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New Laws That Expand The Role Of The Pharmacist In Patient Care

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Abstract

California Senate Bill 493 (SB 493), signed into law on October 1, 2013, marked the recognition of California pharmacists as health care providers, and also enumerated various authorities for pharmacists to provide direct health care services to patients. This article reviews the history of laws enacted which have afforded pharmacists opportunities to provide a variety of direct patient care services, and addresses the most recently implemented statewide protocols authorizing pharmacist involvement in direct patient care designated under SB 493.

Introduction

Over the last 30 years in California and throughout the country, our profession has witnessed an evolution of laws encouraging pharmacists to become more engaged in direct patient care responsibilities. One of the earliest, California Business and Professions Code Section 4103 (Cal. Bus. & Prof. Code § 4103) was introduced in the **1980**s and authorized a pharmacist to take a patient's blood pressure, to inform the patient whether the reading falls "within a high, low, or normal range," and as necessary to advise the patient to consult their physician of choice.[1] Section 4103 further requires a pharmacist who provides blood pressure services to use "commonly accepted community standards in rendering opinions and referring patients to physicians." [1]

In the early 1990s, Congress passed the federal Omnibus Budget Reconciliation Act of 1990 (OBRA '90), which for the first time advanced an *expectation* of pharmacists extending beyond simple oversight of drug distribution and including, or rather, *requiring pharmacists to be involved in both detection and resolution of problems with drug therapy*. [2] As the first federal law to directly regulate the pharmacy profession, OBRA '90 effectively changed the manner in which pharmacy would thereafter be practiced. [2] Congress aimed to save the federal government money on its medication-related budget expenditures, because OBRA '90 required states to establish standards of drug review and patient consultation in order to continue receiving federal funds for their Medicaid patients, thereby effectuating a direct impact on pharmacy practice. [2] Since 1990, most states, including California, have also adopted their own similar regulations through individual state pharmacy practice acts which have extended OBRA's provisions to all patients, not only Medicaid patients. [1] [2]

OBRA '90 laid the foundation for the pharmacist's duty to provide patient consultation in California Code of Regulations Section 1707.2 (CCR § 1707.2) ("consultation law"). [3] The duty to consult under CCR Section 1707.2 crossed the line from *encouraging pharmacists to participate in direct patient care services to mandating their participation*. [3] CCR Section 1707.2 *mandates* a California pharmacist to provide verbal consultation to a patient under four circumstances: (1) whenever a new prescription has not been previously dispensed to that patient; (2) whenever a prescription drug has not been previously dispensed to a patient in the same dosage form, at the same strength, or with the same written directions; (3) whenever the pharmacist, in the exercise of his or her professional judgment, finds it necessary to consult with the patient; and (4) upon request by the patient. [3] The duty to consult mandates that the patient be properly informed on (a) how to use the medication; (b) the importance of complying with the directions on the label; (c) how to store the medication; and (d) the common severe adverse drug actions and interactions. [3]

Notably, when the consultation law first came into effect, a large contingent of practicing community pharmacists were unhappy because they believed that Section 1707.2 requirements directly interfered with the time required for pharmacists working in the community to complete their routine prescription processing workflow. Thus, community pharmacists initially viewed the law

as a burden. [3] Over time, however, the consultation law has become perhaps one of the most important patient care laws in existence, because it affords the pharmacist an opportunity to ensure that patients understand the importance of compliance, as well as the benefits and risks associated with the medications they use. The public at large has also come to recognize the value of the pharmacist's consultation as a significant benefit to patients. In fact, patients generally appreciate, expect, and often pursue the pharmacist's expertise to serve their individual health care needs.

Subsequently, the reach of the consultation law under CCR Section 1707.2 was extended to include, in addition to patient consultation, new requirements for review and maintenance of individual patient medication profiles in CCR Sections 1707.1 and 1707.3, respectively ("medication profile law").[3][4] When properly followed, the medication profile law promotes comprehensive review of a patient's past medication history in the context of a newly presented prescription, a review that is intended to ensure medication compliance and to facilitate detection of, and avoid any possible incompatibilities or drug interactions. [4] A patient's medication profile routinely contains historical information about their individual drug history and medical conditions or problems being treated, and thus serves as a platform for "drug utilization review" (DUR). [4] A patient's medication profile can also alert the pharmacist to potential allergies, contraindications, and even possible intentional or unintentional medication misuse and abuse patterns. [4]

