

Avoiding Common Legal Issues Confronted in Pharmacy Practice: Evaluating Prescriptions with PRN Wording and Calling for Refills

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Abstract

Community pharmacists are cited and/or fined at an alarming rate. Pharmacists can also be charged by the California (CA) Attorney General (AG) or the Board of Pharmacy (BOP) for more severe violations of law and/or professional practice standards, in the form of an Accusation, the administrative equivalent of a civil “complaint.” This article presents a concise review of two pharmacy practice scenarios involving adjudication of refills with implications for practice violations and attempts to clarify best practices in order to meet the expectations of the BOP and avoid problems with a BOP inspection. The scenarios discussed here cover: 1) Use of “as needed” (prn) wording in a prescription (whether in the directions for use or refill context); and 2) Refills of routine and controlled substance prescriptions called in by a pharmacy technician or pharmacy clerk. The authors’ identification of best practices in these refill contexts aims to enhance pharmacists’ understanding of pharmacy law in order to ensure maximum compliance.

Introduction

Community pharmacists are cited and/or fined at an alarming rate. Pharmacists can also be charged by the California (CA) Attorney General (AG) or the Board of Pharmacy (BOP) for more severe violations of law and/or professional practice standards, in the form of an Accusation, the administrative equivalent of a civil “complaint.” Many “cites and fines” reported, and even charges levied by Accusations, whether from the AG, or the BOP, might easily be avoided if community pharmacists were more familiar with the laws and practices commonly scrutinized by Board inspectors.

Often, Board inspections in community pharmacy arise in response to a specific complaint received from a patient, a prescriber, or even a pharmacy employee. Board inspectors routinely follow up on such complaints, and when investigating allegations in the complaint, they seek to determine if a violation indeed occurred. However, while the original complaint may involve a specific act or incident, an inspector responding to a complaint often works from a standard checklist, to allow for methodical investigation and for a determination about whether other potential violations may exist separate and distinct from the allegation in the original complaint.

Most practicing pharmacists do have a reasonable grasp of the laws and regulations affecting pharmacy practice, and can identify what action may or may not constitute a violation. Nonetheless, it is realistically impossible for one individual to keep up with the intricate nuances of every rule. Recognizing the importance of ensuring that

California pharmacists have an up-to-date and working understanding of pharmacy laws and regulations, the California Board of Pharmacy (BOP) recently amended California Code of Regulations (CCR) Section §1732.5 (b), which addresses pharmacist license renewal requirements. ⁽¹⁾ The revised Section 1732.5 (b) took effect July 1, 2019, to allow for development of the two one-hour modules and for all pharmacists to have two years to complete them:

“At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.”⁽¹⁾

The requirement applies to pharmacists whose licenses expire on or after July 1, 2019. Notably, the Board will provide the required two hours of CE on laws and ethics at no charge by means of a video webinar available on the BOP website.⁽¹⁾ In doing so, the Board expects to educate California pharmacists on the most current information on new laws being implemented, as well as in the areas of pharmacy law and practice that routinely result in citations of pharmacists for violations.⁽¹⁾

This article presents a concise review of two pharmacy practice scenarios involving adjudication of refills with implications for practice violations and attempts to clarify best practices in order to meet the expectations of the BOP and to avoid problems with a BOP inspection. These scenarios encompass: 1) Use of “as needed” (prn) wording in a prescription (whether in the directions for use or refill context); and 2) Refills of routine and controlled substance prescriptions called in by a pharmacy technician or pharmacy clerk.

Use of “As Needed” (prn) Wording for Refills or in Directions for Use

In 1995, the BOP published a California Attorney General (AG) Opinion focused on prescriber use of “as needed” or “prn” wording to designate the number of refills authorized on a prescription in its quarterly newsletter, *The Script*.⁽²⁾ By publishing the AG Opinion in *The Script*, BOP highlighted a conceptual legal gap *not addressed in any official pharmacy law or regulation*, namely, the period of validity for a routine prescription.⁽²⁾ In effect, the BOP used *The Script* as a substitute platform by which to educate pharmacists on the period of time a prescription is considered valid. To understand this legal nuance, some additional discussion is necessary before evaluating prescription language that explicitly incorporates “as needed” or “prn” refills.

First, it is essential to review a bedrock principle in the law that describes refill of a prescription for a dangerous drug or device requiring a prescriber authorization, which Californai Business & Professions Code Section 4063, provides:

“No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the *prescriber* orally or at the time of giving the original prescription.... No prescription for any dangerous drug that is a controlled substance may be designated “refillable as needed.”⁽³⁾

Section 4063 dictates that whether the *prescriber* designated the number of refills authorized on the *original* prescription is what determines whether or not a prescription for a non-controlled substance (dangerous drug) may be refilled. Curiously, however, the *period of validity* for a routine prescription is not defined in the language of Section 4063, nor does any other law or regulation define or expressly prescribe it, which leaves an unusual regulatory gap for interpretation.⁽³⁾ Further, this gap begs for answers to a number of questions: *Who* or *what agency* must interpret a contextual gap in a regulation? *How* does a pharmacist know the length of time a prescription is valid? *Where* is that information found?

