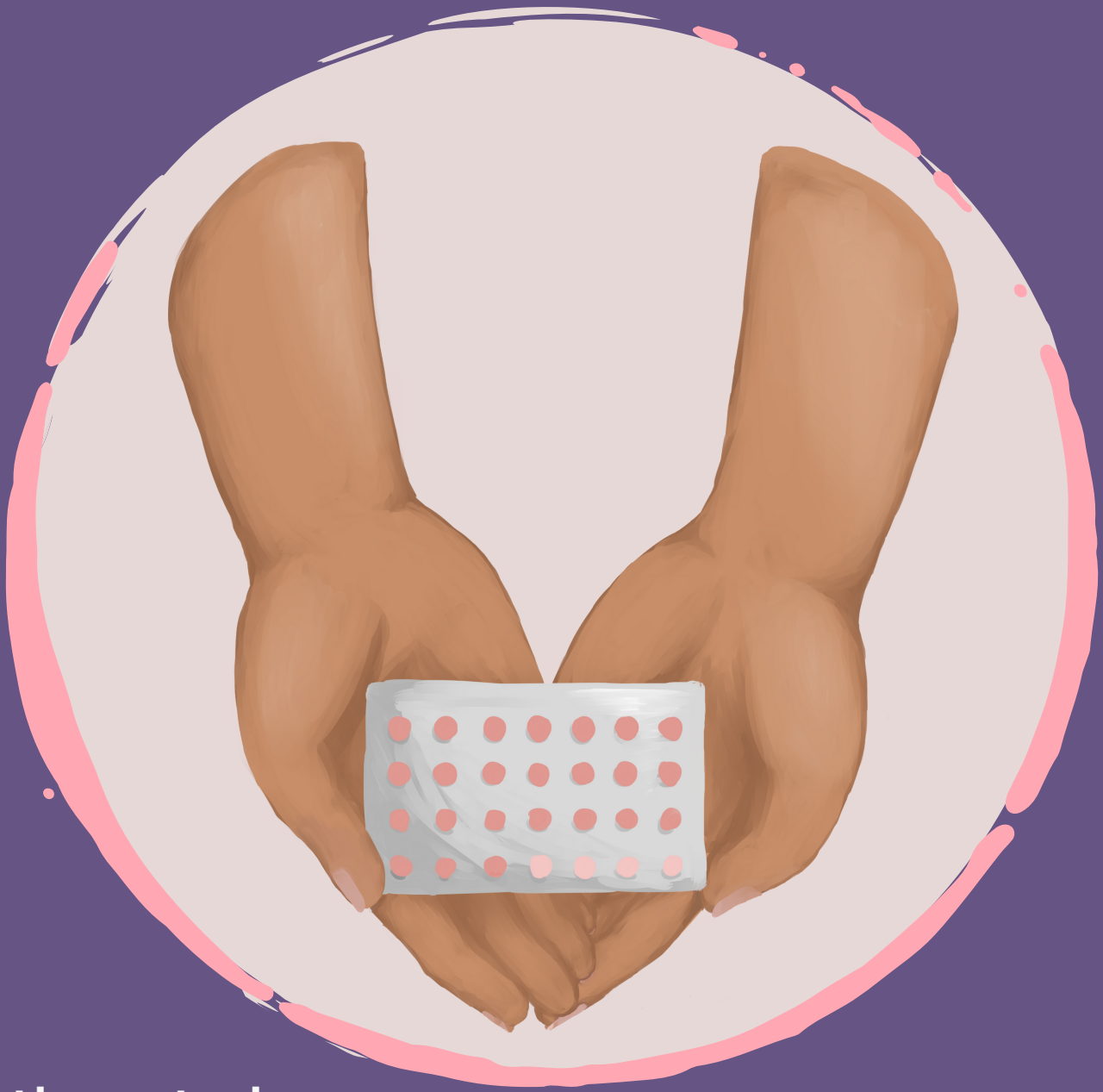
OPENING NEW DOORS TO BIRTH CONTROL

State Efforts to Expand Access to Contraception in Community Pharmacies



birth control pharmacist

2020

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INTRODUCTION

Despite the availability of many birth control methods and the recent expansions in healthcare insurance coverage, people* continue to encounter barriers in accessing birth control. Choices around which birth control method to use are often driven by cost and access considerations. A multi-pronged approach is required to address the various challenges and barriers.

With the exception of emergency contraception, all hormonal contraceptives remain available by prescription only. To switch a product to nonprescription or over the counter (OTC) status, the pharmaceutical companies must submit an application for each individual product and obtain approval from the U.S. Food and Drug Administration (FDA). There are research and advocacy efforts underway to support a future switch.

Expanding the pharmacist scope of practice to include prescribing birth control is a timely strategy to mitigate current access barriers. Pharmacist prescribing allows one stop to the pharmacy for visiting with a qualified healthcare provider and obtaining birth control supplies. Unlike the FDA changing the prescription requirement to allow nonprescription sales of a medication nationwide, healthcare providers' scope of practice -- including prescriptive authority -- is determined at the state level.

In the last 7 years, momentum has been increasing for pharmacist prescribing of birth control. Washington began pioneering this service decades ago by allowing pharmacists to enter into individual collaborative practice agreements with physicians. However, interest in other states mostly began after California passed the first state regulation expanding the pharmacist scope of practice to specifically allow for prescribing birth control under a statewide protocol.

The role of pharmacists and pharmacies in contraception care and related services has since been rapidly expanding. There have been challenges to realizing the full reach and impact of these services.

Table 1. Description of Models of Access to Medications

Model	Description
Prescription[1]	Requires a prescription from a licensed prescriber, at which time the drug can be dispensed by a pharmacist or directly by the prescriber
Pharmacist Prescribing[2]	Requires a prescription, which can be issued directly by a pharmacist with prescriptive authority, most commonly through a collaborative practice agreement,[3] statewide protocol, or standing order; authority can apply to a single drug, a drug class, or a specific disease state
Behind-the-Counter	Over-the-counter with nonclinical restrictions such as age, quantity, location of sale, or documentation (e.g., nicotine replacement, pseudoephedrine)
Over-the-Counter[1]	Available without a prescription at any location with no restrictions; also known as nonprescription or OTC

** This term is used for all people who would be eligible to use hormonal contraception, and generally refers to people assigned female gender at birth including cisgender women, transgender men and some who identify as non-binary or non-conforming. We use people, patients, and women throughout this report.*

[1] *Only two classifications recognized by the US Food and Drug Administration.*

[2] *Pharmacist prescribing includes furnishing per protocol and dispensing per standing order.*

[3] *Collaborative practice agreements also known as collaborative drug therapy agreements.*

Reference: Rafie S, McIntosh J, Gardner DK, et al. Over-the-Counter Access to Emergency Contraception Without Age Restriction: An Opinion of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy. *Pharmacotherapy* 2013;33:549-57.