The early 1990s saw further "expanded scope of practice" laws with CCR Sections 4052.1 and 4052.2, which aimed specifically at appropriately trained pharmacists who practiced in licensed health operations such as, for example, skilled nursing facilities, where physicians were not readily available. [5] Under the "*expanded scope of practice*," a pharmacist working in specific practice contexts could perform specified patient care tasks *pursuant* to a *designated prescriber's* (*or prescriber-group's*) *well-defined protocol*. [5] Sections 4052.1 and 4052.2 authorized a pharmacist practicing in those contexts to: a) order or perform routine drug therapy-related patient assessment procedures, including taking temperatures, pulse rates, and respiration measurements; b) order drug therapy-related laboratory tests; c) administer drugs and biologicals by injection; and d) initiate and adjust the drug regimens for a patient. [6] Since that time, the expanded scope of practice has been extended to all types of pharmacy patient care venues (e.g., hospitals, community, and clinics) as long as there is a prescriber-directed protocol which supports it. [6]

From a historical perspective, Sections 4052.1 and 4052 initially expanded the pharmacist's scope of practice, opening the door for subsequent laws, and served as the springboard for introduction of California Senate Bill 493 (SB 493) in February 2013 by State Senator Ed Hernandez. [7] Shortly thereafter, SB 493 passed in both the California Assembly and Senate and was ultimately signed into law by Governor Jerry Brown on October 1, 2013. [7] For the first time in California, SB 493 recognized pharmacists as health care providers (hence the moniker "California provider status law") with the authority to provide direct health care services to patients.[7] A host of other laws enacted over the past 25 years have also afforded pharmacists opportunities to provide a variety of direct patient care services, including (a) performing skin punctures to test for glucose and cholesterol levels (Cal. Bus. Prof. Code § 4052.4); [8] (b) providing immunizations (Cal. Bus. Prof. Code § 4052.8); [9] and (c) furnishing emergency contraceptive therapy (Cal. Bus. Prof. Code § 4052.3). [10] Cal. Bus. Prof. Code § 4052.3, the first of those authorities listed in SB 493, was enacted April 1, 2013, and followed by the protocols for emergency contraception in the California Code of Regulations § 1746 (CCR § 1746) implemented effective July 1, 2013. [11]

Since the passage of SB 493, the California Board of Pharmacy has developed implementation regulations to support the expanded areas of pharmacist involvement in patient care designated under SB 493. [12] This article provides a discussion of the recent laws allowing new opportunities for pharmacists who want to take the next steps required for any of the various expanded pharmacist patient care practices, such as (a) recognition as an Advanced Practice Pharmacist (APP) (Cal, Bus. & Prof. Code §§ 4210, 4052.6); (b) authority to continue to initiate and administer vaccines (Cal. Bus & Prof Code § 4052.8; CCR § 1746,4); (c) authority to furnish the drug naloxone for suspected opioid intoxication without a prescription (Cal. Bus, & Prof. Code § 4052.01; CCR § 1746.3); (d) authority to furnish hormonal contraception in addition to emergency oral contraception (CCR § 1746.1; Cal. Bus. & Prof. Code 4052.3); (e) authority to furnish nicotine replacement products (CCR § 1746.2); and/or (f) authority to furnish prescription travel medications which do not require a diagnosis and are recommended by the Centers for Disease Control and Prevention (CDC) for individuals traveling outside the United States (Cal. Bus. & Prof. Code § 4052.9; CCR § 1746.5).[13]

The discussion below references provisions contained within California Business and Professions Code Chapter 9, Division 2, Article 3 on Scope of Practice and Exemptions, and Title 16 of the California Code of Regulations, Article 3.5 on Advanced Practice Pharmacist, Article 5 on Dangerous Drugs, and Article 6 on Fees.

