MPR | ASK THE EXPERT

Evolving Access to Oral Contraceptives

A New Prescribing Role for Pharmacists

THE FACULTY

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Forty-five percent of pregnancies in the United States are unintended, according to the most recent data.[1]

The consensus among experts in reproductive health is that lowering the high proportion of unintended (ie, mistimed or unwanted) pregnancies remains a public health priority. Compared with females whose pregnancies are planned, women and girls who have become pregnant unintentionally are more likely to receive inadequate prenatal care, expose their fetus to tobacco and alcohol, give birth prematurely, and bear low-birthweight infants.[1]

Increasing access to contraception is one strategy to help reduce the rate of unintended pregnancies. Fortunately, access to contraception has expanded in recent years. One positive development on the national level has been the implementation of the Affordable Care Act (ACA).[2] This law requires most health insurance plans (except those that are grandfathered) to cover (without cost sharing) at least one contraceptive from each category of methods identified by the FDA.[3] The mandate has saved the average oral contraceptive (OC) user approximately $255 per year and has reduced women's annual overall out-of-pocket spending for OCs by $1.4 billion.[4]

More recently, California and Oregon have become the first states to pass legislation and implement regulations allowing qualified pharmacists to prescribe and dispense certain types of contraceptives, including OCs.[5,6] ***Table 1*** provides an overview of the relevant regulations in those two states. Legislation regarding pharmacist-prescribed contraception is being considered in a rapidly growing number of other states as well.

In the following interview, Sally Rafie, PharmD, a pharmacist specialist who was involved in the development of California's hormonal contraception protocol, and Lorinda Anderson, PharmD, who helped design Oregon's requisite training course for prescribing pharmacists, offer their expert opinions on expanding access to OCs in their respective states.

Q **In your opinion, what are the implications of legislation allowing qualified pharmacists in California and Oregon to prescribe and dispense certain types of contraceptives? What is your take on how women perceive these new laws?**

A **Dr. Rafie:** Increasing women's access to contraception is what the legislation is all about. Women want to be able to decide if and when they have children; giving them the tools to do that is hugely empowering.

For many women in California and Oregon, going to either a clinic or doctor's office to obtain prescription birth control remains an option. However, some women may not have transportation or the time to take a day off from work to sit in a clinic waiting room, so being able to visit a pharmacy in the evenings or on weekends could really help them.

I've been speaking to friends, family, physician and pharmacist colleagues, and patients about the change in pharmacists' prescribing authority in California. For the most part, everyone is really excited about this new development. Of course, questions have been raised as to whether women whose contraception is prescribed by a pharmacist will obtain routine health screenings. Prescribing pharmacists should remind patients of the need to continue seeing a women's healthcare professional for routine breast examinations and Pap smears and should provide patients with referrals whenever appropriate.

Dr. Anderson: In the United States, the rate of unintended pregnancies remains high.[1] The goal of the legislation in California and Oregon is to improve access to contraception as appropriate with a secondary goal of decreasing the rate of mistimed or unwanted pregnancies.

I've had many discussions with groups of pharmacists who prescribe and dispense contraception in Oregon. Occasionally, a pharmacist will notice that a patient has run out of refills on her contraceptive, at which point the pharmacist will offer to prescribe and dispense the product so that the patient will not have to wait for her provider to write a new prescription.

Table 1. Pharmacist-Prescribed Contraception in California and Oregon: Overview of the Regulations

	CALIFORNIA	OREGON
What Pharmacists Can Prescribe	• OCs • Transdermal patch • Vaginal ring • Injection	• OCs • Transdermal patch
Patient Age Restrictions	None	Patients <18 years of age must have previously received a prescription for contraception from a PCP or women's healthcare professional
Training Required	A minimum of 1 hour of continuing education that covers the use of hormonal contraception in accordance with the current US MEC and other relevant guidance from the CDC • An equivalent, curriculum-based training program completed in or after 2014 at an accredited California school of pharmacy is sufficient	A 5-hour online course, which has been approved by the Oregon State Board of Pharmacy • For more information, visit **pace.oregonstate.edu/catalog/comprehensive-contraceptive-education-and-training-prescribing-pharmacist**
How to Obtain Information About Relevant State Requirements	• Visit **pharmacy.ca.gov/licensees/hormonal_contraception.shtml** • Call the California State Board of Pharmacy (916.574.7900)	• Visit **www.oregon.gov/pharmacy/Pages/ContraceptivePrescribing.aspx** • Contact the Oregon State Board of Pharmacy via email (**pharmacy.board@state.or.us**) or phone (971.673.0001)

CDC = Centers for Disease Control and Prevention; OC = oral contraceptive; PCP = primary care provider; US MEC = United States Medical Eligibility Criteria for Contraceptive Use.