> ***"We aren't doing anything less than what they would perform at a doctor's office, so it would be huge for women and access to birth control."***
>
> *– Maren Rasmussen, PharmD, Wisconsin, 2019*

CURRENT LANDSCAPE

As of December 2020, 15 states and the District of Columbia allow for pharmacist prescribing of self-administered hormonal contraception. Twelve states (Washington, Oregon, California, Utah, Colorado, New Mexico, Maryland, Idaho, Montana, Michigan, Hawaii, and Minnesota) have implemented their programs while Virginia, West Virginia, New Hampshire, and the District of Columbia are in the regulatory process pending protocol approval.

Figure 1. States Map of Pharmacist Prescribing of Hormonal Contraception Policies

For up-to-date states map, see https://birthcontrolpharmacist.com/policies/.

Key Policy Elements

States' pharmacist prescribing of hormonal contraception legislation, policies, and program requirements vary with regards to key elements.

Contraceptive Methods
All states and the District of Columbia allow pharmacists to prescribe the pill, transdermal patch, and vaginal ring, with the exception of Colorado which excludes pharmacist prescribing of the vaginal ring. Additionally, California, Hawaii, Maryland, New Mexico, Oregon, and Tennessee also allow pharmacist prescribing of the depot shot. New Mexico further allows pharmacists to provide non-hormonal contraceptive methods such as the diaphragm.

Age Restrictions
Seven states include age restrictions of 18 and over. Oregon had a sunset clause in their legislation that terminated their prior age restriction. New Mexico does not have an age restriction but requires pharmacists to report services provided to patients age 13 and younger. Tennessee has an age restriction of 18+ but allows pharmacists to serve minors if they are emancipated. Imposing an age restriction not only impacts access for young people, but also those who do not have identification to demonstrate their age to a pharmacist, disproportionately impacting migrant women, women of color and low-income women.

Duration
The majority of states do not impose restrictions on the duration a pharmacist can provide services to an individual patient. However, a few states, like Colorado, Oregon, Utah, and Virginia impose limitations whereby pharmacists cannot continue prescribing to a patient beyond two or three years from the initial prescription without evidence of a well woman exam with a provider. Some states alternatively addressed concern about women forgoing routine gynecological screenings by requiring the pharmacist to provide patients with written or verbal information about the need for routine gynecological screening and related referrals. Utah also limits the initial supply to 30 days and requires the pharmacist to monitor the patient at 3 months and again at 6 months.

Pharmacist Training
All states include some level of pharmacist training requirement. In California, Tennessee, and Utah, students graduating from an accredited school of pharmacy do not need additional training. Training requirements vary for each state. Most states require their state Board of Pharmacy and/or Department of Health to approve any training programs which leads to delays and limits the availability of programs. Most states require pharmacists to notify the Board of Pharmacy that they will be participating in the protocol and must provide proof of training.

Notifications and Referrals
Some states have imposed notification requirements that do not exist for other provider types whereby the pharmacist must notify the patient's primary care provider or women's healthcare provider, if they have one. In the case that a patient does not have one, some states encourage or require pharmacists to counsel patients regarding the benefits of establishing a relationship with a primary care provider and/or provide referral information.

Professional Practice and Service Delivery Restrictions
Some states have imposed restrictions on pharmacists' professional practice and service delivery that do not exist for other provider types. For example, Oregon, Colorado, Hawaii, and Tennessee prohibit pharmacists and pharmacies from requiring appointments for birth control. Washington requires pharmacists to post a sign promoting services.

Documentation and Reporting
All states require the pharmacist to document and keep a record of all patient visits. Utah also requires pharmacists to report visit data to their state's Department of Health on an annual basis.

Model
Most states allow for pharmacists to prescribe hormonal contraception through a statewide protocol model. This protocol is typically approved by the State Board of Pharmacy and possibly by the State Board of Medicine, State Board of Nursing, or Department of Health. New Hampshire, Utah, and West Virginia use standing orders, and District of Columbia, Tennessee, and Washington state rely on collaborative practice agreements (CPA). Currently, Idaho is the first to grant pharmacists prescriptive authority without a required protocol, standing order, or CPA.

Legislative Scope of Bill
Most states passed bills focused primarily on allowing pharmacists to provide hormonal contraception directly. However, some states, such as California, Colorado and Virginia, effectively passed wider legislation increasing pharmacists' scope of practice to include prescribing of hormonal contraception among other clinical services like prescription of nicotine replacement products or other medications for tobacco cessation, naloxone, epinephrine, travel, prenatal vitamins, and immunizations.

Payment for Services
Some states address the fees pharmacists are allowed to charge for services in the legislation language itself while other states have left that to rule making or the marketplace. Tennessee's legislation originally proposed a $20 capped fee, but their amended bill specified the individual pharmacist or corporate employer shall set the price. Similarly, Washington DC originally proposed pharmacists charging a $25 fee, but in amendments specified the amount would be determined through regulation by the Department of Insurance, Securities and Banking and mandated that patients have access to copay-free birth control covered by insurers.

Pharmacists in most states have identified payment for services as a challenge to providing contraceptive care. Pharmacists are not recognized by the Centers for Medicare & Medicaid Services (CMS) as providers. Without this recognition, pharmacists are unable to bill third-party payers (Medicare, Medicaid, or commercial insurance) for contraceptive visits across all states and can do so upon state policy change only. Some states have passed legislation recognizing pharmacists as healthcare providers and/or requiring third-party payers to cover for pharmacist services. However, in some states, while Medicaid may be required to cover pharmacist contraceptive services, commercial plans do not carry the same requirement. Rarely do third-party payers opt to cover these services without legislation mandating.

Table 2. Payment vs. Reimbursement

Term	Definition
Reimbursement	A sum paid to cover money that has been spent or lost, typically for products or goods (e.g., prescription drug costs, dispensing fees). Typically covered by health insurance plans.
Payment	A sum paid to cover services rendered by a healthcare provider (e.g., contraceptive counseling). Less commonly covered by health insurance plans when the provider is a pharmacist.

For additional details or to determine ideal elements, please refer to Appendix 1. Model Bill Elements.