Advanced Practice Pharmacist Designation

Advanced Practice Pharmacist (APP) status is a classification limited to licensed pharmacists recognized by the Board of Pharmacy as having the requisite training and skills to provide specifically defined direct patient care services within or outside of a licensed pharmacy.[14]

A board-recognized Advanced Practice Pharmacist may: (a) perform patient assessments; (b) order and interpret drug therapy-related tests; (c) administer vaccines and immunization products; (d) administer epinephrine or diphenhydramine by injection for the treatment of severe allergic reactions; (e) participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and (f) initiate, adjust, or discontinue drug therapy as part of the evaluation and management of patients' diseases and health conditions. [15]

Licensure requirements for consideration as an Advanced Practice Pharmacist (APP) are found in Cal. Bus. & Prof. Code Section 4210, and effective December 13, 2016, APP certification, application, and fee requirements are found in Title 16, California Code of Regulations Sections 1730, 1730.1, and 1749; while effective August 10, 2016, criteria for APP certification programs are found in CCR Section 1730.2. [12] Moreover, to apply for APP status, a pharmacist must have an active license in good standing with the California Board of Pharmacy and must meet at least two of the following requirements:

(1) Possess certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board. [16]

(2) Completed a postgraduate residency in the US through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams. [16]

(3) Provided clinical services to patients (within 10 years of application) for at least one year (1,500 hours) under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system, where such clinical experience included initiating, adjusting, modifying, or discontinuing drug therapy of patients. [16]

Certification as an Advanced Practice Pharmacist (APP) shall be valid for a two-year term which runs concurrent with the certificate holder's license to practice pharmacy in California. [17]

In addition to satisfying Cal. Bus. & Prof. Code Section 4210 (a) (2) and California Code of Regulations Sections 1730, 1730.2 (a) requirements,[18] APP certification programs must also satisfy other criteria under Title 16, California Code of Regulations Sections 1730.2 (b) (1) through (5), [19] which provide:

(1) "The certification program includes specified learning objectives in at least five sequentially ordered education modules covering the following topics: performing patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying, or discontinuing drug therapy.

(2) The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant's understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module.

(3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either an Advanced Practice Pharmacist licensed by the board or an expert with experience in the respective area(s) above who is qualified to teach at a school of pharmacy recognized by the board.

(4) The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification.

(5) The certification program require(s) a minimum of 10 hours of continuing education on the topics identified above every two years to maintain certification. This is in addition to the 30 hours of continuing education required every two years." [19]

New Laws Promoting Direct Patient Care Services Delivered by Pharmacists

Pharmacists Initiating and Administering Vaccines

CCR Section 1746.4 provides the state protocol for

and requires the pharmacist to be certified in: a) administering immunization products by an approved and accredited program; b) administering basic life support, and c) completion of two hours of continuing education every two years. [20] Under CCR Section 1746.4, a pharmacist is responsible to maintain documentation of the patient's vaccination, and to provide certain notifications, including to provide a copy of the vaccine administration record to the patient and to the patient's primary care provider within 14 days of any vaccine administered; or alternatively, to enter the appropriate information in a patient record system shared with the primary care provider. [20]

In addition, CCR Section 1746.4 requires the pharmacist to report the patient's vaccination information to one or more state and/or local immunization information systems within 14 days of the administration of such vaccine and to inform the patient of the vaccine information shared with others. [20]

Pharmacists Furnishing Naloxone Hydrochloride

CCR Section 1746.3, effective on January 27, 2016, provides the statewide protocol for pharmacists furnishing naloxone hydrochloride. [21] CCR Section 1746.3 has a training requirement as well, and pursuant to Section 4052.01, authorizes the appropriately trained pharmacist to furnish naloxone hydrochloride to patients or others seeking help to treat or prevent an opioid overdose. [21] Regardless of the dosage form furnished, whether injectable or nasal naloxone, pursuant to CCR Section 1746.3, the following conditions must be satisfied:

(1) Training (a minimum of one hour of board-approved continuing education specific to the use of naloxone or an equivalent curriculum-based program completed in a school of pharmacy).

(2) Screening each potential naloxone recipient with a series of standardized questions to ascertain the individual's history of opioid use and any possible problems that might arise from the use of the opioid product.

(3) Providing the naloxone recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(4) Providing the naloxone recipient with appropriate counseling and information regarding the naloxone, with the recipient not being allowed to waive the consultation.

(5) Providing the naloxone recipient with informational resources involving referrals to where they may seek further help regarding addiction.

(6) Providing the recipient's physician notice of any drug or device furnished. If the recipient does not have a primary care provider or chooses not to give notification consent, then the pharmacist shall provide a written record of the naloxone issued to a health care provider the recipient chooses at a later date.

(7) Maintaining documentation in a medication record for the naloxone recipient to be kept in the pharmacy for a three-year period.

