Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:
- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:
- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient’s seated blood pressure if combined hormonal contraceptives are requested or recommended.
- Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is properly and appropriately trained in administration of the requested or recommended contraceptive medication.
- When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
  - Dosage;
  - Effectiveness;
  - Potential side effects;
  - Safety;
  - The importance of receiving recommended preventative health screenings;
  - That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).
(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date when the last self-administered hormonal contraception product was furnished or dispensed.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall review and answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists are encouraged to should provide the patient with a copy of at the current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration method-specific factsheet; examples of appropriate guides and factsheets are from the Association of Reproductive Health Professionals, all available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient’s primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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
drug(s) or device(s) furnished and advise the patient to consult a physician appropriate health care professional of the patient’s choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another self-administered hormonal contraception appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMECT as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMECT shall be kept current and maintained in the pharmacy or pharmacy health care facility, and shall be available on the Board of Pharmacy’s website.

Furthermore, generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or pharmacy health care facility for a period of at least three years from the date when the last self-administered hormonal contraceptive was furnished or dispensed. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or pharmacy’s facility’s normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMECT, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2014 in an accredited California School of Pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or pharmacy health care facility shall operate under the pharmacy or pharmacy’s facility’s policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions