

Section 3:

Actions You Can Encourage Your Pharmacy Board to Take

**Your board has many options to ensure women
are not denied access to contraception at the
pharmacy.**

Your pharmacy board has a variety of responsibilities and powers. There are many options at its disposal to make sure women are not denied access to contraception at the pharmacy. These include:

- Initiating rulemaking
- Developing position statements or policy guidance
- Adjudicating complaints and imposing sanctions

This section will walk you through each of these options and help you to decide what is most appropriate for you to pursue with your board.

Rulemaking

Rulemaking is the process by which an administrative law—known as a regulation or rule—is created. State pharmacy boards pass rules to “fill in” existing laws, govern the practice of pharmacy, and provide specific guidance for pharmacists and pharmacies. Regulations and rules have the force of law.

What is the Goal with Rulemaking?

If rulemaking is the appropriate option for your state, you should try to get a rule that ensures a woman access to contraception in the pharmacy and that protects women in the event that a pharmacist refuses to dispense a medication. Appendix B describes the ideal elements that should be included in such a “duty to dispense” rule.

In the event that your pharmacy board is not willing to pass a rule focused on refusals or has a rule or policy that permits refusals, you could seek other rules that would protect patients in other ways, such as non-discrimination or stocking provisions. These other rulemaking “asks” are reviewed in Section 6.

How Do I Learn About My State Board’s Rulemaking Powers?

The process for administrative agency rulemaking is usually available within your state’s Administrative Procedures Act. A state Administrative Procedures Act (APA) lays out the process by which agencies take action. These laws should be available on your state legislative website, the pharmacy board website, or through a legal research engine such as Lexis Nexis or Westlaw. You also can do a basic internet search with the state name and “administrative procedures act.” The APA explains when a rule can be initiated and the process by which it moves from proposed to final rule. You also should check the laws and rules governing your state’s pharmacy board, for additional information about rulemaking specific to the board of pharmacy.

How Can Advocates Initiate Rulemaking?

There is a role for advocates in initiating rulemaking with the board of pharmacy. First, advocates can approach the board about the need for a rule on the issue of pharmacist refusals. It is important to note, however, that pharmacy boards have been resistant to initiate

Pros

- * A rule or regulation has the force of law. The pharmacy board has a responsibility to enforce laws governing the practice of pharmacy. Pharmacies and pharmacists must abide or face disciplinary proceedings.
- * The rulemaking process allows public comment by individuals and organizations. Not only does this give advocates a chance to shape the rule, but also gives advocates a chance to educate and rally the public so that their voice is heard.
- * It may be difficult to convince the pharmacy board it needs to initiate rulemaking. State pharmacy boards have been resistant to pursuing rulemaking on refusals unless there is proof that refusals are occurring. Advocates may need to first file a complaint or bring some other evidence of the problem to the pharmacy board.

Cons

- * Rulemaking involves numerous steps, including drafting and public comment, so the end result could be quite different from the original proposal. A proactive refusal rule could turn into one that permits refusals without patient protections.
- * The rulemaking process can take a very long time.
- * Depending on the state, the legislature or governor may have final say on a rule.
- * The other side has a chance to weigh in, so it is important for proponents of a rule to ensure they are well-organized and prepared to respond.
- * If there is a lot of attention and controversy over a proposed rule, the pharmacy board could get nervous and drop it altogether.

TIP:

Contact NWLC! The National Women’s Law Center can help you find the laws governing rulemaking in your state.

rulemaking unless there is a demonstrated need for the board to address the issue. Section 4 provides tips for bringing evidence to the board about refusals and arguments you can marshal to convince the board to undertake rulemaking.

