NATIONAL HEALTH LAW PROGRAM

Roadmap for State Pharmacy Access Laws

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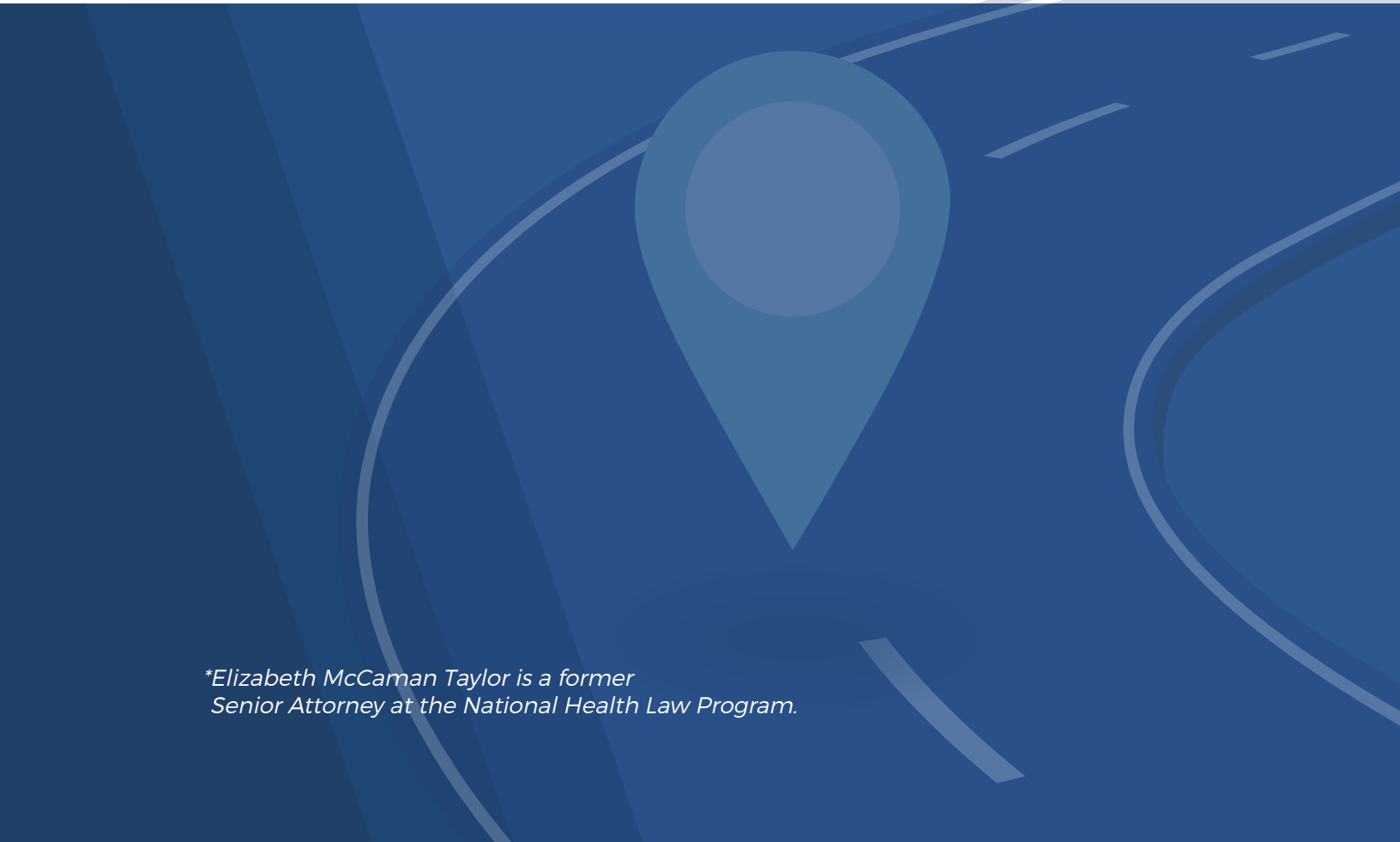

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Introduction

This is a roadmap for state advocates, policymakers, and other stakeholders to understand how best to achieve legislation, state plan amendments, regulation, and other guidance that allow for pharmacist prescribing and pharmacy access for reproductive and sexual health medications, primarily self-administered contraceptives.

The roadmap is divided into four parts:

Part 1: Pharmacy Access Best Practices
Set of overarching best practices for pharmacy access;

Part 2: Crafting Legislation for Pharmacy Access
Step-by-step guide to crafting legislation for pharmacy access, including template language and relevant state examples;

Part 3: State Plan Amendments
Suggested language for state plan amendments, including template language and relevant state examples

Part 4: Additional Resources
Additional resources including regulations, sub-regulatory guidance, informational materials, training, and more.

