

Date of Hearing: April 4, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Rudy Salas, Chair

AB 401 (Aguiar-Curry) – As Amended March 21, 2017

SUBJECT: Pharmacy: remote dispensing site pharmacy: telepharmacy.

SUMMARY: This measure authorizes a remote dispensing site pharmacy to use a telepharmacy system, and would require the Board of Pharmacy (Board) to issue a remote dispensing site pharmacy license; requires a remote dispensing site pharmacy to be located in a medically underserved area; authorizes a pharmacist to serve as a supervising pharmacist to provide telepharmacy services for up to 2 remote dispensing site-pharmacies; authorizes a licensed remote dispensing site pharmacy to order dangerous drugs and devices and controlled substances and authorizes a registered pharmacy technician to receive and sign for the delivered order; authorizes a registered pharmacy technician to work at a remote dispensing site pharmacy and to perform tasks under the supervision of a pharmacist using a telepharmacy system; and, authorizes a pharmacist at a supervising pharmacy to supervise up to 2 pharmacy technicians at each remote dispensing site pharmacy in addition to any pharmacy technicians being supervised at the supervising pharmacy.

EXISTING LAW:

- 1) Establishes the Board within the Department of Consumer Affairs, to regulate the practice of pharmacy (Business and Professions Code (BPC) § 4000 et seq.)

THIS BILL:

- 1) Defines “Remote dispensing site pharmacy” as a licensed pharmacy located in this state that is operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians 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.
- 2) Defines “Supervising pharmacy” as a licensed pharmacy located in this state that oversees the activities of a remote dispensing site pharmacy.
- 3) Defines “Telepharmacy” as a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs and provides for related drug regimen review and patient counseling by an electronic method, including, but not limited to, the use of audio, visual, still image capture, and store and forward technology.
- 4) Provides that dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician at the remote site.

- 5) Requires that a controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist.
- 6) Specifies that the receipt and storage of a controlled substance by a pharmacy technician under this section shall be maintained on video that is accessible to the supervising pharmacy and shall be maintained for 90 days.
- 7) Provides that a telepharmacy system may be used for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at a remote dispensing site pharmacy.
- 8) Directs the Board to issue a remote dispensing site pharmacy license for the purpose of increasing access to dispensing or pharmaceutical care services in the geographic area in which the site is to be located.
- 9) Specifies that a remote dispensing site pharmacy 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.
- 10) Indicates if a pharmacy serving the general public is later established within 10 road miles of a remote dispensing site pharmacy, the remote dispensing site pharmacy may continue to operate.
- 11) Specifies that a remote dispensing site pharmacy shall only be staffed by pharmacists or pharmacy technicians, or both, and shall not employ any unlicensed personnel.
- 12) Permits a pharmacy located in this state to serve as a supervising pharmacy to provide telepharmacy services for up to two remote dispensing site pharmacies.
- 13) Specifies that a supervising pharmacy shall not be located greater than 150 road miles from a remote dispensing site pharmacy, unless otherwise approved by the board.
- 14) States that a supervising pharmacy and remote dispensing site pharmacy shall be under common ownership.
- 15) Provides that if a supervising pharmacy and a remote dispensing site pharmacy are not under common ownership, the supervising pharmacy and remote dispensing site pharmacy shall enter into a written contract or agreement that specifies the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement, consistent with all federal and state laws.
- 16) Requires, that unless staffed by a pharmacist, a remote dispensing site pharmacy shall be staffed by at least one registered pharmacy technician. A technician shall remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. Direct supervision and control does not require the pharmacist to be physically present at the remote dispensing site pharmacy, but

the pharmacist shall use a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy.

- 17) Permits a pharmacist to serve as the pharmacist-in-charge for no more than two remote dispensing site pharmacies in addition to serving as pharmacist-in-charge of a supervising pharmacy.
- 18) Specifies that the pharmacist-in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy shall be responsible for ensuring that both the supervising pharmacy and remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.
- 19) Requires that a pharmacy technician working at a remote dispensing site pharmacy shall have both of the following:
 - a) At least one year of experience in the past three years working in retail pharmacy practice.
 - b) Completed a documented training program on proper use of the telepharmacy system at the remote dispensing site pharmacy.
- 20) Permits a registered pharmacy technician to perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.
- 21) Specifies that a pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:
 - a) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.
 - b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
 - c) Identify, evaluate, or interpret a prescription.
 - d) Interpret the clinical data in a patient medication record system or patient chart.
 - e) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.
 - f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.
 - g) Perform any function that requires the professional judgment of a licensed pharmacist.