Second, citizens—including individuals or associations—may be able to formally request that the pharmacy board develop new rules. This is through a petition or “petition rulemaking.” For example, in Virginia, any “person”²¹ may petition the board of pharmacy at any time to develop a new rule or to amend an existing one.²² Similarly, in Montana, an “interested person” may petition for the adoption, amendment or repeal of rules.²³ Although it will vary by state, each state that allows petition rulemaking will have a process by which the board must consider the petition and respond. Some state procedures provide guidance for the board in its consideration of a petition. For example, the New Hampshire Pharmacy Board specifically bases its decisions on whether a petition for a rule is consistent with established standards for the practice of pharmacy and licensees of the board, whether it lacks rulemaking authority, or whether it is contrary to legislative intent.²⁴

What is the Rulemaking Process?

Once rulemaking has been initiated a series of stages ensue. These stages vary by state but typically consist of: (1) notice to the public that a regulation is being considered or changed; (2) proposal of the regulation; (3) a comment period and/or a hearing, and (4) release of the final regulation and publishing. The typical life cycle for creation of a rule can vary. In Virginia, for example, the regulatory process for rulemaking lasts about eighteen months.²⁵

Notice to the Public

The first stage of rulemaking usually is notice to the public. This stage serves to alert the public to the fact that the board is considering a new rule or an amendment to an existing rule. The board usually will need to explain why it decided to initiate rulemaking on this subject and how the public can get involved. In Washington, for example, agencies are required to prepare a statement for the public at least 30 days prior to initiating proposed rulemaking. Among other things, the notice must discuss “why rules on this subject may be needed and what they might accomplish” and specify “the process by which interested parties can effectively participate in the decision to adopt a new rule and formulation of a proposed rule before its publication.”²⁶

Text of Rule Published

The second stage provides the public with the full text of the rule and more details about it. Idaho, for example, requires that the agency publish notice of proposed rulemaking in the register, which must include a statement describing the rule, the fiscal impact, the text of the proposed rule, the location, date, and time of any public hearings, the manner in which persons may make written comments on the proposed rule, and the deadline for public comments.²⁷

TIP:

You might be able to submit written comments on-line. Virginia, for example, has a website that allows you to submit on-line comments about regulatory changes. <http://www.townhall.state.va.us/>

Public Comment and Hearings

The next stage is the public comment and hearing stage, in which the public can have a voice in shaping the rule and expressing support or disapproval. Usually public comment takes the form of written comments, but states also may allow public hearings. Some states require hearings only if there are requests from the public for one. For example, the Utah Administrative Procedures Act requires a public hearing if ten interested persons or an interested association with more than 10 members requests one in writing within 15 days of the proposed rule’s publication.²⁸

Rule Finalized

The last stage occurs when the final text is prepared and published. Note that some states require the legislature or the governor to approve rules before they become final. In Oklahoma, for example, the governor has 45 days after receiving a rule to approve or disapprove it; if the governor disapproves a rule, it does not become effective, unless approved by the legislature.²⁹

Examples of State Pharmacy Boards that Have Engaged in Rulemaking on the Refusal Issue and the Role Advocates Played

- In August 2005, the **Wyoming** Board of Pharmacy gave notice of intended rulemaking on the issue of pharmacist refusals and asked for public comment. The rule would have allowed pharmacists to refuse to dispense prescriptions based on personal beliefs without adequate patient protections. Advocates learned of the rule and organized. The board received more than 100 letters objecting to the rule

TIP:

It is critical to know ahead of time whether your state’s rulemaking process allows the legislature or governor to reject the rule. You don’t want to put in the work of getting a patient-protective rule approved by the board without a sense of what your governor or legislature is likely to do. Check your state law!

and not a single letter in support.³² Twenty people testified against the rule at the Board's public hearing. At its October 2005 board meeting, the Wyoming Board of Pharmacy rejected the proposal. In doing so, the Board referred to the overwhelmingly negative public comments received from advocates and state groups.