STATE POLICY APPROACHES AND EXPERIENCES

Increasing access to birth control through pharmacists has mostly risen above partisan controversies that often otherwise encumber reproductive health related policy. In some states, legislation was exclusively Democrat sponsored while in other states, legislation was all Republican authored. However, for the most part, bills had bipartisan support. In some states, legislators with medical or public health backgrounds and experience were influential and effective in introducing legislation. In other states, initiatives were led by the pharmacy community. In Utah, legislation was actually prompted by a school of pharmacy graduate student who drafted a "dream bill" for his leadership class after hearing about delays and added costs that his wife faced in obtaining contraceptives in Utah. In Hawaii, the Women's Legislative Caucus introduced legislation; and in Maryland, a female Democratic Senator is credited with taking a significant lead in effectively cultivating support and coordinating efforts to advance and pass the legislation. In Iowa, Republican Governor Richards introduced legislation. It is notable that several states with pharmacist prescribing of contraception took more than one legislative attempt to successfully pass their bills.

Table 3. Summary of State Policies in 2020

State	Available	Authority By	Birth Control Methods	Patient Age Restriction
Oregon	2016	Statewide Protocol	Pill, Patch, Ring, Shot	All ages
California	2016	Statewide Protocol	Pill, Patch, Ring, Shot	All ages
Colorado	2017	Statewide Protocol	Pill, Patch	18 and older
Hawaii	2018	Statewide Protocol	Pill, Patch, Ring	All ages
New Mexico	2018	Statewide Protocol	Pill, Patch, Ring, Shot, Nonhormonal Methods	All ages
Maryland	2019	Statewide Protocol	Pill, Patch, Ring, Shot	All ages
Utah	2019	Standing Order	Pill, Patch, Ring	18 and older
Tennessee	2019	Collaborative Practice Agreement	Pill, Patch, Ring, Shot	18 and older
Minnesota	2020	Statewide Protocol	Pill, Patch, Ring	18 and older (under 18 with prior prescription)
Others Offering via Collaborative Practice Agreement: Washington, Idaho, Montana, Michigan				
Others with Statewide Protocols or Standing Orders in Progress: New Hampshire, Virginia, West Virginia, Washington D.C.				

For up-to-date states summary, see https://birthcontrolpharmacist.com/policies/.

For additional details, please refer to Appendix 2. State Policy Details.

Most states passed bills focused singularly on allowing pharmacists to provide hormonal contraception directly. Some states built on earlier successes of already passing legislation allowing pharmacists to provide other clinical services. For example, Utah passed legislation in 2016 allowing pharmacists to dispense naloxone, an opioid antagonist for home rescue of opioid overdose. In other states, legislation around pharmacist prescribing of hormonal contraception passed while parallel bills introduced in the same legislative session allowing pharmacists to provide other clinical services failed. Washington DC uniquely included allowing pharmacists to prescribe hormonal contraception as part of broader bill around a variety of women's health preventative services.

> ***"Pharmacists have more than enough experience and skills to share information for people seeking contraception, to talk about their options, and to provide medication."***
>
> *– Kelly Blanchard, MSc, President of Ibis Reproductive Health, 2017*

Other states allowing for pharmacist prescribing of hormonal contraception passed wider legislation increasing pharmacists scope of practice overall to provide hormonal contraception among other clinical services like prescription of nicotine replacement products and devices for smoking cessation, naloxone, epinephrine, HIV prevention, travel medications, and immunizations. In Colorado and Virginia, the bill did not mention contraceptive services specifically. In states like California, taking this wider scope approach minimized more detailed focus on age restrictions to access hormonal contraception directly from the pharmacist.

Support and Opposition

Pharmacist prescribing of hormonal contraception legislation was not met with adamant or widespread opposition. In few states, organized medicine opposed efforts generally pushing back on increasing pharmacist's scope of practice. Authors in some states mitigated this type of opposition by avoiding bill language using "prescribing" (opting for "furnishing" in California or "dispensing" in West Virginia) or in Colorado avoiding mention of pharmacist "diagnosing." However, most states experienced wider acceptance and tolerance around use of pharmacist "prescribing" in bill language and this language can be important in recognizing pharmacists' role and aiding reimbursement. At the national and state level, reproductive health and rights organizations and medical associations including the American College of Obstetricians and Gynecologists, Physicians for Reproductive Health support expanding access to contraception. As such, the medical community in some states also raised concern that hormonal contraception should be available over the counter and allowing for pharmacist prescribing was simply adding one barrier with another that did not resolve a bigger access issue. As a result, in some cases state medical associations or reproductive health organizations like Planned Parenthood did not outright endorse efforts and either took a neutral position or declined to take a position. While, in California, Mitchell Creinin, a respected physician and professor serving as Director of Family Planning at the University of California, Davis, testified in favor of removing service barriers by eliminating the proposed requirement for pharmacists to measure patients' blood pressure.

While state pharmacy associations, local schools of pharmacy, and chain pharmacies mostly provided supporting testimony, opposition also came from within the pharmacy community. In a handful of states, community pharmacists expressed opposition to moving this legislative agenda forward namely because they felt it would be stressful and challenging to provide additional new services without fair reimbursement systems in place. Maryland addressed this chief pharmacist concern by including payment mechanisms in the legislation bill language. In West Virginia, pharmacists were also concerned

about providing services to younger women and an amendment restricting services to women eighteen and older was incorporated. In other states, concerns around age restrictions were voiced by other organized groups both in favor and against access for minors. For example, the Family Action Council Tennessee (FACT), an anti-choice non-profit promoting Biblical family values, warned against the legislation particularly noting perceived increased risks for minors while in Oregon, Planned Parenthood was instrumental in adding a sunset clause to eventually eliminate age restrictions.

> ***"After I first heard about the pharmacist-prescribed birth control model, the more I looked at it, and the more it made sense… such a no-brainer."***
>
> *– Joel Kitchens (R), Wisconsin State Representative, 2020*

Detailed State Experiences

It is worthwhile to understand each state's distinct approach and experience advancing pharmacist prescribing of hormonal contraception as some states build on other's best practices and lessons learned while others forge new enhancements that strengthen overall program viability.

WASHINGTON

Effective: 1998
Mechanism: Regulatory Change
Model: Collaborative Practice Agreements
Ages: 18+

The most mature state in pharmacist prescribing of hormonal contraception, Washington leveraged its 1979 laws and regulations to allow pharmacists prescribing rights. In 2003, the state became the first to allow for pharmacy access to hormonal contraception through its Direct Access Study with the University of Washington School of Pharmacy. The collaborative practice protocols developed, positive outcomes and lessons learned set an important foundation for more pharmacists in the state to provide services and for other states like California to build on. Washington passed new legislation to facilitate the success and sustainability of its pharmacy access models. For example, in 2015 legislation (ESSB 5557) passed requiring all health plans to enroll pharmacist as medical providers. As of January 2017, pharmacists in all practice settings can enroll in commercial health plan provider networks and bill for covered patient care services within the pharmacists. The law does not apply to Medicare, Medicaid FFS and Self-Insured plans.