Part I:
Pharmacy Access Best Practices

The following are best practices for pharmacy access. These can be considered overarching best practices or principles for state advocates, policymakers, and other stakeholders to keep in mind as they do this work.

- Patients should have pharmacy access for all self-administered RSH medications, including all self-administered contraceptives.
- Pharmacists should be authorized to prescribe, not just dispense and furnish.
- Patients should not be required to make a pharmacy appointment.
- Patients should not be required to show proof of a prior prescription or doctor visit.
- Pharmacies should provide a private area for the patient consultation.
- Pharmacist consult and administrative fees should be prohibited or capped. Legislation should specify insurance coverage of pharmacist consultation/assessment, dispensing, and administrative fees. Legislation should not alter the requirement that contraceptive drugs, devices and counseling be covered without cost-sharing.
- Patient self-screening should be based on the CDC's U.S. Medical Eligibility Criteria for Contraceptive Use (USMEC). Pharmacists should refer to the most current version of the USMEC when screening women for eligibility and appropriate selection of contraceptive methods, and any self-screening tool should be developed based on this. Criteria, including blood pressure and weight, that are not included in the USMEC, should not be used.
- Young people's access must not be restricted. Legislation should have no age restriction, no requirement for those under age 18 to show proof of a valid prescription or doctor's visit, or any other requirement or restriction not applicable to adult women.
- The state board of pharmacy should be required to track and report on accessibility and use in a way that prioritizes patient confidentiality. Specifically, the board should track the number and geographic locations of participating pharmacy stores, number of pharmacists who have successfully completed the training protocol, and whether contraceptives are adequately stocked in stores.
- Outreach must be prioritized, to patients, pharmacists, pharmacies, and payers.

Step-by-Step Guide to Crafting Legislation for Pharmacy Access

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Part II: Crafting Legislation for Pharmacy Access

STEP 1: PRACTICE OF PHARMACY DEFINITION

Edit the definition of "practice of pharmacy" in the state to include prescribing pursuant to (a new section that will detail the prescriptive authority).

Template Language
The practice of pharmacy includes "prescribing [of drugs and devices] as may be further defined in this chapter and/or board rules and regulations."

State example
Idaho Statutes 54-1705 (2022)

STEP 2: PRESCRIPTIVE AUTHORITY

a. Independent, category-based
Under this model, all qualified pharmacists may prescribe autonomously for any condition within their clinical competence, or any category laid out in statute. This may require a special state accreditation, or may be applicable to all licensed pharmacists in the state.

Template Language
No statutory language other than STEP 1 is required, but board rules and/or regulations should elaborate on the scope of independent prescribing.

b. State Protocol

A statewide protocol provides a standard procedure for determining if a drug is necessary and details how to prescribe and dispense it safely. The statewide protocol provides treatment guidelines and does not require direct partnership with an attending provider. A statewide protocol and a statewide standing order are essentially the same thing, except that a statewide protocol is generally codified into state law through statute and/or regulation, making it less susceptible than a standing order to future administrative changes.

Beyond contraception

Template Language

"(a) A pharmacist may prescribe, order, or administer, in a manner consistent with valid state protocols that are approved by the [Commissioner of Health] after consultation with the Board of Pharmacy and the ability for public comment:
(i) opioid antagonists;
(ii) epinephrine auto-injectors;
(iii) tobacco cessation products;
(iv) tuberculin purified protein derivative products;
(v) self-administered contraceptives;
(vi) dietary fluoride supplements and prenatal vitamins;
(vii) vaccines;
(viii) HIV preexposure and postexposure prohylaxis;
(ix) emergency prescribing of albuterol or glucagon while contemporaneously contacting emergency services;
(x) tests for SARS-CoV for asymptomatic individuals or related serology for individuals by entities holding a Certificate of Waiver pursuant to the Clinical Laboratory Amendments of 1988 (42 U.S.C. § 263a);
(xi) accessory devices, such as spacers, needles, and diabetic testing supplies, where clinically indicated in the judgment of the pharmacist; and
(xii) over-the-counter products where appropriate [to reduce costs to the patient].
(b) The board is authorized to ensure compliance with this subdivision, and is specifically charged with the enforcement of this subdivision with respect to its licensees.
(c) On or before [date], the board, in consultation with interested stakeholders, shall adopt final regulations establishing:
(1) standard procedures that a pharmacist must use to select the appropriate contraceptive to prescribe; and
(2) the conditions under which a pharmacist may prescribe and dispense contraceptives.

If the Board is unable to adopt rules by that date, the Board shall adopt an emergency rule until such time as it completes the rulemaking process."

Limited to contraception

Template Language

"(a) An individual licensed to practice pharmacy pursuant to this act may prescribe and dispense up to a 12-month supply of self-administered contraception if certified to do so by the Board and pursuant to a written protocol established by the Board.