- In September 2005, the **Nevada** Board of Pharmacy began exploring rulemaking on the issue of pharmacist refusals. It initially proposed a draft rule that would have permitted pharmacists to refuse, without adequate patient protections. Advocates, state legislators, and other interested persons got involved, providing oral testimony at board meetings, submitting written testimony to the board, suggesting new language to board staff, and urging the board to amend or drop its proposal. In December 2005, the Nevada board of pharmacy agreed to abandon its proposal, specifically citing the negative public response.³³ Instead, the board adopted a rule permitting a pharmacist to decline to fill a prescription only for professional reasons.³⁴
- After seeking views of the Washington State Pharmacy Association and advocates, in April 2006, the Washington Board of Pharmacy formally decided to pursue rulemaking on the issue of pharmacist refusals. At a subsequent board meeting, it adopted a rule giving significant leeway to pharmacists to refuse to fill prescriptions. Washington Governor Christine Gregoire sent a letter to the pharmacy board strongly opposing the draft rule and urging the board to develop different rules.³⁵ The state board then received nearly 2,500 letters, calls, and emails about the draft rule, with all but 33 opposing them.³⁶ The board eventually adopted a compromise rule, modeled after one submitted to the board by the key stakeholders, including the governor, representatives from the state pharmacy association, a leading pharmacist from the state's school of pharmacy, Planned Parenthood of Western Washington, and the Northwest Women's Law Center.³⁷ The board held public hearings on the compromise rule, which requires pharmacies to deliver medication to consumers. The rule was formally adopted in April 2007.³⁸
- Advocates monitoring the **Iowa** state register learned in March 2007 that the Iowa Board of Pharmacy was considering adopting a rule on pharmacist refusals. The rule would have allowed pharmacists to refuse, without sufficient patient protections. Advocates organized and, after receiving over 300 comments objecting to the rule, the board withdrew the proposal.³⁹

Emergency Rulemaking

Most states allow "emergency" rulemaking, which is a way to bypass the regular lengthy rulemaking process. Emergency rules become effective almost immediately. However, many states have a high threshold for what they consider an "emergency." New Hampshire is typical in requiring the agency to find "that an imminent peril to the public health or safety requires the adoption of a rule with less notice than is required."³⁰ Some states may be even more limited. Montana, for example, says, "An emergency rule may be adopted only in circumstances that truly and clearly constitute an existing imminent peril to the public health, safety, or welfare that cannot be averted or remedied by any other administrative act."³¹

Most states allow for challenges to the rules, either before the rule is in place—such as a challenge to the "emergency" justification—or after-the fact.

Emergency rules are temporary, staying in effect only for a short period of time. After that, an agency must proceed with the regular rulemaking process in order to adopt a permanent rule on the subject.

Issuing Declaratory Rulings or Policy Guidance

Pharmacy boards also have the power to issue informal statements or declarations that interpret their existing laws and regulations and set out guidelines for pharmacies and pharmacists. While these **do not** have the force of law, they provide guidance about the standard of practice. They cannot be the basis for disciplinary proceedings, but can be used to inform disciplinary actions for violations of other laws.

If the pharmacy board in your state is resistant to undertaking formal rulemaking or you anticipate problems with the rulemaking process, a statement or guidance from the pharmacy board might be a better option. It also could lay a foundation for a continued effort to create a rule. For example, the Delaware Board of Pharmacy first issued a policy, and then adopted a rule on the issue.⁴⁰

TIP:

Once guidelines are in place, you might find that you do not need a rule. In New York, after the pharmacy board passed guidelines on the issue of refusals, it designed a process for self-monitoring and responding to refusal incidents. Family Planning Advocates of New York State has not found a need to pursue rulemaking or a more formal complaint process with the board. The profession has acted to resolve isolated incidents and educate other pharmacists so that problems do not arise repeatedly.

What is the Basis for these “Statements” or “Guidance”?

On the topic of refusals in the pharmacy, boards have issued two types of informal statements.