In 2016, Washington passed legislation (HB 2681) to increase awareness of the availability of contraceptives in pharmacies; requiring the Pharmacy Quality Assurance Commission to develop a sticker or sign to be displayed on the window or door of a pharmacy letting the public know of services. In reality, the sign is not widely disseminated or used, and stakeholders have found promotion on social media to be a more effective approach.

Uptake in Washington state is strong with contraception for many years representing the largest number of prescriptions written by Washington pharmacists. Extrapolating from various data sources, stakeholders estimate pharmacists in Washington have served over 3 million patients for contraception overall. Services are mostly cash and Medicaid.

CALIFORNIA

Effective: 2016
Mechanism: Legislation – Pharmacy Practice
Model: Statewide Protocol
Ages: All

California was first state to pass dedicated legislation in 2002 to allow pharmacists to prescribe emergency contraception and advocates in the state continued to lay the groundwork for pharmacist prescribing of hormonal contraception. In 2008, Pharmacy Access Partnership, a center of the non-profit Public Health Institute explored introducing dedicated legislation for pharmacist prescribing of hormonal contraception but faced initial opposition from organized medicine to successfully introduce a bill. In 2013, the California Pharmacists Association moved from a standalone bill approach and took a lead in supporting legislation allowing pharmacists to provide various clinical services focused on public health including immunizations, tobacco cessation, travel medications, and hormonal contraception, in addition to establishing the pharmacist scope to order tests and established a new license category for Advanced Practice Pharmacists. The legislation (SB493) was sponsored by a Democratic optometrist. As legislation encompassed other clinical services, there was no specific mention of age and age restrictions were avoided. Legislation also grandfathered in pharmacy students graduating after 2014 to remove additional training barriers and encourage pharmacist participation. The California Medical Association initially opposed the legislation but became "neutral" on an amended version, and soon all organized opposition was dropped.

The bill was passed in 2013 and became effective January 1, 2014. However, the state experienced delays in the rule-making process and implementation officially started as of April 2016. Studies show about 11% of pharmacies were providing services in the first year. A key challenge for widespread program implementation in California is payment for services. Legislation (AB 1114) was passed in 2016 to require the state Medicaid program to cover selected pharmacist services. As of April 1, 2019, the state Medicaid (Medi-Cal) and family planning programs (FamilyPACT) allow payment for selected pharmacist services including contraception (Level 1 only covers ~5-10 minutes).

OREGON

Effective: 2016
Mechanism: Legislation – Contraception
Model: Statewide Protocol
Ages: All

Oregon became the first state to implement its statewide protocol for pharmacist prescribing of hormonal contraception. Oregon's legislation passed in 2015 with bipartisan support. The bill (HB2789) and was physician led in that both bill sponsors were doctors. Representative Steiner Hayward (Democrat) practiced as a family physician at Oregon Health and Science University and served as the past President of the Oregon Academy of Family Physicians. Representative Buehler (Republican) is a physician member of the Oregon House Committee on Health Care, which reviewed pharmacist scope of practice during its 2015 session. Physician support was important in moving the bill forward.

Legislation was initially limited to oral and transdermal contraceptives but in 2017 the Legislature passed a second bill (HB2527) to broaden the term of "self-administered hormonal contraceptives" to also include the injection and vaginal ring. There were age restrictions in the initial bill limiting access to women 18 and older or those that are younger only with proof of prior prescription from provider. Added into the legislation was a sunset clause effective January 2020 terminating any age restrictions.

Another notable distinct approach and emphasis in Oregon is the required certification for pharmacists. They found that benchmarking training was important in the commercial payor space and also facilitated payment for pharmacist services.

COLORADO

Effective: 2017
Mechanism: Legislation – Pharmacy Practice
Model: Statewide Protocol
Ages: 18+

Pharmacist-prescribed contraception in Colorado was rolled out through 2016 legislation (SB 16-135) allowing Boards of Pharmacy, Nursing, and Medicine and the Colorado Department of Public Health and Environment to collaborate on statewide protocols to address public health needs, improve patient outcomes, and save costs to the health care system. The bill did not mention contraceptive services specifically and push back was more focused on avoiding language like "diagnosing." Pharmacists prescribing of hormonal contraception went live March 2017 and currently upwards of 600 pharmacists are trained. Participation by chain pharmacies (with the exception of Walgreens) is growing and is strongest around college campuses. Colorado drew on Oregon's algorithms and billing approach. The contraceptive product is reimbursed by Medicaid and all major insurers. Addition of the vaginal ring and depot shot services remain priorities to improve their access model.

HAWAII

Effective: 2017
Mechanism: Legislation – Contraception
Model: Statewide Protocol
Ages: All

It took two attempts to pass Hawaii's pharmacist prescribing of hormonal contraception legislation. The first bill was introduced in 2016 with no major opposition but did not pass. Hawaii's Board of Pharmacy made some clarifications on training requirement and then an all women and all Democrat sponsored legislation introduced by Hawaii's Women's Legislative Caucus passed in 2017. The bill borrowed Oregon's legislative language. An interdisciplinary workgroup with representatives from the Daniel K. Inouye College of Pharmacy, Hawaii Pharmacist Association, Hawaii Board of Pharmacy and Hawaii Department of Health supported the legislation and protocol development. No administrative rulemaking was necessary to implement the law and no specific hours of continuing education is required although training must be ACPE approved. Oregon State University worked with Daniel K. Inouye College of Pharmacy to provide trainings for Hawaii Pharmacists. Challenges remain around reimbursement. As one of Hawaii's main insurance carrier is focused on moving toward a "pay for quality" instead of "fee for service" approach, there is more resistance to adding pharmacists to fee for service payment systems.

"Pharmacists already graduate with these skills – so why aren't we able to offer this service?"

– Brooke Griffin, PharmD, Professor of Pharmacy Practice, Midwestern University, 2020

NEW MEXICO

Effective: 2017
Mechanism: Regulatory Change
Model: Statewide Protocol
Ages: All

New Mexico amended its Pharmacist Prescriptive Authority Act created in 2001 to include hormonal contraception in 2017. The state has an active large interdisciplinary workgroup including representatives from University of New Mexico College of Pharmacy and New Mexico's Department of Health, that were involved in drafting the state's hormonal contraception protocol and training requirements. No age restrictions were included in the protocol however pharmacists must report to the State any services they provide to teens under age thirteen. Like California, New Mexico allows recent pharmacy student graduates to provide contraception services immediately upon graduation.

Currently, 34 pharmacies are listed as providing services on the birthcontrolpharmacies.com website. Given the many rural regions in the state, New Mexico is also exploring remote training opportunities for pharmacists including leveraging Extending Community Healthcare Outcomes (ECHO) Telehealth program as a viable webinar type training program for hormonal contraception services.