Sources: California Legislative Information. Senate Bill No. 493[5]; California State Board of Pharmacy. Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception[7]; Oregon Laws 2015, Chapter 649, HB 2879.[6]

From what we've seen in Oregon, it is actually the patients who have been seeking out the new prescribing service at pharmacies, and it seems really popular. For many women, going to a pharmacist for hormonal contraception is more convenient than arranging an office visit with a women's healthcare professional because pharmacies tend to be open in the evenings and on weekends, and patients can be seen on a walk-in basis. This can be very empowering to women because it gives them more control and helps them manage their busy schedules. It also gives them faster and more convenient access to contraception when needed.

Q **Under the Affordable Care Act, insurance plans are permitted to use cost sharing to encourage or discourage use of specific contraceptive products.[3] In your opinion, how much does cost sharing influence the decision of which OC to prescribe? Are there any concerns that cost sharing could prevent a patient from receiving the OC that is optimal for her?**

A **Dr. Rafie:** The good news is that there are many OCs to choose from. So, in most cases, pharmacists are able to find a suitable OC that is covered by the patient's insurance. The even better news is that California passed its own law (Senate Bill 1053)[8] mandating insurance coverage of prescribed birth control products, so cost sharing for OCs in my state is even less of an issue now than it would be otherwise.

Dr. Anderson: Pharmacists are very aware of cost sharing and how to deal with it, based on their experience filing claims with insurance companies and finding out whether there is coverage for a particular product. There are so many OCs available that it really should not be a big deal to find one that would work for a patient and is covered by her insurance.

Q **When choosing from among the many combination OCs available, how do the doses of estrogen factor into your decision (if at all) regarding which OC to prescribe?**

A **Dr. Rafie:** Most combination OCs on the market today contain 10 to 35 mcg of ethinyl estradiol and therefore are considered low dose.[9] The dose of estrogen is only one of several factors to consider when choosing among the combination OCs. Some other factors that should be considered include the type of progestin and noncontraceptive goals, such as menstrual suppression or acne treatment.[10,11]

Dr. Anderson: The doses of estrogen in most combination OCs are really low these days. The guidelines for prescribing combination OCs recommend using "low-dose estrogen," which refers to ethinyl estradiol doses of 35 mcg or less.[9] That being said, the estrogen component of a combination OC does tend to increase the risk for thromboembolism, so I try to start with a lower dose of estrogen whenever possible and appropriate.[9]

Table 2: Guide to Different Types of Oral Contraceptives

PROGESTIN-ONLY ORAL CONTRACEPTIVES
Also known as "mini-pills," progestin-only OCs are a possible option for women who should not take estrogen.
COMBINATION ORAL CONTRACEPTIVES
A combination OC regimen includes active tablets that contain both estrogen and progestin.
In a *monophasic combination* OC regimen, the doses of estrogen and progestin are the same in all of the active tablets. • Also may include tablets that contain inert ingredients or ferrous fumarate
In a *multiphasic combination* OC regimen, the doses of estrogen and progestin in the active tablets may vary. • Also may include tablets that contain inert ingredients or unopposed estrogen
An *extended-cycle combination* OC includes 84 active tablets that contain a fixed dose of estrogen and progestin and 7 days of either placebo or unopposed estrogen. • Intended to limit the occurrence of withdrawal bleeds to 4 times a year
A *continuous-cycle combination* OC contains 28 days of a fixed dose of estrogen and progestin without a hormone-free break. • Intended to help women avoid menses altogether

OC = oral contraceptive.

Sources: Centers for Disease Control and Prevention, *MMWR* 2016[13]; Sech, *Merck Manual* 2013.[9]

Q **For which patients and under what circumstances might one opt to prescribe a progestin-only OC or a combination OC?**

A **Dr. Rafie:** Typically progestin-only OCs come into play when estrogen use is contraindicated. The most common indication for progestin-only OCs is postpartum status, as the risk for blood clots is elevated during the immediate postpartum period.[12]

Combination OCs are used for many noncontraceptive benefits. My decision as to which type of combination OC (***Table 2***) to prescribe is determined in part by whether a patient has specific noncontraceptive goals in mind—for example, whether she is looking to treat her acne, have lighter periods,

or eliminate periods altogether. Her menstrual history and sensitivity to the effects of hormones can be considered as well. Finally, some patients will request a particular OC based on personal experience or on the recommendation of a friend or family member.