The first is an interpretation of existing law. This was the approach taken by the Massachusetts Board of Pharmacy, which responded to a letter asking about pharmacists’ responsibilities to dispense medication. The pharmacy board issued a letter explaining that existing law requires pharmacists to fill valid prescriptions.⁴¹

The second type consists of position statements issued by boards that do not rest on interpretations of existing law. These usually note that there is no provision in existing law governing the issue of refusals, but that the pharmacy board feels it is necessary to provide guidelines for pharmacists and pharmacies who may find themselves in such a circumstance. These position statements then detail practice guidelines for pharmacists and pharmacies in refusal situations. For example, the New York State Board of Pharmacy issued practice guidelines to supervising pharmacists on the question of refusals, laying out the board’s general analysis.⁴²

How Can Advocates Play a Role?

Advocates can ask or petition the board of pharmacy to issue policy guidelines or a statement about the problem of refusals. This can be done informally, through conversations or meetings with pharmacy board members or staff. It also can be done more formally. In Massachusetts, the board’s letter was issued in response to a written inquiry from Planned Parenthood of Massachusetts, Inc.

Other states have formal mechanisms for soliciting statements. For example, Oklahoma has a procedure whereby any person affected by the pharmacy rules can ask for an interpretation of a rule or its application.⁴³

Advocates also can play a role in changing or clarifying existing position statements. In Oregon, for example, advocates were confused by elements of the Oregon Board of Pharmacy’s position statement on refusals. A broad coalition worked successfully with the board to clarify and make the position statement more protective of patient’s rights to access medication.

Examples of Pharmacy Board Statements

Eight pharmacy boards have issued interpretations or policy guidance on refusals in the pharmacy. Appendix A contains details about the content of their statements, as well as citations to the documents.

- The **Alabama** Board of Pharmacy published a statement in its February 2007 newsletter explaining its position on refusals and Plan B®.

Pros

- * Issuing declaratory rulings or policy statements is a quick way for boards to offer guidance to pharmacies and pharmacists without having to go through the rulemaking process.
- * Even though they do not have the force of law, policy statements lay out the board’s expectations and can inform disciplinary proceedings.
- * Statements can easily be changed and updated.
- * Working with the pharmacy board on a policy statement could lay the groundwork for a rule.
- * If the board is willing to intervene constructively with pharmacists who do not follow guidelines, there may be no need for a rule.

Cons

- * Policy statements and guidance do not have the force of law.
- * The guidelines cannot be used as the basis for a charge of professional misconduct.
- * The development of policy statements can take place behind closed doors, without public awareness or input.
- * Boards may be resistant to issue a statement unless they have proof of a problem.
- * Most policy statements issued so far on the subject of refusals are more permissive of refusals than the rules that have been adopted.

It is important to note that just as some boards may be resistant to initiating formal rulemaking, boards may not want to develop a position statement on the topic of refusals. The National Women’s Law Center asked the pharmacy board in one state to issue a position statement on refusals after a woman was refused EC. The Board declined to issue a position statement, stating that it wanted to avoid creating “the appearance of impropriety or bias” in case a complaint on this topic ever comes before the board.

TIP:

Be aware that even if you play a role in getting the pharmacy board to draft guidelines, it might not be an open process. Family Planning Advocates of New York State found that although they were able to convince the New York State Board of Pharmacy to draft guidelines governing refusals, the board drew up the guidelines and passed them behind closed doors, without public input.

- In its March 2006 newsletter, the **Delaware** State Board of Pharmacy published its position on pharmacist refusals.
- In 2004 the **Massachusetts** Board of Pharmacy provided an interpretation of existing state law on refusals, in response to a written inquiry.
- On November 21, 2005 the **New York** State Board of Pharmacy issued a letter to supervising pharmacists that details its analysis of refusals in the pharmacy, in response to questions raised about the issue. The guidelines are available on the board's website, under "Current Issues in Pharmacy."
- The **North Carolina** Pharmacy Board published a policy statement in its January 2005 newsletter about the issue of refusals in the pharmacy. It is now available on the board's website, under "Pharmacist FAQs."
- The **Oregon** Board of Pharmacy published a position statement on refusals in its November 2005 newsletter. The board then clarified it in June 2006. The statement is available on the board's website, under "Position Statements."
- The **Pennsylvania** Board of Pharmacy adopted a statement of policy in October 2007.
- The **Texas** State Board of Pharmacy posted a statement on its website about EC and refusals.