- 22) Allows a pharmacist at a supervising pharmacy to supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.
- 23) Requires that a telepharmacy system shall maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients.
- 24) Requires that 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.
- 25) States that patient counseling shall be provided using audio-visual communication for all prescriptions dispensed from a remote dispensing site pharmacy.
- 26) Requires that a telepharmacy system shall do all of the following:
 - a) Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription.
 - b) Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription.
 - c) Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed.
 - d) 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.
 - e) 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.
- 27) States that 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.
- 28) Requires that all records of prescriptions dispensed shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription.
- 29) Specifies that a pharmacist from the supervising pharmacy shall complete a monthly in-person, self-inspection of each remote dispensing site pharmacy using a form designated by the board and shall retain all inspection reports.
- 30) Requires a perpetual inventory shall be kept for all controlled substances stored at a remote dispensing site pharmacy.

- 31) Requires all controlled substances at a remote dispensing site pharmacy to be stored in a secure cabinet or safe that is locked.
- 32) Specifies that a pharmacist from the supervising pharmacy shall perform inventory and inventory reconciliation functions at a remote dispensing site pharmacy to detect and prevent the loss of any controlled substance.
- 33) Requires the pharmacist-in-charge of a remote dispensing site pharmacy to review all inventory and inventory reconciliation reports taken and to establish and maintain secure methods to prevent losses of any controlled substance. The board shall develop written policies and procedures for performing the inventory reconciliation reports required by this section.
- 34) Requires a pharmacist from the supervising pharmacy to compile an inventory reconciliation report of all Schedule II controlled substances at a remote dispensing site pharmacy at least once every three months. This compilation shall require all of the following:
 - a) A physical count, not an estimate, of all quantities of Schedule II controlled substances at the remote dispensing site pharmacy. The biennial inventory of controlled substances as required under federal law may serve as one of the mandated inventories under this section in the year that the federal biennial inventory is performed, provided that the biennial inventory was taken no more than three months from the last inventory required by this section.
 - b) A review of all acquisitions and dispositions of Schedule II controlled substances since the last inventory reconciliation report.
 - c) A of inventory reports to determine if there are any variances.
 - d) All records used to compile each inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.
- 35) Requires a remote dispensing site pharmacy to report to the board, in writing, any identified losses of controlled substances and possible causes of the loss within 30 days of discovering the loss unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss. If the remote dispensing site pharmacy is unable to identify the cause of the loss, the remote dispensing site pharmacy shall undertake further investigation to identify the cause of the loss and security improvements necessary to prevent any additional losses of controlled substances.
- 36) Specifies that causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.
- 37) Requires that the inventory reconciliation report shall be dated and signed by the individual or individuals performing the inventory and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy. A countersignature shall not be required if the pharmacist-in-charge personally completed the inventory reconciliation report. The inventory

reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

- 38) Requires a remote dispensing site pharmacy shall utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.
- 39) Specifies that unless a pharmacist is present at the remote dispensing site pharmacy, a remote dispensing site pharmacy shall not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system shall allow for tracking of entries into the remote dispensing site pharmacy and the pharmacist-in-charge shall periodically review the record of entries.
- 40) Requires that the remote dispensing site pharmacy shall retain a recording of facility surveillance, excluding patient communications, for a minimum of 90 days.
- 41) Makes findings and declarations.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. This bill is sponsored by the author. According to the author, “A pharmacist is a critical member of a comprehensive healthcare team. However, there are approximately 115 designated communities in 47 California counties that do not have access to a pharmacist within 10 miles. For people living in these communities, visiting a pharmacist can mean up to a 90 mile drive. This is a significant barrier to accessing quality healthcare services. Authorizing remote dispensing pharmacies to operate throughout the state in these medically underserved communities provides opportunities for better patient education, increased medication adherence, and better health outcomes.”