(b) The protocol shall include the following requirements:

(1) If the pharmacist has not already undergone training as part of the pharmacist's formal education program, that the pharmacist complete a training program approved by the Board for prescribing and dispensing of self-administered contraceptives;

(2) That the patient use a self-screening tool that will identify patient risk factors for the use of self-administered contraceptives, based on the current US Medical Eligibility Criteria for Contraceptive Use developed by the Centers for Disease Control and Prevention; and

(3) That when a self-administered contraceptive is prescribed and dispensed, the patient shall be provided, in a manner that ensures patient confidentiality, appropriate counseling and information on the product furnished."

(c) The board is authorized to ensure compliance with this subdivision, and is specifically charged with the enforcement of this subdivision with respect to its licensees.

(d) On or before [date], the board, in consultation with interested stakeholders, shall adopt final regulations establishing:

(1) standard procedures that a pharmacist must use to select the appropriate contraceptive to prescribe; and

(2) the conditions under which a pharmacist may prescribe and dispense contraceptives.

If the Board is unable to adopt rules by that date, the Board shall adopt an emergency rule until such time as it completes the rulemaking process."

State examples

Maryland SB 363 (2017), Virginia HB 1506 (2020)

c. State Standing Order

Standing orders enable assessment and drug dispensing without the need for clinician examination or direct order from the attending

provider at the time of the interaction. Under a standing order, certain authorities (sometimes a government official like the state Secretary of Health, sometimes authorized prescribers in local clinics or pharmacies) can write "standing orders" that act like a prescription for everyone in a given population; it could be as broad as everyone in the state, or limited to students at a specific campus or patients in a certain hospital. Standing orders also provide treatment guidelines. We only recommend a statewide standing order.

Template Language

"(a) The department shall ensure that a statewide standing order is issued to authorize the dispensing of self-administered contraception by a licensed pharmacist. The statewide standing order shall include, but not be limited to, written, standardized procedures or protocols for the dispensing of self-administered contraception by a licensed pharmacist.

(b) Notwithstanding any general or special law to the contrary, a licensed pharmacist may dispense self-administered contraception in accordance with the statewide standing order issued under subsection (a). Except for an act of gross negligence or willful misconduct, a pharmacist who, acting in good faith, dispenses self-administered contraception shall not be subject to any criminal or civil liability or any professional disciplinary action by the board related to the use or administration of self-administered contraception.

(c) Before dispensing self-administered contraception authorized under this section, a pharmacist must complete a training program approved by the commissioner on self-administered contraception; provided, however, that the training shall include, but not be limited to, proper documentation, quality assurance and referral to additional services, including appropriate recommendation that the patient follow-up with a medical practitioner.

(d) Except for an act of gross negligence or willful misconduct, the commissioner or a physician who issues the statewide standing order under subsection (a) shall not be subject to any criminal or civil liability or any professional disciplinary action.

(e) The board shall adopt regulations to implement this section, which will include:

(1) The standard procedures that a pharmacist must use to select the appropriate contraceptive to dispense to a patient or to refer the patient to a health-care practitioner for treatment;

(2) The conditions under which a pharmacist may dispense contraceptives."

State example
Massachusetts Session Law Chapter 127 (2020)

d. Collaborative Practice Agreement (CPA)
We do not recommend this route. It is burdensome on both pharmacists and partner prescribers.

STEP 3: INSURANCE COVERAGE

a. Private insurance, contraception specific

Template Language
"Coverage required by this section shall include reimbursement to a pharmacist who counsels on, prescribes, and dispenses contraception pursuant to [statute.]"

State example
Hawaii Statutes § 431:10A-116.6 (2017)

Template Language
"If covered for other drug benefits under the program, plan or policy, a prescription drug benefit program, or a prescription drug benefit offered under a health benefit plan as defined in [relevant statute] or under a student health insurance policy, must provide payment, coverage or reimbursement for outpatient consultations, including pharmacist consultations, examinations, procedures and medical services that are necessary to prescribe, dispense, deliver, distribute, administer or remove a contraceptive."

State example
Oregon House Bill 2527 (2017)

b. Private insurance, array of services

Template Language
"(a) For health plans, policies, contracts, or agreements issued, amended, adjusted, or renewed on or after January 1, [202x]:
(1) Benefits may not be denied for any health care service performed by a pharmacist licensed under [statute] if:

(A) The service performed was within the lawful scope of the pharmacist's license;
(B) The plan would have provided benefits if the service had been performed by another health care provider; and
(C) The pharmacist is included in the plan's network of participating providers.
(2) The health plan shall include an adequate number of pharmacists in its network of participating health care providers.
(b) Health benefit plans, policies, contracts, or agreements issued, amended, adjusted, or renewed on or after January 1, [202x], that delegate credentialing agreements to contracted health care facilities shall accept credentialing for pharmacists employed or contracted by those facilities. Health plans shall reimburse facilities for covered services provided by network pharmacists within the pharmacists' scope of practice per negotiations with the facility."