(8) Maintaining all recipients' naloxone records in privacy, as will be noted in the pharmacy's policy and procedures. [21]

Pharmacists Furnishing Hormonal Contraception

As discussed above, an earlier provision, Cal. Bus. & Prof. Code Section 4052.3, [10] [11] previously authorized the pharmacist to furnish emergency oral contraceptives. Effective April 8, 2016, CCR Section 1746.1 authorizes a specially trained pharmacist to also furnish patients with monthly regimens of contraceptive agents. (22) Similar to the other pharmacist-directed patient care protocols, requirements for furnishing self-administered hormonal contraception include:

(1) Furnishing of a hormonal contraceptive agent must be in accordance with a protocol approved by the Board of Pharmacy and the Medical Board of California.

(2) The hormonal contraceptive may be in a variety of dosage forms that include oral, transdermal, vaginal, or by depot injection.

(3) Steps the pharmacist must follow when furnishing a contraceptive:

   (a) Requiring the patient to complete a self-screening tool (22-response standardized questionnaire) and review the responses to gain insight about any potential negative history or current problems the patient may be experiencing that may possibly prevent the product from being furnished. If the patient is to be continued on the hormonal contraceptive agent, the patient must complete a new questionnaire each year, or whenever the patient indicates a major health change.

   (b) Measuring and recording the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.

   (c) Ensuring that the patient is counseled and appropriately trained in the administration of the contraceptive drug.

   (d) Providing the patient with a medication guide on hormonal contraceptives. [22]

The self-screening tool completed by the patient, as well as other records concerning the individual furnished with a hormonal contraceptive, must be kept for a three-year period from the last entries on any such records.[22] Based on answers to the self-screening survey, and further questioning of the patient, the pharmacist should determine whether it is appropriate to furnish or not furnish the hormonal contraceptive agent. [22] If furnished, the pharmacist must notify the patient's primary care provider that a contraceptive product was provided. [22] In the event the patient does not have a primary care provider, the pharmacist must provide the patient with a written record of the contraceptive agent furnished, and advise the patient to consult with a health care provider of their choice. [22] Selection of a specific hormonal contraceptive product must be from a Board of Pharmacy approved list, and provided in accordance with the state protocol. [22] To be recognized as a furnisher of hormonal contraceptives, the pharmacist must successfully complete a minimum of one hour of a Board-approved continuing education program covering basics of furnishing hormonal contraceptive agents. [22]

Pharmacists Furnishing Nicotine Replacement Products

Under CCR Section 1746.2, a pharmacist furnishing prescription-form nicotine replacement products must comply with a protocol approved by the California Board of Pharmacy and the Medical Board of California. [23] When furnishing a nicotine replacement product, the pharmacist is required to develop and maintain a record of the patient's response to certain key questions on their individual history and use of tobacco products, such as: (a) review of current use; (b) status of being or planning to be pregnant; and (c) general questions about the patient's health, and in particular questions about cardiovascular diseases or disorders. [23] In order to furnish such products, the pharmacist must follow the enumerated policies and procedures associated with prescription nicotine replacement products. [23]

Since these products come in a variety of forms (gum, lozenges, patches, nasal sprays, and inhalers), the pharmacist's judgment in making recommendations concerning nicotine replacement products is invaluable. Similar to other pharmacist patient care protocols, when a prescription nicotine replacement product is provided to the patient, the pharmacist must notify the patient's primary care provider of the product furnished. [23] If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug provided, advise the patient to consult a health care provider, and make the information given to the patient also available to the health care provider. [23]

The pharmacist is further required to complete a minimum of two hours of an approved continuing education course every two years which focuses on smoking cessation therapy and nicotine replacement therapy. [23]

Pharmacists Furnishing Travel Medications

The Board of Pharmacy has also proposed the addition of CCR Section 1746.5 to extend a pharmacist's scope of practice to travel medications. [24] The final proposed regulation text for CCR Section 1746.5 is currently pending in the Office of Administrative Law (OAL), and consistent with ordinary rulemaking procedures, once the text is approved by OAL, the regulation shall become effective on the first day of the following quarter, unless the board requests and is granted an earlier effective date by OAL.[25] Section 1746.5, as proposed, will permit specially trained pharmacists to furnish travel medications to patients traveling outside the United States, and since the provision has not yet been finalized, the associated implementation regulation may have additional amendments or modifications prior to its ultimate adoption. [25] Once CCR Section 1746.5 becomes operative, the law will require the pharmacist to:

(1) Complete requisite training, including:

   (a) An approved travel medicine training program, which must consist of at least 20 hours and cover each element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine;

   (b) The CDC Yellow Fever Vaccine Course;

   (c) A certificate course in basic life support;

   (d) A minimum of two hours of continuing education focused on travel medicine, which can be part of the pharmacist's usually required 30 hours of continuing education every two years. [25]

(2) Perform a good faith evaluation prior to furnishing travel medication, including evaluation of a patient's travel history using destination-specific travel criteria. [21] The travel history must include all the information necessary for a risk assessment during pretravel consultation, as identified in the CDC Yellow Book. [25]

(3) Provide required notification to the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of dispensing those drugs or devices. [25] If the patient does not have a primary care provider or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs/devices furnished and advise the patient to consult a physician of the patient's choice. [25]

(4) Maintain required documentation for each travel medication provided by the pharmacist, which includes a patient medication record maintained and securely stored in a physical or electronic manner such that the information is readily retrievable during the pharmacy's normal operating hours. [25] A pharmacist providing patients advice on travel medicine shall provide the patient with a progress note fully documenting the clinical assessment and travel medication plan [25] Proposed text for CCR 1746.4 provides that the pharmacist shall also provide the patient with a written document that reflects the clinical assessment and travel medication plan.[25]

In summary, the only authority announced in SB 493, but which has yet to be implemented (at the time this article is written) pertains to the authority on travel medicines, for which final approval is pending in the Office of Administrative Law (OAL).[25] According to the procedure, once the travel medicine regulation text is approved by OAL, the regulation "becomes effective on the first day of the following quarter, unless the board requests and is granted an earlier effective date by OAL." [25] Notwithstanding that, by the time this article appears in print, the various pharmacist authorities granted under SB 493 should be fully implemented. More detailed information discussing various SB authorities can be found at http://www.pharmacy.ca.gov/about/sb493.shtml. [26]

What Does the Future Hold for Pharmacists as Patient Care Providers?

This discussion illustrates how laws encouraging pharmacists to become more engaged in direct patient care have evolved over the years. However, most recently, the landscape of health care delivery appears to be changing so rapidly that it seems almost naive to expect that our pharmacy profession will keep pace with it. That begs the question: What should education and training in a Doctor of Pharmacy (PharmD) program look like to keep up with the evolving health care landscape? Whether by dosage adjustments or initiating drug therapy, the pharmacy profession is certain to carve out new and evolving roles in new and evolving practice contexts, which the academy of pharmacy educators is already incorporating into the PharmD curriculum. Senator Hernandez's SB 493 initiative has conferred extended significance to a pharmacist's role in today's world of proliferating medication use by patients. Moreover, SB 493 accomplished much more than simply recognizing pharmacists as health care providers. SB 493's adoption into law in October 2013 provided both form and substance to what a *pharmacist can do, and how pharmacists can play a vital role* in providing patient care services.

As this article goes to press, all but one of the advanced practice authorities has been implemented. The proposed protocol under CCR Section 1746.4 for pharmacists to provide travel medicines is still pending review in the OAL; however, it remains likely to be approved and implemented very shortly. The pharmacy profession should look forward to these new direct patient care responsibilities serving as an impetus for further expansion of the scope of clinical pharmacy practice. The authors would like to believe that full implementation of SB 493's provisions unlocks a passageway toward clinical pharmacy services either yet to be defined, and/ or the adoption of pharmacy services that may currently be in a testing phase. The pharmacy profession will continue to make inroads to expand the scope and paradigm of pharmacy practice, as well as the multitude of contexts in which pharmacists serve in a clinical capacity, such as under physician-directed protocols in specialty clinics, managing asthma, hypertension, anticoagulation, oncology, psychiatric disorders, and diabetes therapies.

New doors of opportunity are certain to open for pharmacists striving toward clinical practice, monitoring, and improving patients' health outcomes where their medical conditions are treated or controlled with drug therapy. Perhaps the even grander implication of SB 493 suggests that one day, physicians will *diagnose* and pharmacists will *decide the specific drug therapy* that a patient needs, and thereby pave the way for the pharmacist of the hopefully near future to be recognized and/or liberated as the drug *prescriber* rather than simply the drug *furnisher* linked to a particular prescriber-directed protocol. Of course, only time will tell…and … well, we shall see!

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