NATIONAL WOMEN'S LAW CENTER
EXPANDING THE POSSIBILITIES

WRITTEN COMMENTS FOR THE IOWA BOARD OF PHARMACY REGARDING PHARMACY REFUSALS

The National Women's Law Center ("Center"), based in Washington, D.C., is a nonpartisan, non-profit organization dedicated to improving the lives of women and girls. Through its Pharmacy Refusal Project, the Center has been at the forefront of the issue of pharmacist refusals to dispense contraception, working to protect patient access to contraception (including prescription and non-prescription emergency contraception) in pharmacies throughout the country. Although the Center has learned that proposed rule § 657—8.10 to the Iowa Administrative Code is no longer being considered by the Iowa Board of Pharmacy Examiners ("Board"), the Center is pleased to submit comments that detail some of the perils pharmacist refusals pose, discuss preexisting pharmacy regulations that inform this debate, and propose some patient-protective measures that the Board could adopt if it decides to promulgate another rule enabling pharmacists to refuse to provide medication. The suggestions below stem from the Center's prior experience working with pharmacy boards and legislatures in other states to establish patient-protective policies and assisting women who have been refused.

I. Background

The vast majority of pharmacists do not refuse to fill prescriptions based on their personal beliefs and instead provide vital health services to the community and are a critical part of the health care system. However, recent reports of pharmacist refusals to dispense contraception have surfaced across the country, in over a dozen states, ranging from California to Texas to Wisconsin. These refusals have occurred at major drugstore chains like Rite-Aid and Walgreens in addition to smaller independent pharmacies, and have affected everyone from rape survivors in search of emergency contraception to married mothers in need of their birth control pills. Active obstruction of women's access to contraception goes beyond even refusal to dispense certain drugs. Pharmacists who refuse to dispense also often have refused to transfer a woman's prescription to another pharmacist or refer her to another pharmacy. Other pharmacists have confiscated prescriptions, misled women about the availability of certain drugs or their mechanism of action, publicly lectured women about morality, or delayed access to drugs until they are no longer effective.

Pharmacist refusals can have devastating consequences for women's health. Access to contraception is critical to preventing unwanted pregnancies and to enabling women to control the timing and spacing of their pregnancies, with real consequences for maternal and infant health and mortality. A woman who wants two children must use contraception for roughly three decades of her life. For some women, pregnancy can entail great health risks and even endanger their lives. Also, women rely on prescription contraceptives for a range of medical purposes in addition to birth control, such as

amenorrhea, dysmenorrhea, and endometriosis. These refusals interfere with the ability of women to meet their own basic health needs.

Refusals to fill prescriptions for emergency contraception (EC) or to provide non-prescription (also known as over-the-counter, or OTC) EC are particularly burdensome. EC is an extremely time-sensitive drug, and is most effective if used within the first 12 to 24 hours after contraceptive failure, unprotected sex, or sexual assault. If not taken within 120 hours, this drug is ineffective. Despite the recent decision by the Food and Drug Administration (FDA) to make EC available without a prescription to women 18 and older, pharmacist refusals are still a problem. Under the FDA's conditions, EC is kept behind the counter, so even women who do not need a prescription must interact with pharmacists or other pharmacy staff who may have strong personal beliefs against providing the drug. Although non-prescription EC has been on pharmacy shelves only for a few months, there have already been a number of refusal incidents. In fact, there may actually be an increase in refusals, as more women are made aware of the drug and request it at their pharmacies.

Pharmacist refusals are detrimental to all women, but rural and low-income women, as well as survivors of sexual assault, are at particular risk of harm. In Iowa, where there are many rural areas, traveling from one pharmacy to another in search of medication may not be possible. These women may be unable to travel to another pharmacy to access prescription contraception or find a location that will provide them with EC OTC without considerable hardship, and thus some may forgo the drug altogether, resulting in unintended or medically ill-advised pregnancies. For rape survivors who are turned away, being put at risk of pregnancy presents an additional trauma that no woman should have to endure: the uncertainty of waiting to see if she is pregnant, and the hard decisions that follow.