Basically, interpretation of a statute or of a regulation is universally recognized as a *question of law*. Notwithstanding that since the BOP is an administrative agency, its interpretation of a statute passed by the California legislature or of its own regulation (e.g., Section 4063) commands substantial weight, ultimately, “resolution of a legal question rests with the courts.”⁽⁴⁾ That said, short of a lawsuit to interpret the language and intent of a statute or a regulation, which is resolved only by a final court decision, the BOP would submit a *question of law* to the California Attorney General (AG) for consideration and the AG would research the gap and offer a written *opinion*, which would serve as a guideline. The AG is “authorized to give opinions on questions of law to legislators, heads of state agencies, district attorneys, county counsels, sheriffs, and to city attorneys in their prosecutorial capacities.”⁽⁵⁾

An AG Opinion is defined as an opinion written by a state attorney general interpreting a legal provision (statute or regulation). As a written interpretation of *existing* law, an AG Opinion is *advisory* only; i.e., it *does not* create new law or correct unintended, undesirable effects of a law. The nature of an AG Opinion essentially means: 1) It is *not* binding (does not have the force or effect of law); 2) Its scope of application is strictly limited to the facts presented by the official initiating the request for the opinion; and 3) It can be changed by the AG, or recalled due to subsequent court decisions and/or legislative enactments.

Thus, in the above manner, the BOP requested the AG Opinion on the period of validity for a routine prescription. Specifically, the AG Opinion provided that based upon a pharmacist’s professional judgment, routine (non-controlled) prescriptions may be refilled only for *up to one year*, if a prescriber designated “prn” for the number of refills authorized. For all intents and purposes, the AG essentially defined the period of validity for a routine prescription as *one year*. The BOP published the Opinion in *The Script* (1995) expressly for the purpose of “closing the gap” left by Section 4063 and to inform and educate pharmacists that a prescription should be considered *valid only up to one year*. Since then, the one-year rule has been adopted as a standard of pharmacy practice.

Evaluation of a routine prescription which authorizes “as needed” or “prn” refills is informed and guided by the AG advisory opinion providing that a routine prescription is valid for up to one year.⁽²⁾ Even if an original prescription is written “refill prn,” a pharmacist *may only* refill such a prescription for *up to one year* (*within* the one-year period) before the pharmacist is *required* to contact the prescriber (in order to authorize it as an entirely *new* prescription).⁽³⁾ However, the same permissive language does not apply to C-III, C-IV or C-V prescriptions, for which a “prn refill” designation is *not* acceptable.⁽³⁾ While the law requires the prescriber’s signature and the prescription issue date to be in the *prescriber’s* handwriting for C-III through C-V prescriptions, the specific number of refills *may* be written by a designated associate preparing the prescription or printing it out, or alternatively, the number of refills may be written on C-III through C-V prescriptions *by the pharmacist* after confirming the number of authorized refills with the prescriber.⁽³⁾ When a pharmacist receives a C-III through C-V prescription with a “prn” refill designation, the original prescription may be filled only once, and for any refill thereafter, the pharmacist must contact the prescriber to verify the number of refills authorized, and insert that specific number in the refill column.⁽⁴⁾

A different approach applies to refilling a prescription for an otherwise routine (non-controlled) medication where *directions for use* are written as “prn.”⁽⁶⁾ For example, in the case of a routine (non-controlled) prescription that states “take one tablet prn,” refills may be allowed, assuming of course that the pharmacist can consult the patient to confirm that they understand how to take the medication, and how often.⁽⁶⁾ On the other hand, a C-II, III, IV, or V controlled substance with the directions “take one tablet prn” would be legally inadequate, impermissible to fill or refill. Moreover, as a standard of practice, “take one tablet prn” *provides* inadequate directions, *even if* the patient understands how to take the medication and how often.⁽⁷⁾ In general, a pharmacist must confirm the frequency and conditions for use of a controlled substance with the prescriber, and include that information on the prescription (e.g., “Take one tablet every 4 hours for pain if needed”) when dispensed. Notably, information on the frequency and conditions for use of a C-II through C-V controlled substance is critical to determining patient compliance with the prescriber’s directions for use and also assessing appropriate frequency of refills. That is, frequency and directions for use are critical information to a C-II through C-V prescription, in order that a pharmacist can determine whether or not it is appropriate in the pharmacist’s professional judgment to refill the prescription upon subsequent refill requests.

