist Licensure Examination (NAPLEX) <u>and</u> the Multistate Pharmacy Jurisprudence Examination for Louisiana (MPJE-La). Applicants pursuing licensure through license transfer are not required to retake the NAPLEX.
- A review of prior actions and criminal history, is completed when all documents have been received and payment processed.



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New Pharmacy Intern Registration Requirements

Application: Application for New Louisiana Pharmacy Intern Registration.

Age Requirement: 18

Fee: \$50.00

Required Attachments:

- **Proof of Identity** Birth certificate, passport, or naturalization papers. Social Security Card. Legal documents for any name changes that have occurred.
- Photo Passport style (head and shoulders only) photograph of the applicant.
- **Verifications** List of all professional credentials ever held. For each license listed, verification of licensure in another jurisdiction is required.
- **Prior Actions** If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation
 - o Certified copies of documents from relevant court or government agency
- **Electronic Business Request** Statement attesting that it is the applicants wish to conduct electronic business with the Board. This statement can be written or typed but must be signed by the applicant.

Applicant Responsibility

• **Enrollment** – Any applicant enrolled in a College of Pharmacy outside of Louisiana should have the school submit proof of enrollment, on the school letterhead directly to the board.

Criminal Background Check: The board will supply the applicant with materials necessary to perform a criminal background check (CBC) with the Louisiana State Police (LSP) and the Federal Bureau of Investigation (FBI). LSP and FBI may take 2-8 weeks to process the CBC depending on the method of submission the applicant selects. The CBC will be waived for applicants that have previously completed the requirement through this agency.

Board Review:

- Option A For students enrolled in a school of pharmacy located in Louisiana, the school will
 automatically send the Board a roster of enrolled students. Students enrolled outside Louisiana,
 should request the administrative office of that school to send the confirmation of their enrollment
 directly to the Board office.
- Option B For students that have graduated from a school of pharmacy located in Louisiana, the school will automatically send the Board a Certification of Graduation. For students that have graduated from a school of pharmacy located outside the State of Louisiana, the transcript, confirming graduation, will be verified through NABP.
- **Option C** Students that have graduated from a foreign pharmacy school must hold a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate issued by NABP.
- A review of prior actions and criminal history is completed when all requirements have been met.





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New Pharmacy Technician Candidate Registration Requirements

Application Type – Online: Application for New Pharmacy Technician Candidate Registration.

Age Requirement: 18

Fee: \$50.00

Required Attachments:

- **Proof of Identity** Birth certificate, passport, or naturalization papers. Documents not in English must be translated by a professional translating service. Social Security Card. Legal documents for any name changes that have occurred.
- **Photo** Passport style (head and shoulders only) photograph of the applicant.
- **Verifications** List of all professional credentials ever held. For each license listed, verification of licensure in another jurisdiction is required.
- **Prior Actions** If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation.
 - o Certified copies of documents from relevant court or government agency.
- **Electronic Business Request** Statement attesting that it is the applicants wish to conduct electronic business with the Board. This statement can be written or typed but must be signed by the applicant.
- Eligibility for Credential -
 - Option A. proof of enrollment in a nationally-accredited and board-approved pharmacy technician training program.
 - Option B. Proof of successful completion of a high school approved by a state department of education or an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential AND proof of successful completion of a board-approved technician certification examination:
 - PTCB certificate dated 2000 or later OR
 - ExCPT certificate dated 01/01/18 or later should be submitted.

Criminal Background Check: The board will supply the applicant with materials necessary to perform a criminal background check (CBC) with the Louisiana State Police (LSP) and the Federal Bureau of Investigation (FBI). LSP and FBI may take 2-8 weeks to process the CBC depending on the method of submission the applicant selects. The CBC will be waived for applicants that have previously completed the requirement through this agency.

Board Review: A review of prior actions and criminal history, is completed when all documents have been received and payment processed.



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New Pharmacy Technician Certificate Requirements

Application: Application for New Pharmacy Technician Certificate.

Age Requirement: 18

Fee: \$100.00

Required Attachments

- **Proof of Identity** Birth certificate, passport, or naturalization papers. Documents not in English must be translated by a professional translating service. Social Security Card. Legal documents for any name changes that have occurred.
- Photo Passport style (head and shoulders only) photograph of the applicant.
- **Verifications** List of all professional credentials ever held. For each license listed, verification of licensure in another jurisdiction is required.
- **Prior Actions** If the applicant provided an affirmative response to any questions regarding prior actions:
 - Letter of explanation
 - o Certified copies of documents from relevant court or government agency
- **Electronic Business Request** Statement attesting that it is the applicants wish to conduct electronic business with the Board. This statement can be written or typed but must be signed by the applicant.
- **Evidence of Training** Based on option selected for issuance of PTC. Proof of practical or past experience must be documented on forms supplied by the board.
 - Option A: proof of completion document from the pharmacy technician training program.
 - Option B: evidence of at least 600 hours of practical experience earned in compliance with Board rules.
 - Option C: document a minimum of one year experience as licensed pharmacy technician in another US jurisdiction.
- Examination Proof of successful completion of one of the required examinations:
 - A PTCB certificate dated 2000 or later OR
 - o ExCPT certificate dated 01/01/18 or later should be submitted.

Criminal Background Check: The board will supply the applicant with materials necessary to perform a criminal background check (CBC) with the Louisiana State Police (LSP) and the Federal Bureau of Investigation (FBI). LSP and FBI may take 2-8 weeks to process the CBC depending on the method of submission the applicant selects. The CBC will be waived for applicants that have previously completed the requirement through this agency.

Board Review: A review of prior actions and criminal history, is completed when all documents have been received and payment processed.