When a new patient comes to my clinic and requests a prescription for an OC, I generally like to start with a monophasic combination product because the dose in all of the active tablets remains the same.[9]

That eliminates some opportunities for errors if the wrong pill is taken. Monophasic products also allow for extended and continuous cycles.[10]

Of course, I am happy to prescribe a multiphasic combination OC if the patient has had a positive experience with such a product already or if she has a health concern that is best addressed through use of a multiphasic product. Also, a multiphasic combination OC may be an appropriate option for women who experience breakthrough bleeding during their cycle.

The extended- and continuous-cycle combination OCs are appropriate for women who do not want to have a hormone-free interval that results in a withdrawal bleed every 28 days.

Dr. Anderson: Progestin-only pills tend to stand out as being really different from the other OCs because they are a possible option for patients who should not take estrogen.[12]

A major difference between monophasic and multiphasic 28-day combination OCs is that women who take a monophasic 28-day combination OC and wish to avoid menses during a particular month have the option of skipping the hormone-free tablets and immediately starting a new pill pack.[10] I find that breakthrough bleeding—also known as spotting—is more likely to occur with continuous use of a multiphasic combination OC, so I don't recommend skipping the hormone-free tablets when using a multiphasic product.

Some patients prefer to have fewer periods or avoid menses altogether because they experience painful periods or mood swings when taking the inactive tablets. For those patients, it may make sense to prescribe an extended- or continuous-cycle combination OC.

Q **What questions/concerns should pharmacists expect to address when counseling a patient who is being prescribed an OC?**

A **Dr. Rafie:** The consultation may look somewhat different depending on the patient's needs. For instance, the visit will be very straightforward for a woman who is new in town and has not yet established a relationship with a local healthcare provider, but who has been on the same OC for 5 years and is in need of a refill.

Other patients come to me with a long history of the OCs they have tried and the problems they have experienced. In those cases, I collect a detailed history and use that to figure out which particular balance of hormones might work best and then explain the reasons why I am recommending a particular OC. This is a more complicated visit.

Sometimes patients ask questions about the risk for blood clots, a potentially life-threatening complication. Although data suggest that users of combination OCs are at significantly greater risk for developing venous thromboembolism (VTE) than non-users, keep in mind that the absolute risk for VTE among users of combination OCs is in the range of 3 to 9 cases for every 10,000 women-years, whereas the risk for VTE is much higher among non-users who are pregnant or postpartum (5-20 cases and 40-65 cases per 10,000 women-years, respectively).[14,15]

Dr. Anderson: It's important to discuss the possible side effects of OCs so that patients know what to expect. Some side effects, such as breakthrough bleeding, go away within a few months after starting the OC.[10] If patients know that up front, they will be more likely to continue taking the product that has been prescribed to them. It is also important to caution patients about the potential for blood clots and other serious adverse events that may require immediate follow up with a healthcare professional. Additionally, patients should be reminded that OCs do not protect against sexually transmitted infections.

When prescribing a progestin-only OC, the pharmacist needs to let the patient know that every single pill within a pack contains active ingredients; there are no hormone-free days. The pharmacist should also underscore the fact that a progestin-only OC has a very stringent adherence requirement. If a progestin-only OC is taken more than 3 hours late, it is actually considered a missed pill, and the patient must use a backup method of contraception for at least 48 hours after that.[13]

"When prescribing a progestin-only OC, the pharmacist needs to let the patient know that every single pill within a pack contains active ingredients."

– Dr. Anderson

If a patient is being prescribed a combination OC for the first time and the pill pack includes inactive tablets, the patient should be reminded that she can expect to experience menstrual bleeding while taking those tablets.

As mentioned previously, patients who are prescribed a multiphasic combination OC should know that skipping the hormone-free tablets and immediately starting a new pill pack is ill-advised because it increases the likelihood of breakthrough bleeding.

Q **In your experience, what are some common side effects that may occur with OC use? In the event that a patient finds specific side effects persistent and/or bothersome, what do you recommend in terms of next steps?**

A **Dr. Rafie:** Some of the more commonly reported side effects of OC use include breakthrough bleeding, weight gain, and mood changes.[10,16-18] These side effects vary from patient to patient.