In summary, to *refill* a prescription, first determine if it is a legend drug (routine prescription) or controlled substance, and then follow the relevant steps below:

- A. For legend drug (routine prescription):
 1. Must be *less than one year* from original issue date. If original prescription is *more than one year old*, submit prescription request to prescriber, but *must* treat provider response as a *new* prescription;
 2. If no refill is authorized on original prescription, contact the prescriber for refill request; prescriber response *may be received* by pharmacist, intern pharmacist, technician, or clerk for a prescription less than one year from original issue date;

3. If original prescription authorized refills (including PRN refills), refill as long as timing is appropriate for refill. If all of the refills have been used on a prescription within the one-year period, a technician or clerk may still call for additional refills up to the one-year time limit.
- B. For C-III through C-V prescriptions, *may* refill prescription, *if*:
1. Less than six (6) months from issue date of original prescription;
 2. No more than total of five refills; *and*
 3. Total refill quantity does not exceed 120 days total (120 days does *not* include the original prescription fill).
- C. C-II prescriptions (special rules apply)
1. Not refillable
 2. Consecutive partial fills are allowed up to the full quantity written within 30 days of first partial dispensing

Calling for Refills by Pharmacy Technicians and Pharmacy Clerks

Under the law, whether a licensed pharmacy technician or a non-licensed pharmacy clerk may receive prescription refill information over the phone from a patient is left to the discretion of the pharmacist.⁽⁸⁾ Under the supervision of a registered pharmacist, a pharmacy technician or other non-licensed personnel, such as a pharmacy clerk, may also request and receive refill authorizations for non-scheduled as well as controlled substance prescription medications from a prescriber's office.⁽⁸⁾ With respect to routine (non-controlled) prescriptions and C-III, C-IV and C-V prescriptions of record, either a pharmacy technician or a pharmacy clerk may obtain refill authorization from a prescriber's office.⁽⁸⁾ However, there are circumstances under which a prescription may not fall within lawful parameters to refill (described below), and only a pharmacist or a pharmacy intern may initiate the request for authorization and/or receive the authorization to fill from a prescriber's office.

Permissible refill parameters exist for both routine (non-controlled) and controlled substance prescriptions in C-III, C-IV, and C-V. For routine prescription medications, an entirely new prescription form is required, and a *new* prescription must be created where a refill request proposes any "change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained."⁽⁹⁾ Additionally, for routine prescriptions, if the original prescription is more than a year old, irrespective of the number of refills remaining, a new prescription must be obtained by either a pharmacist or a pharmacy intern.⁽⁹⁾ Further legal restrictions are imposed on refills for C-III through C-V prescriptions, which prohibit a pharmacist from (a) *dispensing or refilling* a C-III through C-V prescription more than six (6) months after the date of the original prescription;⁽⁹⁾ or (b) refilling a C-III through C-V prescription more than five (5) times; and (c) refilling no more than an amount totaling a 120-day (4-month) supply for all refills of that prescription taken together.⁽¹⁰⁾ The rule under Section 11200 can be summarized by a simple mnemonic: "6 months, 5 refills, 4-month supply," or, for ease of reference, simply as the "6-5-4" rule.⁽¹⁰⁾ Absolutely no prescription for a C-II controlled substance can be

refilled at all.⁽¹¹⁾

In summary, in order to fulfill a patient request to continue (refill) a prescription medication where a prescription refill is not legally permissible, the prescription must be rewritten and treated as a "new" prescription by a pharmacist or a pharmacy intern if:

- A. The prescription is for a routine prescription medication, and either has no additional refills left or is over a year old;
- B. The prescription is for a C-III, C-IV or C-V controlled substance, and:
 1. The original prescription is more than 6 months old (since date written);
 2. All five refills have been filled (no refills remaining); or
 3. The total refills provided will exceed a 120-day (4-month) supply.

Whether an order is for a routine (non-controlled) or controlled prescription medication, it is important to remember that once a prescription does not fall within lawful parameters for a refill (described above), a *new* prescription blank is required to generate the *new* prescription.⁽⁹⁾⁽¹⁰⁾⁽¹¹⁾

Conclusion

Each year critical laws affecting pharmacy practice are newly implemented. Pharmacists can find it difficult to keep up with the new laws, and seldom have opportunity to review older laws that may affect their daily practice. These realities can expose pharmacists practicing for a considerable time, who may not realize that practices adopted a long time ago, or previous interpretations of existing law, may run contrary to the BOP expectations or wording of a current or new law. Even a conscientious practitioner may be surprised when a BOP inspector points out that one or another practice or policy runs afoul of BOP expectations and/or is not in the best interest of patient care. The authors attempted to address two pharmacy practice scenarios involving adjudication of refills with implications for practice violations and to summarize best practices with the goal of improving pharmacists' understanding of nuances in California pharmacy law and maximizing BOP compliance.

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