Respond to Complaints

Another tool for pushing pharmacy boards to address the problem of pharmacist refusals is filing a formal complaint. Each pharmacy board has a process by which consumers can file complaints specifying violations of pharmacy laws and rules.

What is the Goal of Filing a Complaint?

The complaint process will not result in any monetary gain for the consumer, but rather could result in sanctions against the pharmacy or pharmacist.

Possible board actions in response to a complaint include:

- Monetary fines against the pharmacy or pharmacist
- License suspension or revocation
- Mandatory education and training programs
- Conditions or restrictions on the pharmacist's or pharmacy's license, including a change in pharmacy procedures

Sanctions will redress the harm to the victim who filed the complaint, and help prevent future problems from that pharmacist or pharmacy. The discipline also could have a deterrent effect among other pharmacists or pharmacies in the state. Disciplinary results are made public by the pharmacy board—usually in the board's newsletter—so other pharmacies and pharmacists will be put on notice.

Although the pharmacy board only investigates and deals with the specific complaint before it, filing a complaint in the case of a refusal also could show the pharmacy board that there is a problem not fully addressed by current law. This could convince the board that it should adopt a policy or rule addressing refusals. For example, a complaint to the board after a refusal in North Carolina eventually led the board to adopt its refusal policy.

Pros

- * Complaints are fairly easy to submit.
- * Pharmacy boards have to investigate and respond to complaints that are filed.
- * Complaints may result in discipline of the refusing pharmacist or pharmacy.
- * Complaints are a great way to get consumers involved.
- * Complaints can establish the need for more patient protection.
- * Complaints can serve as a springboard to developing a position statement or rulemaking.

Cons

- * Refusal victims may be unwilling to file a complaint.
- * It can take a long time to resolve a complaint.
- * The complaint process is not usually transparent or open to the public.
- * A complaint itself will not result in a policy or rule on the issue. Pharmacy boards limit their investigation and resolution to the specific incident identified in the complaint.
- * A pharmacy board may decide there was no violation of law and not impose discipline on the pharmacist or pharmacy, especially if there is not strong language in existing pharmacy laws and rules.

TIP:

If your state already has a good rule in place governing refusals, the complaint process can be useful in demonstrating to the pharmacy board the need for continued and vigorous enforcement.

TIP:

For more information about state pharmacy board complaint processes, contact MergerWatch. They surveyed each state pharmacy board's website for information on the complaint process. <http://www.mergerwatch.org/>

It's important to remember that a complaint could yield nothing, which you should think about when deciding whether to file one. In one state, the National Women's Law Center worked with local advocates to file a complaint after a refusal. There was not strong law, but advocates felt it was important to try to push the pharmacy board on this issue. The pharmacy board adjudicated the complaint, but found that the pharmacist met the acceptable standard of care and no discipline was imposed. The complaint also did not spur the pharmacy board to take further action.

What Role Can Advocates Play?

Advocates can work with refusal victims to file complaints with the state pharmacy board. They can assist victims in drafting complaints, alleging violations, and asking for discipline. Advocates are not generally permitted to file a complaint on behalf of an individual. Only a few states seem to permit another individual—such as a health care provider—to file on behalf of the victim.

What is the Complaint Process?

The complaint process will vary from state to state. The best place to start is your pharmacy board website, which may have step-by-step instructions and forms available. Various pharmacy boards will give a consumer the option of filing electronically, by mail, or even by phone. A typical complaint will ask for the complainant's name and contact information, details about the pharmacy, including the name, location, and pharmacist's name if known. Most forms then provide a blank space where you can include a detailed description of the refusal incident. See Appendix C for the text of a complaint that was filed after a refusal to dispense EC.

Note that anonymous complaints are accepted in a few states, but this can hamper the process. The Maryland Board of Pharmacy, for example, notes that although a complaint can be made anonymously, "this may prevent the Board from effectively investigating and resolving the complaint."⁴⁴

TIP:

Before filing a complaint, take notice of any possible deadlines, time limits, or procedural requirements.

