

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8618 www.pharmacy.ca.gov



REMOTE DISPENSING SITE PHARMACY APPLICATION INSTRUCTIONS

The Board is authorized to issue a remote dispensing site pharmacy (RDSP) license that meets the criteria pursuant to Chapter 9, Division 2, Article 8 (section 4130, et seq.) of the Business and Professions Code.

IMPORTANT: Please follow these instructions completely. Failure to submit the necessary items will delay the processing of your application. <u>Please allow approximately 45 days from the date your application is</u> <u>submitted before checking on the status</u>. The contact person designated on the application will be advised if additional information is necessary.

Any application not completed within 60 days after being notified by the Board of deficiencies may be deemed abandoned, and the applicant will be required to file a new application and meet all the requirements in effect at the time of application. Fees applied to this application are not transferable or refundable.

A checklist is provided with these instructions. The Board encourages the submission of all required documentation with the application as well as the use of the checklist to assist with the application process. The Board may request additional documentation to confirm or substantiate information in the application. When submitting documents to the Board, please make a copy for your records.

A RDSP and supervising pharmacy shall be under common ownership located in California that is:

- exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified California licensed pharmacy technicians as defined in Business and Professions Code section 4132; and
- where pharmaceutical care services including, but not limited to, the storage and dispensing of prescription drugs and controlled substances, drug regimen review, and patient counseling are remotely monitored and/or provided by a licensed pharmacist using telepharmacy technology.

A RDSP shall comply with all state and federal laws regulating the practice of pharmacy. A RDSP shall only be located in a medically underserved area unless otherwise approved by the Board. For purposes of this section, a "medically underserved area" means a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site.

If a RDSP dispenses more than 225 prescriptions per day, calculated each calendar year, it must cease to be a RDSP and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy. The RDSP must notify the Board upon identifying it has dispensed more than 225 prescriptions per day, calculated in the calendar year, for consideration to become a full-service pharmacy.

CHECKLIST FOR FILING A REMOTE DISPENSING SITE PHARMACY APPLICATION

A RDSP license is nontransferable. All approved change of ownership and change of location applications will result in a new license number being issued. Operating the facility prior to a new license being issued is unlicensed activity and may result in disciplinary action by the Board.

- **Change of Ownership:** A change of ownership requires Board approval <u>before</u> the sale. A change of ownership application (form 17A-4) for the Supervising Pharmacy is required to be submitted in addition to this application.
- **Change of Location:** A change of physical location requires Board approval <u>before</u> the relocation.
- 1. Application Processing Fee is \$1,730. Include a check or money order made payable to the California State Board of Pharmacy. The application fee is nonrefundable.
 - To apply for a temporary license, an additional fee of \$890 must be submitted in addition to the application processing fee. If other than a change of ownership and/or location, include a written letter signed by the owner, partner, officer, member that clearly explains why it is in the best interest of the public for the Board to issue a temporary license. <u>This fee is</u> <u>nonrefundable.</u>
- **2.** Remote Dispensing Site Pharmacy Application (17A-106): Complete the entire application and submit with original signatures.
 - **Doing Business As (DBA):** If using a DBA, submit a Fictitious Business Name Statement if the dba is different than the supervising pharmacy.
- **3. Organizational Chart:** Include a business ownership organizational chart that clearly documents the applicant's business ownership structure. Include each level of ownership with corresponding percentage of ownership to the top tier, percentages owned by all parties, list the top five executive officers under the appropriate entity, and identify the pharmacist with the majority ownership including the percentage. If submitting a change of ownership application, include both the pre and post-closing organizational structures.
- 4. Lease Agreement/Grant Deed: Submit a copy of the signed lease agreement, including any amendments and/or extensions, or a copy of the grant deed.
- 5. Pharmacy Technician Experience Affidavit for a Remote Site Dispensing Pharmacy (17A-E10): Submit a completed Pharmacy Technician Experience Affidavit for a Remote Dispensing Site Pharmacy for each California licensed pharmacy technician listed on the application that will be employed at the RDSP with original signature. The RDSP shall only employ pharmacy technician(s) meeting the qualifications under Section 4132 pursuant to Business and Professions Code section 4131.

The RDSP must comply with having the required telepharmacy system installed and operating pursuant to the following Business and Professions Code section 4133.

(a) A telepharmacy system shall maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the RDSP's personnel and patients.
(b) A telepharmacy system shall facilitate adequate pharmacist supervision and allow the appropriate exchange of visual, verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs.

(c) Patient counseling shall be provided using audio-visual communication prior to all prescriptions being dispensed from a RDSP.

(d) A telepharmacy system shall be able to do all of the following:

(1) Identify and record the TCH preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription.

(2) Require a pharmacist to review and compare the electronic image of any new prescription presented at the RDSP with the data entry record of the prescription.

(3) Require the TCH to use barcode technology to verify the accuracy of the drug to be dispensed.

(4) Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing.

(5) Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery.

(e) The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191).

(f) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the RDSP and shall be maintained for three years after the filling of the prescription.

A RDSP license must be renewed annually, and the renewal date must be the same as the underlying supervising pharmacy license. The RDSP license must be canceled by operation of law if the underlying supervising pharmacy license is not current, valid, and active.



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REMOTE DISPENSING SITE PHARMACY LICENSE APPLICATION

Bus. & Prof. Code section 4130, et seq.

A Remote Dispensing Site Pharmacy (RDSP) is a licensed pharmacy located in California that is exclusively overseen and operated by a supervising pharmacy. Unless staffed by a pharmacist, a RDSP shall be staff by at least one qualified registered pharmacy technician. The RDSP where pharmaceutical care services, including, but not limited to, the storage and dispensing of prescription drugs and controlled substances, drug regimen review, and patient counseling, are remotely monitored or provided, or both, by a licensed pharmacist through the use of telepharmacy technology.

A RDSP is issued to the supervising pharmacy. The supervising pharmacy may not obtain more than one RDSP license. A RDSP must be located in a medically underserved area which is a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site. A RDSP may dispense no more than 225 prescriptions per day.

1. RDSP (Name of Pharmacy cannot exceed 65 characters including spaces)

| Name of RSDP as it will appear on the | License – may include DBA | | |
|--|--|--------------------------------------|-------------------|
| Legal Name of RDSP (if different from | above) | | |
| Address of RDSP Street | City | State | Zip Code |
| Telephone Number of RDSP | Email Address | | |
| . Type of Application: New Ch | nange of Location Change of Owner | ship of Supervis | ng Pharmacy |
| Temporary License Request | Anticipated Opening/Owne | rship Change/M | ove Date |
| contact person and any person who h owner of the applicant business. An a | discuss the status of this application with as signed the application as an officer, pa uthorized owner may designate addition on by submitting the Authorization to Rel o the contact person via email. | artner, member, al individuals to | and/or receive |

| Name of Contact Person | Telephone Number | Email Address | |
|------------------------|------------------|------------------|--|
| For Board Use ONLY | | Date Cashiered: | |
| Date Processed: | _ Date Issued: | Cashiering #: | |
| Processed by: | Issued by: | Amount Received: | |
| 17A-106(2/2020) | Page 1 of 4 | | |

4. Change of ownership/location of the RDSP Provide the exact name, address, and license number as listed on the current RDSP license. If a change of ownership, a change of ownership application (form 17A-4) for the Supervising Pharmacy is required to be submitted in addition to this application.

| Name listed on the Current RDSP License | RDSP License Number | | |
|---|---------------------|-------------------|-------------|
| Address: Street | City | State | Zip Code |
| Expiration Date of License | Effective Date of | Change of Ownersh | ip/Location |

5. Supervising Pharmacy The supervising pharmacy must not be located at a distance greater than 150 road miles from the RDSP. A supervising pharmacy means a licensed pharmacy in California that is owned and operated by a person or persons where the majority of the beneficial interest in, as well as the management and control, resides with at least one Board licensed pharmacist that exclusively oversees the operations of a RDSP. Please note: If the supervising pharmacy is not currently licensed with the California State Board of Pharmacy, also complete and submit a Community Pharmacy License Application along with the required fees.

| Name of Supervising Pharmacy as it appears on the License | | License Number and Expiration Da | |
|---|---------------------------|----------------------------------|------------|
| Location of Supervising Pharmacy Street | City | State | Zip Code |
| Telephone Number of Supervising Pharmacy | Email Address | | |
| 6. Type of Ownership | | | |
| Is the supervising pharmacy and the RDSP und | ler common ownership? | | |
| Yes No If yes, please identify the type | e of ownership. | | |
| Individual Partnership Nonpro | ofit Corporation Clo | se Corporation LL | C Trust |
| | | | |
| Name of Board License Pharmacist with Major | rity Ownership | Pharmacist Lice | nse Number |
| Telephone Number of Pharmacist | Email Address | | |
| 7. Location of RDSP | | | |
| A. Is the RDSP located in a medically underse | erved area? | | Yes No |
| B. Is the supervising pharmacy located 150 r | | ie RDSP? | _Yes No |
| Provide the number of road miles the RDS | SP will be from the super | vising pharmacy. | |

8. Pharmacy Technician(s)

List the name(s) of the pharmacy technician(s) (TCH) that will be employed at the RDSP and confirm each TCH has met the requirements as defined in Business and Professions Code section 4132. Attach a completed Pharmacy Technician Experience Affidavit for a Remote Dispensing Site Pharmacy (form 17A-E10) for each TCH listed below.

| Name of TCH | TCH License Number | Satisfied §4132 |
|-------------|-----------------------|-----------------|
| | | YesNo |
| | | Yes No |
| | | YesNo |

- **9. RDSP Telepharmacy System Compliance** Is the RDSP compliant in having the required telepharmacy system installed and operating pursuant to Section 4130, et seq., of the Business and Professions Code?
 - ____ Yes ____ No

I, as the Pharmacist-in-Charge (PIC), have read and understood Business and Professions Code section 4130. Initial Date

I, as the pharmacist with majority ownership, have read and understood Business and Professions Code section 4130.