Reimbursement created a barrier for wider program uptake. A pharmacist reimbursement parity bill (HB578) was introduced in 2019 but did not pass. A second bill, Pharmaceutical Service Reimbursement Parity (HB42) was enacted February 2020 making New Mexico the first state that requires clinical services provided by pharmacists to be covered under all health insurance plans, including Medicaid. Specifically, the legislation enabled pharmacist clinicians and other pharmacists with prescriptive authority to receive payment for clinical services from groups at the standard contracted rate as a licensed physician, physician assistant or advanced practice certified nurse practitioner.

TENNESSEE

Effective: *In Progress*
Mechanism: Legislation – Contraception
Model: Collaborative Practice Agreements
Ages: 18+

In the 2015-2016 legislative session, Sen. Steve Dickerson, a Republican and anesthesiologist, sponsored SB 1677 to allow pharmacists to enter into collaborative agreements with physicians, to prescribe birth control. He pitched the bill as one way the state could help prevent unintended pregnancies and save women and taxpayers related costs associated with unplanned pregnancies. Sen. Jeff Yarbro (D-Nashville) proposed a similar bill in the same session (SB 1958/HB 1847) which did not move.

The Family Action Council Tennessee did some public awareness and social media campaigns about what they saw as problems of the bill, including the lack of age restrictions as a public health danger. The bill added age restrictions allowing pharmacists to serve women ages eighteen and older or emancipated minors. The Tennessee Medical Association worked with Tennessee Pharmacists Association on amendments to create a bill that would be acceptable to both parties and the Tennessee Medical Association was neutral on the bill as amended. The bill included a pharmacist administrative

fee originally proposed at $20, but the amended bill allowed the individual pharmacist or corporate employer to set their consultation fee. Pharmacists will be able to prescribe medication for up to one year (or one prescription with 11 refills); and only for uninsured patients.

The bill cleared the Senate health and welfare committee on a 7-1 vote after members of the panel heard testimony from Dr. Leonard Brabson, the state chairman of the American College of Obstetricians and Gynecologists. Sen. Joey Hensley (R-Hohenwald) cast the lone committee vote against the bill based on his concerns around the logistics of pharmacist-patient conversations, whether an annual physical exam is needed and whether women would lie about not being smokers to the pharmacists. He also felt birth control was already readily available through the health department. Ultimately the bill passed in Tennessee's House 84-4 and in Senate 23-8 and signed into law April 2016.

Tennessee's rulemaking took another two years, which is not unusual in the state. Rulemaking was completed April 2019. Pharmacists are currently completing training for the program to make services available.

UTAH

Effective: 2019
Mechanism: Legislation – Contraception
Model: Standing Order
Ages: 18+

Utah's legislation is a prime example of how a student and community member can inspire legislative efforts. Wilson Pace, a 29-year-old pharmacy graduate drafted a "dream bill" for his leadership class after hearing about delays and added costs that his wife faced in obtaining contraceptives in Utah. He reached out to local lawmakers and Senator Todd Weiler and Representative Raymond Ward, both Republicans, sponsored SB 184 to allow pharmacists to provide hormonal contraception to adult women under standing orders with a physician.

Notably, Rep. Ward is a family physician with a PhD in Pharmacology from University of Washington and Sen. Weiler is a lawyer who sponsored anti-abortion legislation requiring women to watch informational sessions discouraging procedures.

Utah already passed legislation in 2016 allowing pharmacists to give out the opioid antagonist naloxone for overdose rescue. And in 2017 on a national level, Utah Republican Rep. Mia Love and Iowa Republican Senator Joni Ernst introduced legislation in Congress, HR 421 known as the "Allowing Greater Access to Safe and Effective Contraception Act" to pave the way for making birth control over the counter. This bill was reintroduced in March 2019 by Senator Ernst.

SB 184 passed both houses without a single opposing vote in the 2018 general session.

On March 27, 2019, Utah Department of Health (UDOH) Executive Director Dr. Joseph Miner issued a standing order allowing adult women in Utah to obtain selected contraceptive medications from participating pharmacists without needing a prescription. The order requires a patient to see a women's health care provider at least once every two years if they wish to continue utilizing the standing order. Women will be responsible for covering the cost of their medications and the consultation with their pharmacist, either by utilizing insurance coverage or paying out of their pocket. Pharmacists are required to complete an online training and must register with the UDOH. They will also be required to

submit annual reports on their dispensing activities to UDOH. Students at Utah pharmacy schools will receive the requisite training as part of their curriculum moving forward.

MARYLAND

Effective: 2019
Mechanism: Legislation – Contraception
Model: Statewide Protocol
Ages: All

Legislation in Maryland was initiated and led by Senator Shelly Hettleman, who actively engaged and gained support from various stakeholders including physicians, nurse practitioners and pharmacists as well as reproductive health advocates like Planned Parenthood, before introducing legislation. From the onset, she incorporated billing language in the legislation to address pharmacist concerns about providing services without adequate reimbursement. She used a public health framework to communicate about the bill and given her early groundwork, the bill moved quickly through the legislature without any formal opposition and passed April 2017, with the program becoming effective after rule making and protocols passed in March 2019. The first training program was approved in March 2019. Also, as of January 1, 2019, qualified pharmacists and pharmacies may enroll with Maryland Medicaid as a Pharmacist Prescriber provider type. Pharmacists must provide proof of training to the Maryland Board of Pharmacy at least 15 days before participating in the protocol.

WASHINGTON D.C.

Effective: *In Progress*
Mechanism: Legislation – Contraception
Model: Collaborative Practice Agreements
Ages: All

As early as 2011, Advocates for Youth, a non-profit based in Washington DC has been working to lay a foundation to allow pharmacists to provide hormonal contraception directly to women in the district. Councilmember David A. Catania and several co-sponsors introduced the “Collaborative Care Expansion Act of 2012” to generally permit pharmacists to enter into collaborative practice agreements with physicians. With support from the Medical Society of the District of Columbia, the legislation was approved by the Mayor and Congress, effective October 2012. However, a lengthy and back logged rule-making process delayed protocol development and actual hormonal contraception program implementation was not realized.

So, in 2017, Councilman Charles Allen accompanied by several council member co-sponsors introduced the Defending Access to Women’s Health Care Services Amendment Act of 2017 in response to Republican efforts to repeal the Affordable Care Act. Councilman Allen has a public health background and was a graduate fellow with the federal Department of Health and Human Services who worked on expanding community-based health options. Among a variety of preventative health services, his proposed bill specifically allowed pharmacists to prescribe up to 12 months of hormonal contraception after women self-screen using a tool created by the DC Board of Pharmacy. While the legislation did not detail age restrictions, it did specify in amendments that instead of allowing pharmacist to charge a $25 fee, insurers would be required to pay for contraceptives under the law. The law requires that patients have access to copay-free birth control, regardless of whether the receive coverage through insurance providers, Medicaid, or the D.C. Healthcare Alliance. Amendments

also incorporated include a provision for religious exemptions for certain employers. The legislation tasked the D.C.'s Board of Pharmacy to specify exact rules and regulations. The legislation, known as Defending Access to Women's Health Care Services Amendment Act of 2018 (B22-106), was unanimously passed by the D.C. Council, approved by Mayor Muriel Bowser and enacted by Congress effective March 2018.

Representatives from the District of Columbia Boards of Pharmacy and Medicine met in February 2019 to discuss rulemaking to authorize pharmacists to prescribe hormonal contraceptives in the District of Columbia. A joint committee drafted regulations and the District of Columbia Board of Pharmacy discussed regulations at its recent April 2019 meeting.

NEW HAMPSHIRE

Effective: *In Progress*
Mechanism: Legislation – Contraception
Model: Standing Order
Ages: All

In New Hampshire's 2017 legislative session, HB 264 was first passed to establish a commission to study allowing pharmacists to prescribe oral contraceptives via protocol. The commission, representing the state medical society, American Congress of Obstetricians and Gynecologists, Board of Pharmacy, pharmacists, nurse practitioners, nurses, Department of Health officials, Planned Parenthood, and Title X clinics generated a report unanimously voting for and recommending pharmacist prescribing of hormonal contraception in the state.

A bill was then proposed in the 2018 session by Senator Mariellen MacKay, who switched her affiliation from Democratic to Republican in 2017. The legislation was co-sponsored by nine other lawmakers from both political parties. Despite momentum and support, the bill experienced unexpected opposition in the House Health and Human Services committee led by Democrat Rep. Mindi Messmer who objected to what she said was insufficient screening procedures and that pharmacists were overstretched to handle the additional responsibility. The committee recommended the bill be killed, 13-8 but it was able to move forward in a House vote particularly having evidence-based reports from multiple professional medical associations and recent passage of an additional bill (SB 421) mandating insurers offer 12-month prescriptions for contraceptives.

The law requires the Board to adopt rules related to educational requirements to comply with the statute, work with the commissioner of the New Hampshire Department of Health and Human Services (DHHS) to develop both the content and format of the standardized information sheet, and to create a statewide protocol that is approved by the boards of medicine and nursing and DHHS.

Over the past several months, the Board has held stakeholder meetings to address the requirements for a statewide protocol, educational requirements, and a statewide standing order for delegate-limited prescriptive authority. A statewide protocol has been developed and approved by the New Hampshire boards of medicine and nursing and by DHHS. A lead physician at Dartmouth-Hitchcock's Obstetrics, Gynecology & Nurse Midwifery Department has agreed to author a statewide standing order.

Northeastern University has an agreement with the University of Oregon for New Hampshire pharmacists to complete their extensive and comprehensive ACPE-accredited educational training program on hormonal contraceptives. Rules have been drafted and were open for public comment and review by the Board at its April 2019 meeting. Their goal was to have New Hampshire's pharmacist

prescribing of hormonal contraception program operational by Fall 2019. The Board is also in discussions with the New Hampshire Insurance Department regarding payment for the clinical services related to the evaluation and completion of documentation necessary to issue and dispense an oral hormonal contraception therapy.

WEST VIRGINIA

Effective: 2020
Mechanism: Legislation – Contraception
Model: Standing Order
Ages: 18+

West Virginia's 2019 bill, HB 2583, or better known as the "Family Planning Access Act" was introduced by bipartisan cosponsors and was passed June 17, 2019, allowing pharmacists to dispense self-administered hormonal contraception pursuant to a statewide standing prescription by the state health officer. The bill initially started without age restrictions and had widespread stakeholder support, although some pharmacists voiced objections to serving women below age eighteen. An amendment was introduced by Senator Rucker to restrict services to women ages eighteen and older. Other details were left to be determined in the rule making protocol development. A parallel separate bill allowing pharmacists to dispense tobacco cessation medication also passed in the same legislative session. HB 4198, introduced January 2020 and effective June 2020 permits a patient to a 12-month supply of contraceptive agents. Shortly after, Senate bill 787 (SB787) was passed and became effective July 1, 2020 acknowledging pharmacists as medical providers, allowing for provider status and reimbursement for pharmacy consultation.

IDAHO

Effective: 2019
Mechanism: Legislation – Pharmacy Practice
Model: Prescriptive Authority
Ages: All

Idaho's 2019 bill, HB 182, amended section 54-1704 of Idaho code to revise provisions regarding products that may be dispensed. Under this act, the scope of practice for pharmacists was revised to include prescribing of drugs or devices for conditions that do not require a new diagnosis, are minor and self-limiting, have a test used to guide diagnosis, or threaten the health of the patient if a prescription is not immediately dispensed. Drugs that are excluded are controlled substances, compounded drugs, or biological products. Hormonal contraception would be allowed based on these restrictions.

MINNESOTA

Effective: 2020
Mechanism: Legislation – Pharmacy Practice
Model: Statewide Protocol
Ages: 18+ and <18 with prior prescription

In 2020, the Minnesota Legislature passed bill HF3727 sponsored by Rep. Rena Moran and was approved, as amended, by the House Health and Human Services Policy Committee. The law will allow pharmacists to independently prescribe three categories of drugs: self-administered hormonal contraceptives, opioid antagonists, and nicotine replacement products. In order to prescribe these drugs, pharmacists must follow protocols developed by the Minnesota Board of Pharmacy. The protocols were developed in consultation with the Minnesota Department of Health, the Minnesota Boards of Medical Practice and Nursing, and professional associations representing advanced practice registered nurses, pharmacists, physicians, and physician assistants. The Minnesota Board of Pharmacy has released a Pharmacist Prescribing Protocol, last updated 12/24/20 that specifies the steps pharmacists should take when prescribing self-administered hormonal contraceptives. This protocol was approved on 12/30/20.

VIRGINIA

Effective: *In Progress*
Mechanism: Legislation – Pharmacy Practice
Model: Statewide Protocol
Ages: 18+

Virginia's 2020 bill, HB 1506, was signed into law by Governor Ralph Northam in April 2020. The law will allow pharmacists to dispense self-administered birth control, like pills and patches, as well as the depot shot, directly to patients over 18. The bill also allows pharmacists to furnish opioid antagonists, epinephrine, fluoride supplements and prenatal vitamins that require a prescription. Pharmacists can also dispense prescription medications if they cost less than an over-the-counter version. On September 9, 2020, Virginia adopted a protocol, algorithm, and self-screening questionnaire for pharmacists to use when prescribing hormonal contraception and emergency contraception, but they have yet to be implemented.

IMPLEMENTATION

Fully realizing pharmacist prescribing of hormonal contraception at the state level generally follows a shared trajectory:

While pharmacist prescribing of hormonal contraception legislation passes relatively quickly in each state, many states experienced long delays in their rule-making process to develop and approve protocols and/or screening assessments and/or pharmacist trainings to realize actual program implementation. Nearly half of the states that passed legislation took another year or more to go through their rule making process, with states like California taking over two years and Tennessee two years. Some states required multiple Boards and Departments develop and approve protocols and several states formed multidisciplinary workgroups or committees to develop protocols and related screening tools. Having model protocols from other states expedited the process for some states. California developed the first self-screening questionnaire that was then adopted by Oregon and used in conjunction with a newly developed algorithm, which is now used by a few other states. Notably, pharmacists measuring blood pressure as part of the screening requirement, ultimately facilitated pharmacist's ability to bill Medicaid in Oregon and receive payment for assessment of a body system.

"We're literally blazing trails here, which is really exciting, and we know it's going to benefit patients, but it is a bit maddening sometimes how slow the process works."

– Jon Roth, Executive Director of California Pharmacists Association, 2016

Once protocols are in place, training pharmacists is the next step towards implementation. California originally proposed no specified training requirements to remove barriers to pharmacist participation but settled on 1 hour of continuing education required while grandfathering in all school of pharmacy graduates after 2014. New Mexico also grandfathered in pharmacy students. Oregon opted to have pharmacists certified and this approach served them well for billing and reimbursement. Oregon State University's College of Pharmacy developed five-hour online state-based Comprehensive Contraceptive Education and Certification training program that has been adapted to a four-hour program for several other states.

Billing, reimbursement and insurance coverage is by the far the biggest impediment to widespread program implementation. And states have addressed billing and reimbursement challenges in a variety of ways. Most states moved away from allowing a set pharmacist fee in legislation or protocol language, and several chains across states have implemented flat pharmacist prescribing fees ranging from $25-$50. A tension exists with Medicaid billing and "provider status" in some existing pharmacist prescribing of hormonal contraception models. For example, under a collaborative practice agreement model, a pharmacist is technically not an independent prescriber making use of the appropriate billing codes challenging. In Oregon, getting pharmacists certified facilitated their ability to bill. In California, in 2018 lawmakers passed a separate law requiring the state to pay pharmacists for their time when they prescribe hormonal contraceptives. New Mexico introduced a pharmacist reimbursement parity bill this year which did not pass but expected to advance next session. Some states have expanded their "Provider status" to include pharmacists to aid in billing. More recently, states like Maryland have included payment mechanisms directly into legislation which if possible is a best practice for other states to replicate.

Beyond pharmacist reimbursement, another significant hurdle in leveraging pharmacist ability to provide birth control directly to women is a major lack of public awareness these services are available. All states experienced local and even national press coverage when their laws passed, however services were not actually available at that time. Press coverage was nearly non-existent when rulemaking was completed and programs could technically start.

Additionally, as programs are not government mandated or funded, states lack a centralized coordinating organization to focus on increasing public awareness and letting women know which pharmacies provide these services. Attempts by states, like Washington, to require posting a sign in pharmacies to promote services have not been as effective as promoting available services and locations online.

Overall, program implementation does not occur as one distinct moment, making it more challenging to effectively communicate and promote to both pharmacists and women. Having centralized resources for states to avoid reinventing the wheel would be helpful.

Conclusion

Direct access to birth control through pharmacist prescribing has been realized in many states in the last few years. Pioneering efforts in Washington allowed pharmacists to prescribe hormonal contraception with collaborative practice agreements and, more recently, California led the way for other states with the first statewide protocol specifically expanding pharmacists' scope to include prescribing hormonal contraception. While state policies have not realized their full potential and there is room to optimize existing and future programs to meet people's needs, there have been many successes leading to increased access. Pharmacist prescribing of contraception is an important strategy to increase access to contraception in the United States and pharmacies will remain a critical access point to contraception.

"This is an invaluable service – especially for people like me who are experiencing a lapse in insurance coverage."

– Natalie C., Patient, The Pharmacists Clinic, 2016

Additional Information and References

For additional information on this topic, visit https://birthcontrolpharmacist.com.
For a comprehensive list of references on this topic, visit https://birthcontrolpharmacist.com/research.

APPENDIX

Appendix 1. Model Bill Elements.

Element	Best Practice	Examples	Less Preferable Approaches	Examples	Rationale/ Explanation
Mechanism	Statewide protocol	**CA**, **HI**, CO, MD, MN, NM, OR	CPA, Standing order	DC, NH, TN, UT, WV	CPA and standing order are more restrictive with logistical barriers.
Procedures	CDC MEC guidelines with patient self-screening questionnaire	**CA**, **HI,** CO**,** MN, NM, NH, VA	BOP-developed procedures and algorithms		CDC MEC guidelines are up-to-date and considered the national standard of practice.
Methods	Contraception	**CA, NM**, OR, VA	Specific methods (oral and transdermal)	CO	Evidence supports no restriction. "Self-administered" can be interpreted as excluding the shot. "Hormonal" may be interpreted as excluding ulipristal acetate EC and excludes diaphragm, gel, and condoms.
Age	Not specified	CA, DC, MD, NH, NM	18+	UT, TN, CO, WV, WA, HI, MN, VA	Evidence supports no restriction.
Duration	Not specified	CA, NM, TN, MD, NH, VA	3 years	UT, CO, OR, HI, MN, WV	Evidence supports no restriction.
Counseling	Not specified	CO, HI, MD, VA	Specific counseling points listed in legislation and/or protocol	OR, MN, NM, TN, WV, UT	Counseling included in pharmacist professional standard of practice.
Training	ACPE-accredited curriculum-based or continuing education training program	**CA**, **HI**, **MN**, CO, NH	Approved by Board of Pharmacy or any other entity	UT, MD, TN, OR, NM	Requiring approvals leads to delays & limits availability of programs.
Reporting, Referrals, and Notifications	Not specified		Registry reporting PCP notifications Referrals to clinics	CA, UT, NM, MN, OR, CO, HI, TN, MD	Prevents barriers for pharmacist participation & promotes access for patients.
Patient Awareness	Public awareness campaign	**NJ**			Helps remove barrier of patient unawareness.
Insurance Status	Not specified	CA	Restricting	TN	Removes barriers for patients with insurance.
Practice Restrictions (i.e., prohibiting appointments)	Not specified	CA, MD, MN, VA, NH	Restricting	UT, CO, OR, HI, TN	Restricts professional practice and service delivery.
Product Reimbursement	Not specified		Anything other than requiring coverage when prescribed by pharmacist		Not necessary to address.
Payment for Pharmacist Service	Require for all private and Medicaid plans to cover				Prevents barriers for pharmacist participation & promotes access for patients.