When discussing side effects that may occur with OC use, bear in mind that not all side effects are negative. For example, taking an OC may result in lighter bleeding, less menstrual pain, and/or less acne, depending on which product is used.[11]

I always encourage patients to come back and see me if they are experiencing any problems with their OC. The type of side effect often dictates whether I need to adjust the dose of estrogen or progestin. This also opens the door to discussing other methods without that side-effect profile. Based on the information provided to me, I will find one or two alternatives that might be suitable and then will let the patient know what she can expect with those other options to help her choose.

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>
> – Dr. Rafie

Dr. Anderson: In my clinical experience, I have found that breakthrough bleeding, or spotting, is one of the most common side effects of OC use and is a leading reason why some women discontinue their OCs. I urge pharmacists to tell patients that spotting usually goes away within the first few months of OC use.[10,16,17]

Other common side effects among women taking combination OCs include nausea and breast tenderness.[10]

A side effect qualifies as "persistent" if a patient continues to experience it for at least 3 cycles. Spotting in the first half of the cycle while taking a combination OC can be addressed by prescribing a combination OC with a higher dose of estrogen—eg, increasing from 20 to 30 mcg.[10] In contrast, decreasing the estrogen dose can remedy a patient's nausea and breast tenderness.[10]

In what type of situation should a pharmacist refer patients to a women's healthcare professional or other healthcare provider for contraception?

Dr. Rafie: If you suspect that a patient is pregnant or may have a sexually transmitted disease, you will want to refer her to an obstetrician/gynecologist or another appropriate healthcare provider. A referral is also warranted if your review of a patient's medical history alerts you to the presence of a contraindication to one or more types of hormonal contraception that is either undiagnosed or precludes you from prescribing the method preferred by the patient.

You may encounter patients who have yet to establish a relationship with a women's healthcare provider. One option is to suggest that those patients visit Planned Parenthood or a community clinic. That being said, I would like to encourage prescribing pharmacists to forge relationships with physicians and other providers in their communities to make the referral process more efficient.

For example, if an obstetrician/gynecologist calls your pharmacy with a prescription, take a moment to mention that you have begun prescribing hormonal contraception and that you would like to partner with healthcare professionals in your community. Then ask that physician if it would be acceptable for you to send patients to him or her and find out what kinds of patients he or she is interested in seeing. You might also consider inviting the obstetrician/gynecologist to come visit your pharmacy and meet with you. These overtures can lead to a collaborative relationship that benefits patients and providers alike. This way the physician is not caught off guard when a patient mentions that her OC was prescribed by a pharmacist.

> "I would like to encourage prescribing pharmacists to forge relationships with physicians and other providers in their communities to make the referral process more efficient."
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Dr. Anderson: If you are reviewing a patient's health history and learn that she has an underlying risk factor for blood clots, you will want to refer her to a women's healthcare professional. In Oregon, we are finding that patient encounters requiring a referral from the pharmacist are more common than we had expected. In most of those cases, hypertension is the reason for the referral.

A referral is also warranted if you have prescribed an OC to a patient and she experiences a side effect that requires immediate intervention, such as abdominal pain, chest pain, headaches, eye problems, or severe leg pain. Any patient who experiences one of these warning signs should be told to stop taking her OC immediately.[10]

Q **What would you like to communicate to your colleagues regarding the appropriate training and knowledge that should be acquired in order to begin prescribing contraceptives? Can you recommend any relevant resources that your colleagues could consult if needed?**

A **Dr. Rafie:** I encourage my pharmacist colleagues to seek out training if they are at all interested in prescribing contraception. Successful completion of the training does not mean you are obligated to start providing the service, but I think it is a really great first step in just figuring out what the service might look like in your pharmacy.

Also, keep in mind that you do not have to be an expert in women's health or family planning to be able to provide the basic level of service to women. I have no doubt that any pharmacist who undergoes the requisite training in California will be able to measure a patient's blood pressure, review her medical history, and apply the US Medical Eligibility Criteria for Contraceptive Use (US MEC).[12] Granted, it can get more complicated if a patient has had an unfavorable experience with several OCs in the past. If a pharmacist does not feel equipped to take on these complicated cases or has time limitations, it is perfectly acceptable to refer those patients to an obstetrician/gynecologist, family planning clinic, or to an expert pharmacist.

The CDC website, **www.cdc.gov/reproductivehealth/contraception/usmec.htm**, includes some links to really great resources, such as the full US MEC document[12] and a chart summarizing the US MEC, both of which can be used to help determine which contraceptive methods are safe to prescribe to a particular patient. The website also includes a link to the US Selected Practice Recommendations for Contraceptive Use (US SPR).[13] I recommend reading the US SPR document in its entirety because it explains how the different methods of contraception can be used and provides information with respect to screening, monitoring, and managing side effects. Additionally, pharmacists should sign up on the CDC's website for updates regarding any of the resources listed there.