II. Restricting Pharmacist Refusals

When the Board reconsiders the issue of pharmacist refusals, we urge the Board to consider prohibiting altogether refusals based on personal beliefs. As discussed below, existing provisions of Iowa pharmacy regulations give strong support to such a position. In so doing, the Board would join three pharmacy boards in other states that prohibit refusals by pharmacists based on any reason other than professional judgment.

<u>Existing Iowa Pharmacy Regulations</u>

The Iowa pharmacy regulations already contain language that imposes a duty on pharmacists to fill prescriptions and could be read to prevent pharmacists from refusing to provide medication, especially contraception, based on their personal beliefs.

First, Iowa regulations support the idea that pharmacist refusals for reasons other than professional judgment compromise pharmacists' role in the health care system. Rule § 657—8.2 defines pharmaceutical care as "a comprehensive, *patient-centered*, outcomes-oriented pharmacy practice in which the pharmacist accepts responsibility for

assisting the prescriber *and the patient* in optimizing the patient's drug therapy plan and works to promote health, to prevent disease, and to optimize drug therapy" [emphasis added]. Other rules detail the animating purpose of pharmaceutical care and enumerate the variables pharmacists may legitimately take into account when providing that care. For example, rule § 657—8.2(2) notes that "in providing pharmaceutical care, the pharmacist shall access and evaluate patient-specific information, identify drug therapy problems, and utilize that information in a documented plan of therapy *that assists the patient or the patient's caregiver in achieving optimal drug therapy*" [emphasis added]. Similarly, rule § 657—8.21 illustrates the medical and scientific considerations that pharmacists appropriately take into account in conducting a "prospective drug use review." Personal moral objections are not enumerated as acceptable reasons for denying patient care, because they are not congruent with the achievement of "optimal drug therapy" for patients. Thus, pharmacists in Iowa have a duty to fill all prescriptions and requests for medication absent scientific or medical concerns.

Second, Iowa regulations explicitly prohibit sex discrimination in the practice of pharmacy,[1] and pharmacist refusals to provide contraception violate that provision. This is true for several reasons:

- Only medication taken by women (and usually sought at the pharmacy by women) is subject to such refusals;
- Only women are at risk of pregnancy, and thus subject to possible health consequences of an unintended pregnancy from not being able to access medication;
- Only women have other conditions that are managed or treated with hormonal contraceptives, such as amenorrhea and endometriosis;
- Only women have to suffer the humiliation of being turned away by a pharmacy;
- Only women face the potential additional cost of travel and time necessary to visit another pharmacy in the hopes that another location will provide contraceptives;
- Only women face the potential additional cost of a doctor's visit, travel and time necessary to replace a prescription if the pharmacy refuses to return it.

Contraceptives, including over-the-counter emergency contraception, are a form of health care that only women need and use. Refusing to provide medication that is used only by women, and whose consequences fall disproportionately on women, constitutes sex discrimination.[2]

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[1] IOWA ADMIN. CODE 657-8.11(6) states "It is unethical to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, *gender*, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services" [emphasis added].

[2] Identifying a pharmacy's refusal to dispense contraception as a form of sex discrimination finds support in the employment context. Employers who provide insurance coverage for prescription drugs but exclude contraceptives have been found to discriminate against women. The administrative agency charged with interpreting our nation's employment antidiscrimination laws, the Equal Employment Opportunity Commission, has found failure to cover contraception as part of a comprehensive prescription drug benefit to constitute sex discrimination in violation of federal law. U.S. Equal Employment Opportunity Comm'n, Commission Decision on Coverage of Contraception (Dec. 2000), *available at*

Because of these preexisting provisions in the Iowa pharmacy regulations, the Board may legitimately consider pharmacist refusals to be disfavored or even prohibited under current law.

Precedent in Other States

If the Board adopted the position that pharmacist refusals were prohibited under Iowa law, that action would be consistent with three other states that explicitly require pharmacists to ensure that valid prescriptions are filled, and do not permit pharmacists to refuse to dispense medication on the basis of personal beliefs.

