Explanation of Changes without Regulatory Effect

The Department of Health Care Services (Department) proposes changes without regulatory effect to amend California Code of Regulations, title 22, section 51479. The proposed amendments in the accompanying regulation text are changes without regulatory effect because the changes would not materially alter any requirement, right, responsibility, condition, prescription, or other regulatory element of any California Code of Regulations provision. Specifically, the proposed amendments discussed below, are in accordance with California Code of Regulations, title1,

- section 100(a)(1) to renumber, reorder or relocate a regulatory provision,
- section 100(a)(4) to revise structure, syntax, cross-reference, grammar, or punctuation, and
- section 100(a)(5) to change an "authority" or "reference" citation for a regulation.

Background

The Department administers California's Medicaid Program called Medi-Cal. The Medi-Cal program provides comprehensive health care services including medical, dental, mental health, substance use disorder, and long-term care for low-income individuals including families with children, pregnant women, seniors, persons with disabilities, and children in foster care. The regulations that govern the Medi-Cal program are located in the California Code of Regulations, title 22, division 3, which include Medi-Cal provider requirements to be eligible for payment (reimbursement) for rendering Medi-Cal services.

Discussion of Proposed Changes

<u>California Code of Regulations, title 22, section 51479</u> specifies provider requirements related to the dispensing of prescription drugs or devices. The Department proposes to amend this section to correct an outdated cross-reference, from California Business and Professions Code (BPC) section 4229.5 to BPC section 4064. This amendment is necessary since BPC section 4229.5 was repealed and replaced with BPC section 4064 by <u>Assembly Bill (AB) 2802 (Granlund, Chapter 890, Statutes of 1996)</u>.

The proposed amendment is a change without regulatory effect since it was the Legislature's intent that the revised provisions be an extension of the prior law. This intent is supported by the following excerpt from the Legislative Counsel's Digest for AB 2802, which states,

"This bill would repeal the existing pharmacy law and would reenact it as revised and reorganized. The bill would state that it is the intent of the Legislature that these revised provisions be constructed as a continuation of the prior law."

The legislative intent is further supported by the similarity in language between BPC section 4229.5 (enacted in <u>AB 2195 (Tucker, Chapter 1115, Statutes of 1987)</u> and BPC

section 4064 (enacted in AB 2802). The text of BPC section 4229.5 and BPC section 4064 are the same, except for one non-substantive difference where the words "or her" are added to BPC section 4064 to clarify that the pharmacist could be a male or female.

BPC section 4064 was subsequently amended (to the current version) by <u>Senate Bill</u> (SB) 1349 (Committee on <u>Business and Professions</u>, Chapter 549, Statutes of 1997). With these amendments, the original intent and language of the statute still remains the same, despite the re-wording and re-organization. This is supported by the excerpt from the Legislative Counsel's Digest of SB 1349, which explains the amendment to BPC section 4064 as follows:

"(7) Existing law sets forth procedures under which a prescription for a dangerous drug or device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering. These provisions require the pharmacist to inform the patient and the prescriber and make every reasonable effort to contact the prescriber.

This bill would recast this provision. The bill would apply this provision if the prescriber is unavailable to authorize the refill and it is the pharmacist's professional judgment that failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. The bill would provide that a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this provision, notwithstanding the prohibition in (6) above or any other law."

Based on this information, the Department proposes to amend California Code of Regulations, section 51479 as follows:

- Re-designate subsections (1) and (2) to subsections (a) and (b) to be consistent with the formatting of other regulations within California Code of Regulations, title 22, division 3, subdivision 1.
- Update the cross-reference to the BPC from section 4229.5 to section 4064, which is necessary since BPC section 4229.5 was repealed and replaced with BPC section 4064.
- Update the Authority citations to include Health and Safety Code Section 20, which is necessary to acknowledge the re-organization of the Department.

The Department requests these amendments as changes without regulatory effect as they do not materially alter any requirement, right, responsibility, condition, prescription, or other regulatory element of any California Code of Regulations provision.