Dr. Anderson: The requirements in terms of appropriate training and knowledge for prescribing pharmacists vary according to state law. I encourage pharmacists who practice in Oregon to visit the state's board of pharmacy website (**www.oregon.gov/pharmacy/Pages/ContraceptivePrescribing.aspx**), which explains all of the requirements and includes links to the requisite training course.

The website also includes links to some useful resources from the CDC, such as the US SPR[13] and a chart summarizing the US MEC.[12] The US SPR document consists of recommendations regarding examinations and tests that

may be needed before initiation of a contraceptive method. The US MEC chart lists a number of different disease states and makes it easy to determine whether an OC is appropriate for a particular patient.

Q **Do you have any concluding remarks that you would like to share with our readers?**

A **Dr. Rafie:** Pharmacists who have begun prescribing hormonal contraception in California should discuss the experience with their peers so that other pharmacists across the state are better prepared to roll out and market the service in the future. Also, I would like to stress the importance of creating a private space where the encounter between prescribing pharmacist and patient will not be seen or heard. In my own research, I have learned that many young women harbor concerns about privacy and confidentiality. In short, counseling about contraception is not something that we want to be providing exclusively over the counter.

> "I would like to stress the importance of creating a private space where the encounter between prescribing pharmacist and patient will not be seen or heard."
>
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Additionally, I recommend that pharmacists market their prescriber status by adding their practice location to Bedsider's health center locator tool at **https://providers.bedsider.org/pharmacists**. This will make it easier for patients to find pharmacists who are qualified to prescribe hormonal contraception.

Finally, I would like to remind my colleagues that they are not expected to be family planning experts. Prescribing OCs and counseling patients on related reproductive health issues are going to be two of the many services that they provide.

Dr. Anderson: We need to remember that prescribing is now considered part of a pharmacist's scope of practice here in Oregon. In my outreach efforts, I have noticed some trepidation among pharmacists who have yet to complete the training that the state requires in order to prescribe hormonal contraception. Most pharmacists find that the training not only addresses their questions and concerns but also helps them feel more confident in their ability to prescribe oral contraception.

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About the Experts

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Sally Rafie, PharmD, BCPS, is a pharmacist specialist at UC San Diego Health, where she practices in the women's health clinic. She also is founder of a community-based, pharmacist-run clinic and leads the Birth Control Pharmacist project, which helps pharmacists achieve and maintain clinical competence in the area of contraception. Additionally, Dr. Rafie is volunteer faculty at the UC San Diego, Skaggs School of Pharmacy & Pharmaceutical Sciences.

Dr. Rafie received her PharmD degree from UC San Francisco. Subsequently, she completed her residency at UC San Diego. She previously provided hormonal contraception and related services at a local Planned Parenthood clinic.

A member of several national work groups to expand access to contraception, Dr. Rafie serves on a state council aimed at enhancing preconception health. She was involved in the development of the California State Board of Pharmacy hormonal contraception protocol that went into effect on April 8, 2016. Moreover, she is a lead trainer on hormonal contraception for pharmacists and pharmacy students in California and nationwide.

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Lorinda Anderson, PharmD, BCPS, is a faculty member at Oregon State University/Oregon Health & Science University College of Pharmacy, where she coordinates the P2 Pharmacy Practice course and teaches the women's health lectures in therapeutics.

Dr. Anderson received her PharmD degree from the University of Utah, College of Pharmacy, in Salt Lake City. She completed her residency at the Good Samaritan Regional Medical Center, where she continues to maintain practice as an inpatient pharmacist.

A specialist in women's health, Dr. Anderson serves on the advisory council for the One Key Question® Initiative, the goal of which is to ensure that more pregnancies are wanted, planned, and as healthy as possible. Additionally, she is a member of the Oregon Board of Pharmacy work group that has implemented legislation allowing pharmacists to prescribe oral contraceptives and transdermal contraceptive patches. Notably, she was the lead designer of and contributor to the 5-hour online program that trains and certifies pharmacists in Oregon to prescribe hormonal contraception.

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Resources

Below are helpful links to the latest on generic medications, reference guides, printable brochures, tips on medication disposal, nutrition, and more.

Ask the Expert Newsletter: Evolving Access to Oral Contraceptives

Two pharmacists discuss the new prescribing role for pharmacists in California and Oregon.