Maine pharmacy law and regulations make clear that pharmacists may refuse only for professional reasons and no other reason – such as personal beliefs – is allowed.[3] The *Massachusetts* Board of Pharmacy issued a letter responding to an inquiry about pharmacists' refusals to provide EC.[4] Interpreting existing pharmacy provisions, the Board concluded that pharmacists are required to fill a valid prescription, including those for EC, pursuant to a review for contraindications and similar concerns. The Board emphasized that there is *no* class of drugs exempt from the general requirement of dispensation. In *Nevada*, where the pharmacy board recently passed a new rule permitting a pharmacist to decline to fill a prescription only for professional reasons, the general counsel of the pharmacy board stated that refusals based on other considerations—such as personal or moral beliefs—could result in discipline by the state.[5]

Following the examples of these states and relying on existing Iowa pharmacy regulations that lend strong support, the Board could prohibit pharmacist refusals based on personal beliefs. However, if the Board wishes to consider a provision permitting pharmacist refusals based on personal beliefs at another time, the provision must provide adequate patient protections. The proposed rule § 657—8.10 did not do so. In the next section, we discuss the steps other states have taken to protect patients and suggest how the Board could craft a refusal provision to ensure patients receive their medications in a timely manner.

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http://www.eeoc.gov/policy/docs/decision-contraception.html. The majority of federal courts that have considered this question have similarly concluded that an employer's exclusion of prescription contraception from an employee insurance plan gives rise to a claim of sex discrimination until Title VII. *See, e.g.*, Erickson v. Bartell Drug Company, 141 F.Supp.2d 1266 (W.D. Wash., 2001); *but see* In re Union Pacific Employment Practices Litigation, No. 06-1706 (8th Cir. March 15, 2007). Along these lines, Iowa has a law mandating contraceptive coverage in individual and group health insurance policies. IOWA CODE ANN. § 514C.19.

[3] CODE ME. R. 02-392 ch. 19, § 11 (*citing* ME. REV. STAT. ANN. tit. 32 § 13795(2)).

[4] Letter from President James T. DeVita, The Commonwealth of Massachusetts Board of Registration in Pharmacy, to Dianne Luby, President/CEO, Planned Parenthood League of Massachusetts, Inc. (May 6, 2004) (on file with the National Women's Law Center).

[5] NEV. ADMIN. CODE § 639.753, *available at* http://www.leg.state.nv.us/NAC/NAC-639.html#NAC639Sec753. For details on the comments of the general counsel to the pharmacy board, see Cy Ryan, *Pharmacy Asked to Withhold Judgment*, LAS VEGAS SUN, May 6, 2006, *available at* http://www.lasvegassun.com/sunbin/stories/sun/2006/may/06/566613322.html.

III. Enabling Pharmacist Refusals with Adequate Patient Safeguards

Six states – California, Delaware, Illinois, New York, North Carolina, and Oregon – accommodate personal beliefs of individual pharmacists while ensuring that the patient receives medication in a timely manner, ideally at the same pharmacy. The laws, regulations and guidance promulgated in these states have consistently put the burden on the *pharmacy* to establish protocols in case of a refusal and to ensure that the patient receives the medication in a timely manner. Additionally, guidance issued by pharmacy boards in Delaware, New York and Oregon have made it clear that refusing pharmacists may not interfere with a patient's right to receive medication, may not lecture patients, and must take steps to avoid the possibility of abandoning or neglecting patients. Any rule promulgated by the Board should contain similar patient protective provisions.

Need for Enhanced Patient Protections in Proposed Regulation

There are several ways the Board could add and strengthen patient protections if the Board decides to recognize a right of refusal in the future. We discuss the concepts that underlie these suggestions below.

A. Duty to Patient

1) *Referral within Pharmacy*: In order to ensure access to medication in the event of a pharmacist refusal, it is important that pharmacies have systems in place to ensure that prescriptions or requests for medication are filled expeditiously and without additional burdens to patients. Former proposed rule § 657—8.10 put a burden on pharmacy personnel, but it did not go far enough. The proposed rule stated that "pharmacy personnel shall assist… a patient requesting a drug not provided based on the pharmacist's conscientious objection and refusal[] to identify another pharmacy or other lawful source that *may be able* to provide the drug" [emphasis added]. This language does not provide enough protection for pharmacy customers. Under this wording, a pharmacist could comply with the letter of the rule by simply handing pharmacy customers a phone book and telling them to call other pharmacies themselves, or by "referring" customers to a pharmacy in an inconvenient location.