State examples
Washington SB 5557 (2015-2016), West Virginia SB 787 (2020)

c. Medicaid/CHIP

Template Language
"The Medicaid and Children's Health Insurance programs, including both the fee-for-service and managed care medical assistance programs, shall cover expenditures incurred for [self-administered contraceptives OR drugs and devices] prescribed and dispensed by a pharmacist pursuant to [statute], including pharmacist assessment and consultation. The Department shall apply for any necessary federal approvals to implement this section by [date]."

State examples
Illinois 305 ILCS 5/5-5.12d (2022), Maryland SB 363 (2017), Nevada SB 190 (2021)

STEP 4: OUTREACH & IMPLEMENTATION

Template Language

"(a) The Board of Pharmacy shall feature the active protocol conspicuously on its website."

(b) The Board shall maintain a list of all pharmacists certified to prescribe and dispense contraception, including the location of the pharmacy where the pharmacist currently practices, and make that list readily available to the public."

(c) A pharmacy shall display in stores and online a list of the times during which a pharmacist certified to prescribe and dispense contraception is available.

(d) The Commissioner of Health shall establish a public awareness campaign to inform the general public concerning the ability to obtain self-administered contraceptives from a pharmacist pursuant to [statute]. There shall be appropriated to the Department of Health such funding as shall be necessary to implement the provisions of this section."

State examples

New Jersey S275 (2022-2023), Washington DC Act 22-246 (2018)

Part III:
State Plan Amendments

Following is suggested language for state plan amendments, including template language and relevant state examples.

Adding multiple practitioners

Template Language
"Other Practitioner Services–
All other practitioners covered by the Medicaid agency include, but are not limited to, the following licensed practitioners: pharmacists, … These practitioners are limited to services within their scope of practice and specialty area."

State example
Washington SPA 20-0029

Adding only pharmacists

Template Language
"Other Practitioner Services–
A. Pharmacist Prescriber practitioners are able to furnish services within the scope of their practice as defined by State Law.
B. The Pharmacist Prescriber covers a patient assessment to determine whether or not patients are eligible to receive contraceptives and, if eligible, which contraceptive to prescribe when the services are provided by a licensed and legally authorized pharmacist in the state in which the service is provided."

State example
Maryland SPA 19-0001

Part IV: Additional Resources

REGULATIONS

Regulations are the place to get into details. While each state's details are going to be a little different depending on community need, there are a number of basic components that most regs should include. For a range of examples, see ID, MD, TN, UT, OR, CA. As a note, some states consider regulations and a state protocol to be one in the same, while others promulgate both regulations and a separate board-approved protocol (see sub-regulatory guidance below).

a) Definitions

If the statute uses a term like "self-administered contraceptive," this is a good place to define exactly which products are contained therein (basically everything except LARCs and sterilization).

b) Training

Regs should address the required components of a satisfactory training program, including whether some pharmacy school curriculums may meet this requirement. The regs could also include the process the Board of Pharmacy will follow to approve trainings. The regs should address whether continuing education is required, and how pharmacists should document their completed training (e.g. keep a copy on file at the pharmacy or send in advance of prescribing to the Board).

c) Screening & Counseling

Regulations should indicate the specific process a pharmacist must follow in screening and counseling patients. For screening, the regulations could specify the use of a self-screening tool, using the US MEC, and product selection. For counseling, the regulations could specify what information must be provided, any informed consent requirements, and expectations regarding referrals.

d) Recordkeeping

Each state has slightly different expectations for how pharmacies maintain patient records, including the information to be saved, the

duration, how it is stored, and who, if anyone, the information is transmitted to, such as the patient's primary care provider.

e) Patient Access
If the state wants to prohibit pharmacies and pharmacists from requiring an advance appointment, or wants to put a cap on fees for self-pay patients, regs are the most appropriate place for those details.

SUB-REGULATORY GUIDANCE

a) Statewide protocol
See NH, NM, VT protocols

b) Standing order
See MA (emergency contraception) and VT (naloxone and COVID tests)

c) OTC list
See CO

Note that any standing order or protocol related to the dispensing of OTC products, with or without a prescription, should not require any special training from a pharmacist and should comport with FDA's determination that users can self-select and self-manage the product.

d) All Plan letter
See CA

e) State bulletin
See NM

INFORMATIONAL MATERIALS

a) Public-facing websites
See MA, OR, CA

b) Provider-facing materials
See MD (Medicaid and general), WA, NM (informed consent), CA (pharmacy manual), Birth control pharmacist

c) FAQs
See CO

d) Maps
See Birth control pharmacies

e) Marketing materials
See Birth control pharmacist

TRAINING

a) Continuing education
See CA, WA, OR, Birth control pharmacist

b) Billing webinars
See OR