Background. *Pharmacist Practice and Regulation.* Pharmacists are healthcare professionals who understand the biochemical mechanisms and actions of drugs, drug uses, therapeutic roles, side effects, potential drug interactions, and monitoring parameters. Pharmacists provide counseling on the appropriate use and effects of prescribed drugs. Pharmacists must obtain the Doctor of Pharmacy degree before they are eligible to sit for the North American Pharmacist Licensure Examination (NAPLEX) to enter into pharmacy practice (Accreditation Council for Pharmacy Education, *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*, 2011).

In 2014, the United States Bureau of Labor Statistics reported that there were 297,100 pharmacist jobs. The majority (65 percent) of those pharmacists work in retail settings, about 22 percent work in hospitals, and the remainder work in mail-order or Internet pharmacies, pharmaceutical wholesalers, physicians’ offices, and for the Federal Government (US Bureau of Labor Statistics. *Occupational Outlook Handbook*, 2010–11). In California, pharmacists are regulated by the State Board of Pharmacy. There are 42,691 pharmacists and 70,624 pharmacy technicians with active licenses in the state.

Regulation of Pharmacies. There are 7081 pharmacies regulated by the Board. Of these, 513 are hospital pharmacies. The Board reported it also regulates 506 non-resident pharmacies which are generally including mail order pharmacies. The board has additional licenses for those pharmacies that perform sterile compounding and are located in California (890) and ship into CA from another state (91). The Board does not currently regulate remote dispensing pharmacies.

Telehealth and Telepharmacy. In 2011, California passed the Telehealth Advancement Act. This Act updated the state's definition of telehealth, simplified approval processes for telehealth services, and expanded the range of medical services that may be provided via telehealth. The law establishes legal parity between the direct and remote delivery of pharmacy care.

Telepharmacy is the delivery of pharmaceutical care via telecommunications to patients in locations where they may not have direct contact with a pharmacist. Services may include drug therapy monitoring, patient counseling, authorization for prescription drugs, and monitoring of formulary compliance utilizing teleconferencing or videoconferencing. Telepharmacy may also include remote dispensing of medications by automated packaging and labeling systems.

Other States and Jurisdictions. Implementation of telepharmacy began in the 2000s in response to myriad factors including changes in Medicare reimbursement rates and the recession. The impact of these changes was a significant decline in independent pharmacies in rural areas. To date, 20 states have passed legislation to permit telepharmacy. North Dakota was the first state to implement telepharmacy regulations, and the United States Navy operates the largest telepharmacy program.

This measure would authorize the Board to issue remote dispensing pharmacy licenses for facilities that connect a licensed pharmacist to patients using a telepharmacy system. Approximately 115 underserved communities, as defined as having no pharmacist within a 10 mile radius, across 47 different counties would be eligible to receive services via this measure. The remote dispensing pharmacy would be staffed by a registered pharmacy technician, who meets additional training criteria, and would be supervised virtually by a licensed pharmacist at a separate location. The pharmacist-in-charge is required to be located at a traditional pharmacy within 150 miles and four hours of the remote dispensing pharmacy. This measure also establishes minimum standards for the remote dispensing location in order to ensure safety and quality control. These include standards for the telepharmacy technology, security requirements, and processes for ordering, stocking, and recording different types of drugs.

ARGUMENTS IN SUPPORT:

The California Pharmacists Association supports the bill and writes, “Through utilizing telepharmacy technology, pharmacists will be able to provide counseling to patients when they pick up their prescriptions at the remote dispensing pharmacy in medically underserved areas. The ability for patients to access the services of a community pharmacy is essential in ensuring continuity of care and adherence to directions given by prescribing physicians.”

Cardinal Health writes in their letter of support, “Access to prescription medications and pharmacist consultations in settings that are convenient to California citizens will improve healthcare for your constituents. Cardinal Health is committed to supporting thoughtful land

effective legislation that aligns with our mission of making healthcare safer and more cost effective.”

REGISTERED SUPPORT:

California Pharmacists Association
Cardinal Health

REGISTERED OPPOSITION:

None on file.

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