   To protect patients, a provision governing refusals should place the burden on *pharmacies* to ensure that patients receive their medication *on the premises*. Individual pharmacists would be able to refuse, but pharmacies would be required to ensure that patients received their medication at the pharmacy without delay. For example, Illinois's regulation states that "[u]pon receipt of a valid, lawful prescription for a contraceptive, a pharmacy must dispense the contraceptive, or a suitable alternative permitted by the prescriber, to the patient or the patient's agent without delay, consistent with the normal time frame for filling any other

prescription."[6] This ensures that pharmacists have the right to refuse, but only if the patient can get the medication they need in an appropriate time frame *and without leaving the premises*. Such a rule would require pharmacies to establish protocols for cases of refusals. As the New York Board of Pharmacy noted in its guidance, such protocols may include scheduling two pharmacists for duty.[7] In addition, such a rule would be congruent with the policies of several major drugstore chains, including CVS, Rite-Aid, Walgreens and Kmart.[8]

We recognize that an in-store referral provision will have the greatest impact on sole proprietors who have personal objections to certain medications. In our view, it is precisely in these situations, where there are often a limited number of pharmacies and long distances between pharmacies, that refusals can have the most harmful effect on those seeking medication, and therefore should not be allowed. However, others such as Governor Rod Blagojevich, who promulgated the Illinois regulation on pharmacy refusals, have chosen to address this issue by allowing pharmacies who do not sell *any form* of prescription contraception to opt out of Illinois's contraception dispensation requirements.

2) *Conditions of Refusal:* Former proposed rule § 657—8.10(1)(a) would have allowed pharmacists to refuse to provide medication if the pharmacist was "unsatisfied as to the legitimacy *or appropriateness* of the prescription presented" [emphasis added]. This clause of the proposed rule was not subject to any patient-protective provisions—pharmacists who decided that a prescription was "inappropriate" would not be obligated to help patients locate another source of medication. If the Board were to propose a similar clause in a future rule, it would be important to clarify the term "appropriateness," to make sure that pharmacists were only refusing on those grounds (and thus exempt from patient-protective provisions) if they had concerns about the *clinical or medical appropriateness* of a particular drug. It should not be possible for a pharmacist to mask a religious or moral objection as a concern about a medication's "appropriateness" and thus avoid taking steps to help patients.

3) *Confidentiality/Dignity*: There have been several instances where pharmacists not only refused to provide pharmacy customers with important medication, but also subjected those customers to public

[6] ILL. ADMIN. CODE tit. 68, § 1330.91 (2005).
[7] Letter from Lawrence H. Mokhiber, Executive Secretary, New York State Board of Pharmacy, to Supervising Pharmacists, Re: Policy Guideline Concerning Matters of Conscience (Nov. 18, 2005), *available at* http://www.op.nysed.gov/pharmconscienceguideline.htm.
[8] Behind the Counter: PPFA Brings You the Real Story, http://www.saveroe.com/campaigns/fillmypillsnow/scored (last visited March 30, 2007).

lectures, scolding, or other forms of humiliating treatment. Iowa regulations already prohibit some of the behavior to which women have been subjected in other states; for example, rule § 657—8.11(8) states that a pharmacist may not exhibit "unprofessional behavior in connection with the practice of pharmacy" and defines unprofessional behavior to include verbal abuse, intimidation, harassment and degradation of character. In addition, rule § 657—8.16 delineates the limited number of situations when confidential information may be released. Any future proposals for refusal clauses should reference these sections of the rules, because it is important to remind pharmacists that they must limit their advice to professional matters, such as contraindications or drug interactions, rather than advocate their personal beliefs.