TIP:

Pay attention to which agency or department handles complaints for pharmacists and pharmacies. For example, in Montana it is the Department of Business Standards; in New York, the Office of Professions within the Department of Education; and in Rhode Island the Board of Medical Licensure receives the complaint before forwarding it to the pharmacy board.

What Happens After A Complaint Is Filed?

After the complaint is filed, the board investigates the incident. The investigation phase can be lengthy and in some states may take over a year to resolve. Investigations sometimes include interviews with the complainant, the licensee, or other appropriate individuals, as well as on-site visits to the pharmacy to make observations.

After the investigation, the board may make a ruling or it may hold a hearing. In some states, a hearing is mandatory; in others, the board decides whether to hold a hearing; and in others one of the parties must request a hearing.

Although it is not necessary, it is helpful to refer to the law or regulation that you believe the pharmacist or pharmacy has violated. Although most states do not have laws or policies specifically governing refusals, there are many provisions that exist in state pharmacy laws and regulations that could be violated in a refusal situation. The National Women's Law Center's legal guide to refusals in the pharmacy, *Don't Take "No" For an Answer*, explains other provisions that could be relevant, depending on the particular situation and laws of your state. It is available at <http://www.nwlc.org>. The National Women's Law Center also is available to assist you in finding the laws, regulations, and policies in your state that could be used in a complaint.

Depending on the state, the board also could file a complaint before a state Administrative Law Judge (ALJ). The ALJ then makes a finding as to whether there has been a violation and recommends an appropriate remedy. The board may then be able to accept, reject, or amend the ALJ's decision.

Can Board Decisions be Appealed?

Appeal of a board decision resolving a complaint varies by state and is generally governed by the state's Administrative Procedures Act. In some states, it is possible to appeal a decision and have a case referred to the attorney general of a state, an administrative law judge, or state court.

TIP:

Remember that the process for complaint resolution is state-specific. You should check your state's pharmacy laws and rules, as well as the state Administrative Procedures Act. The National Women's Law Center is available for help in finding these laws and rules.

Examples of Complaints on Refusals

Using the complaint process to discipline a pharmacist in the absence of a specific law governing refusals.

- A complaint was brought against a pharmacist in **Wisconsin** for refusing to transfer a prescription for contraception. Although there was no specific law in Wisconsin governing the issue of refusals, an administrative law judge (ALJ) found that the pharmacist violated existing regulations prohibiting unprofessional conduct. The ALJ recommended that the pharmacist be required, as a condition of retaining his license, to file a plan specifying "the steps he will take to ensure that a patient's access to medication is not impeded by his declination(s)." The pharmacist also was charged the cost of the disciplinary proceedings.⁴⁵ The Wisconsin Pharmacy Board unanimously accepted these recommendations and approved the sanctions against the pharmacist.

Using the complaint process to push the board on rulemaking.

- In **Washington** state, advocates worked with individuals to file 9 complaints against a pharmacy that refused to stock EC.⁴⁶ The complaints alleged a violation of Washington's existing stocking rule, which requires that a pharmacy "maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients."⁴⁷ According to advocates in the state, this helped to pressure the pharmacy board, which ultimately adopted a rule guaranteeing access to medication at the pharmacy.

Using the complaint process to change pharmacy policy state- and nation-wide.

- Advocates in **Massachusetts** helped three women file complaints to the state pharmacy board after they were refused EC at Wal-Mart. The complaint alleged that Wal-Mart's refusal to stock EC violated existing Massachusetts pharmacy law.⁴⁸ The Massachusetts Pharmacy Board responded quickly, finding that the Wal-Mart policy violated state law and ordered Wal-Mart to stock and dispense EC.⁴⁹ This led to a change at all Wal-Marts in Massachusetts and helped build momentum for a national effort, which was successful in getting Wal-Mart to change its policy nationwide.