Appendix 2. State Policy Details.
Including legislative references, including bill number and year, and relevant state statutory citations.

Passed

State	Status	Model	Legislation	Legislation Scope	Provider Status, Coverage Parity^, or Payment for Services Addressed?	Effective	Protocol Passed	Age Restriction
Washington	Implemented	Collaborative Practice Agreements	N/A	Rx Scope	Coverage parity for commercial insurance (ESSB 5557)	1979 Binding 1981	N/A	18+
California	Implemented	Statewide Protocol	SB 493	Rx Scope	Provider status in original bill; Payment for hormonal contraception service for Medicaid in subsequent bill (AB 1114)	01/01/2014	04/16/2016	None
Oregon	Implemented	Statewide Protocol	HB 2879 (and later HB 2527)	HC Only	Provider status, permits health insurers to provide payment for services provided by pharmacists through practice of clinical pharmacy or pursuant to statewide drug therapy management protocol (HB 2028)	07/06/2015 (and later 06/14/2017)	01/02/2016 (and later 01/01/2018)	None
Colorado	Implemented	Statewide Protocol	SB 16-135 HB 18-1313	Rx Scope	Coverage parity in areas with a health professional shortage (HB 18-1112)	2017	03/17/2017	18+
Hawaii	Implemented	Statewide Protocol	HB 675 SB 513	HC Only	Not Addressed	07/01/2017	07/01/2017	None
New Mexico	Implemented	Statewide Protocol	2001	Rx Scope	Coverage parity for group health plans (HB42)	06/09/2017	04/20/2017 (effective 06/09/2017)	None

State	Status	Model	Legislation	Legislation Scope	Provider Status, Coverage Parity^, or Payment for Services Addressed?	Effective	Protocol Passed	Age Restriction
Tennessee	Implemented	Collaborative Practice Agreements	SB1677	HC Only	Provider status through managed care insurance issuers (HB 405/SB 461)	04/27/2016	04/18/2018	18+
Washington DC	Pending Rules & Protocol Approval	Collaborative Practice Agreements	B19-657 B22-106	Rx Scope	Not Addressed	B19-657 10/22/2012 B22-106 03/28/2018	08/17/2018	None
Utah	Implemented	Standing Order	SB 184	HC Only	Not Addressed	5/8/18	3/27/2019	18+
Maryland	Implemented	Statewide Protocol	HB613 SB363	HC Only	Payment for services addressed in original bill	March 2019	March 2019; Mandated by 9/1/2018	None
New Hampshire	Pending Rules & Protocol Approval	Standing Order	HB 1822	HC Only	Not Addressed	01/01/2019	N/A	None
West Virginia	Implemented	Standing Order	HB 2583	HC Only	Coverage parity for health plans issued or renewed on or after 01/01/21 (SB 787)	06/17/2019	N/A, pharmacies required to set up their own standing orders	18+
Idaho	Implemented	Statewide Protocol	HB 182	Rx Scope	Not Addressed	07/01/2019	03/12/2019	None
Minnesota	Implemented	Statewide Protocol	SF 13	Rx Scope	Not Addressed	05/28/20	12/30/20	18+ and <18 with prior Rx
Virginia	Pending Emergency Regulations	Statewide Protocol	HB 1506	Rx Scope	Not Addressed	07/01/20	Pending	18+

^Coverage parity refers to coverage for service provided by all provider types within scope of practice, including pharmacists.

Other Policies Under Consideration or Attempted

Note: This is not an exhaustive list. The landscape is constantly evolving.

State	Bill #	Author/ Sponsor	Date Introduced	Status
Arkansas	HB1290	Aaron Pilkington (R)	01/28/19	Failed House, but motion by Rep. Jeff Wardlaw (R) to expunge the vote was approved, allowing bill to be considered later. Ultimately failed in Senate Committee 4/24/19.
Arizona	SB 1493	Sen Ugenti-Rita (R)	02/03/20	Passed Senate 02/20/20. Legislation is on hold due to COVID. Assigned to House Rules Committee 05/20/20.
Illinois	HB 1442	Michelle Mussman (D)	01/29/19	Proposed bill using standing orders model. Referred to Rules Committee on 4/12/19. Failed on 12/31/20.
Iowa	SF513 (HF727, formerly HSB214)	Governor Kim Reynolds (R)	03/06/19	Proposed bill using standing orders model passed Senate 03/27/19. House version HF727 amended on 04/15/19 and referred to Human Services as of 04/27/19. Notably, Iowa is one of two states where all rulemaking has to get reapproved through legislation, which takes another 18 months to pass.
Missouri	HB 1410	Sheila Solon (R)	01/8/20	Read 01/08/20 in House. Referred to House Children and Families Committee 05/15/20.
Nevada	SB361	Nicole Cannizzaro (D)	03/19/19	Passed unanimously in Senate with amendment. Referred to Assembly Committee on Commerce and Labor on 06/03/19, which failed to meet.
New Jersey	S1139	Sen Vitale (D)	01/30/20	Introduced in Senate and referred to Senate Health, Human Services and Senior Citizens Committee 01/30/20.
New York	S6811	Toby Ann Stavisky (D)	02/24/16	Referred to Senate Higher Education Committee 02/24/16.
Rhode Island	H5549 S2388	Camille F.J. Vella-Wilkinson (D) Sen McKenney (D)	03/28/19	Passed House 06/12/2019. Referred to Senate Health and Human Services 06/21/2019. Introduced in Senate and re-referred to Senate Health and Human Services 02/13/2020.

State	Bill #	Author/ Sponsor	Date Introduced	Status
South Carolina	S. 448 HB3844	Sen Davis (R) Todd Rutherford (D)	01/29/19 02/05/19	Referred to Senate Committee on Medical Affairs on 01/29/19. Referred to Committee on Medical, Military, Public and Municipal Affairs on 02/05/19.
Texas	SB835 HB4285	Borris Miles (D) William Zedler (R) Donna Howard (D)	02/14/19 03/08/19	Referred to Health and Human Services Committee on 03/01/19. Left pending in House committee 05/01/19.
Wisconsin	LRB-0325/1 LRB-3281/2 AB290	Joel Kitchens (R) Melissa Sargent (D)	05/17/19 06/13/19	Restricted to patients over 18, only included patch and pills. Sargent's bill would eliminate age restrictions and add depot injection and vaginal ring. Failed House 04/01/2020.

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