4) *Misrepresentation*: There have also been instances where pharmacists misled pharmacy customers about the availability of contraception in the store or about the mechanism of action of a particular contraceptive. Iowa regulations already prohibit this behavior; rule § 657—8.11(1) states that a pharmacist "shall not make any statement intended to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in [a] pharmacy." As with the provisions regarding unprofessional behavior, future proposals for refusal clauses should also reference this section of the rules, because it is important to remind pharmacists that misleading patients with the intent of delaying access or giving inaccurate information about a medication may subject them to discipline.

B. Duty to Employer

Former proposed rule § 657—8.10(2) contained a notice provision which would have required pharmacists to notify their employers about their objections to certain types or classes of drugs *prior* to a refusal in order to facilitate employers' ability to comply with legal obligations. This is an important provision to include in any refusal clause, because it enables pharmacies to meet their legal obligations. California law requires pharmacists to provide written notice before refusing to provide medication to customers, and also makes pharmacists' ability to refuse conditional upon their employer's ability to accommodate patients without undue hardship, which is consistent with federal law.

> A licentiate may decline to dispense a prescription drug or device only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which her or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation to the licentiate's objection. The licentiate's employer shall establish protocols that ensure that

the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order.

CAL. BUS. & PROF. CODE § 733(b)(3).

C. Out-of-Stock Drugs

Former proposed rule § 657—8.10 contained patient protections that were the same for out-of-stock ("unavailable") drugs as they were for drugs that patients were unable to access because of a refusal based on personal beliefs. If the Board considers drafting another rule, it may wish to separate these two very different obstacles to obtaining medication. In Illinois, for example, a patient who has requested an out-of-stock drug has three options. The patient can request that the pharmacy "obtain the contraceptive under the pharmacy's standard procedures for ordering contraceptive drugs not in stock, including the procedures of any entity that is affiliated with, owns, or franchises the pharmacy," the prescription can be "transferred to a local pharmacy of the patient's choice under the pharmacy's standard procedures for transferring prescriptions for contraceptive drugs, including the procedures of any entity that is affiliated with, owns, or franchises the pharmacy," or the patient can request that the pharmacist return the unfilled prescription to her. ILL. ADMIN. CODE tit. 68, § 1330.91 (2005). Patient choice is critical to any out-of-stock provision.

D. Preserving Pharmacist Duties

Although the Board may wish to limit the reasons that a pharmacist can refuse, any refusal provision should clarify that pharmacists' traditional duties—such as engaging in a Prospective Drug Review—continue to apply in all circumstances.

E. Ensuring Access to EC OTC

Any refusal provision should ensure that the same protections available to patients with prescriptions for contraception are also available to women 18 and older who request EC OTC (non-prescription EC). The FDA's decision to approve EC OTC should be seen as an important effort to ensure easier access to this medication. However, FDA conditions still require all women to request EC at the pharmacy counter – even those 18 and older – because they must show identification to pharmacy personnel before they can be given the non-prescription product. It would be ironic if patient protections were applied to women age 17 and younger that had valid prescriptions for EC, but were not extended to women 18 and older that requested EC OTC. For these reasons, any rule addressing refusals

based on personal beliefs should ensure that whatever duties to the customer exist for prescription drugs also exist for EC OTC.

The Washington State Board of Pharmacy is considering a proposed rule whose language the Board may want to replicate in order to include EC OTC in the ambit of any future rule it promulgates. The Washington rule puts the burden on the pharmacy to ensure access, and states in part that "Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute *drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies*…" [emphasis added].[9]

It is also important for pharmacy personnel to be instructed that providing EC OTC is a task shared by all pharmacy employees, including pharmacy interns and technicians. The FDA's approval letter requires EC OTC to be sold only in locations staffed by a licensed pharmacist, but the pharmacist herself does not bear the sole responsibility for providing the drug – anyone that is legitimately behind the pharmacy counter bears the ability and the responsibility to check patients' identification and provide EC OTC.

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Thank you in advance for your consideration of our suggestions. If you have any questions, please do not hesitate to contact Gretchen Borchelt (Counsel) of the National Women's Law Center at 202/588-5180.

[9] Draft Text WAC 246-869-010 Pharmacies' Responsibilities, *available at* https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/documents/WAC246-869-010.pdf (last visited March 30, 2007).