Initial _____ Date _____

10. Pharmacist-in-Charge List the designated PIC of the supervising pharmacy. The PIC of the supervising pharmacy shall also serve as the designated PIC at the RDSP.

Name of PIC

Pharmacist License Number

Telephone Number of RDSP

Email Address

Certification:

I certify that I have read and reviewed this application and will comply with the requirements of Business and Professions section 4130, et seq. as the PIC of the supervising pharmacy and the RDSP.

I certify that, the California licensed TCH(s) employed at the RDSP, have met the requirements pursuant to Section 4132 of the Business and Professions Code.

Signature of PIC

Print Name

Date

APPLICANT AFFIDAVIT

This application must be approved by the California State Board of Pharmacy before a RDSP will be issued. The applicant RDSP shall not conduct business in California until a license is issued. If changes are made during the application process, the applicant may need to submit a new application with appropriate fees. Any application not completed within 60 days after being notified by the board of deficiencies may be deemed to have been abandoned, and the applicant will be required to file a new application and meet all the requirements that are in effect at the time of application. Fees applied to this instant application are not transferable or refundable. Failure to provide any of the requested information may result in the application being considered incomplete. Any material misrepresentation in the answer of any question is grounds for denial or subsequent revocation of the license and is a violation of the California Penal Code.

The information will be used to determine qualifications for licensure under the California Pharmacy Law. The official responsible for information maintenance is the executive officer of the Board. The information may be transferred to another governmental agency, such as a law enforcement agency, if necessary, to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential and exempted by Civil Code section 1798.38.

A RDSP license shall be renewed annually, and the renewal date shall be the same as the supervising pharmacy license. The RDSP license must be canceled by operation of law if the supervising pharmacy license is not current, valid, and active. If a RDSP dispenses more than 225 prescriptions per day, calculated each calendar year, it must cease to be a RDSP and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy. The RDSP must notify the Board immediately upon identifying it has dispensed more than 225 prescriptions per day and request consideration to become a full-service pharmacy.

REQUIRED SIGNATURES – Provide original signature.

Under penalty of perjury under the laws of the State of California, the person whose signature appears below, certifies compliance with California Pharmacy Law and says:

- 1. The pharmacist with majority ownership of the applicant remote dispensing site pharmacy and supervising pharmacy named in the foregoing application, is duly authorized to make this application on its behalf and is at least 18 years of age.
- 2. Has read the foregoing application and knows the contents thereof and that each and all statements therein made are true.
- 3. No person other than the applicant or applicants has any direct or indirect interest or management and control in the applicant pharmacy business to be conducted under the license for which this application is made.
- 4. Understands that falsification of any information in this application may constitute grounds for denial or subsequent discipline of the license.
- 5. All supplemental statements are true and accurate.
- 6. A change of ownership application may be withdrawn by either the applicant or the licensee with no resulting liability to the California State Board of Pharmacy.



PHARMACY TECHNICIAN EXPERIENCE AFFIDAVIT FOR A REMOTE DISPENSING SITE PHARMACY

This form must be completed by the licensed California pharmacy technician (TCH). A TCH must satisfy each of the following requirements pursuant to Business and Professions Code section 4132 prior to working in a Remote Dispensing Site Pharmacy (RDSP).

- (1) Possess a TCH license that is in good standing.
- (2) Possess and maintain a certification issued by an approved TCH certifying program.
- (3) Possess one of the following:

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- (A) A minimum of an associate degree in pharmacy technology;
- (B) A minimum of a bachelor's degree in any subject; or
- (C) A certificate of completion from a course of training specified in Title 16, California Code of Regulations section 1793.6.

(4) Complete a minimum of 2,000 hours of experience working as a TCH within the two years preceding first commencing work in the RDSP.

This is to certify that I have met the following requirements in section A and B prior to working at an RDSP.

A. I meet all of the following requirements. (Please initial or check the requirements you have met.)

- Possess a California TCH license that is in good standing. TCH License Number _
- Possess and maintain a certification issued by an approved TCH certifying program. The Board approved certifying programs are: Pharmacy Technician Certification Board (PTCB) and certifications dated on or after January 1, 2017 from the National Healthcare Association Pharmacy Technician Certification Program (ExCPT).

Name of TCH certifying program: _____ Certification Number: ____

- Completed a minimum of 2,000 hours of experience working as a TCH within the two years preceding first commencing work in the RDSP.
- B. I have completed at least one of the following. (Please initial or check the requirement you have completed.)
- A minimum of an associate degree in pharmacy technology
- _____ A minimum of a bachelor's degree in any subject
- _____ Complete a course of training specified in Title 16, California Code of Regulations section 1793.6.

I certify under penalty of perjury under the laws of the State of California that all statements given on this form herein are true, and that I meet the requirements as required by law. I further certify that as a California licensed pharmacy technician my license was not revoked, suspended, or on probation in the state during the time my work experience was gained to meet the requirements of Business and Professions Code section 4132 to qualify to work in a RDSP. I understand that an application may be denied, or any license disciplined, for fraud or misrepresentation.

Printed Name of TCH

Signature