



OFFICE OF THE ATTORNEY GENERAL  
STATE OF ILLINOIS

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FILE NO. 09-002

LICENSED OCCUPATIONS:  
Authority of Advanced Practice Clinicians  
to Dispense and Administer Mifepristone

The Honorable Heather Steans  
State Senator, 7<sup>th</sup> District  
M120 Capitol Building  
Springfield, Illinois 62706

Dear Senator Steans:

I have your letter inquiring whether, under the Illinois Abortion Law of 1975 (the Abortion Law) (720 ILCS 510/1, *et seq.* (West 2006)), physician assistants or advanced practice nurses (collectively referred to as advanced practice clinicians (APCs)), may dispense mifepristone under the supervision of a physician.<sup>1</sup> For the reasons discussed below, it is my opinion that the Abortion Law permits APCs to dispense and administer mifepristone under a physician's supervision consistent with APCs' authority to provide medical care under Illinois law.

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<sup>1</sup>Mifepristone is sold under the brand name Mifeprex and is also known as RU-486.

## BACKGROUND

### United States Food and Drug Administration Approval of Mifepristone

In 1996, the Population Council submitted a new drug application for mifepristone to the United States Food and Drug Administration (FDA). On September 28, 2000, the FDA approved the use of mifepristone, in combination with another medication (misoprostol), for the medical termination of an intrauterine pregnancy during early pregnancy. See Memorandum from Department of Health & Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research to NDA 20-687 MIFEPREX (mifepristone) Population Council (September 28, 2000) (FDA Memorandum), at 1.<sup>2</sup> The FDA approved mifepristone under Title 21, Subpart H of part 314 of the Code of Federal Regulations, which applies when the FDA concludes that a drug can be used safely only if distribution or use is restricted, such as to certain physicians with special skills or experience.<sup>3</sup> FDA Memorandum at 6.

The FDA requires that mifepristone be provided "by or under the supervision of a physician" who is qualified to diagnose pregnancy duration and ectopic pregnancies, to provide surgical intervention in cases of incomplete abortion or severe bleeding, or has made plans to provide such care through other qualified physicians and is able to assure patient access to

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<sup>2</sup>Available at <http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf>.

<sup>3</sup>21 C.F.R. §314.500 *et seq.* (2008). Subpart H applies to certain new drugs that have been studied for their safety and effectiveness in treating serious life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments. FDA Memorandum at 6.

medical facilities equipped to provide blood transfusions and resuscitation, if necessary.<sup>4</sup> FDA Memorandum at 6. In addition, the FDA approved mifepristone for distribution directly to qualified physicians only. FDA Memorandum at 4. However, the FDA specifically stated that the limited distribution to physicians "does not preclude another type of health care provider, acting under the supervision of a qualified physician, from dispensing the drug to patients, provided state laws permit this." FDA Memorandum at 4-5. Thus, whether APCs in Illinois may dispense mifepristone to patients turns on the authority that State law grants to APCs.

**Authority of Advanced Practice Clinicians under Illinois Law**

APCs are specially educated, state-regulated medical professionals who practice under physician supervision. A number of Illinois statutes set forth the authority of APCs to practice medicine under an agreement with a physician and, specifically, to prescribe and dispense prescription drugs. The clear starting point for any analysis of the authority to dispense prescription drugs is the Medical Practice Act of 1987 (the Medical Practice Act) (225 ILCS 60/1 *et seq.* (West 2006)). Section 33 of this Act (225 ILCS 60/33 (West 2007 Supp.)) authorizes licensed physicians to purchase and dispense drugs requiring a prescription in the regular course of practicing medicine. Section 54.5 of the Medical Practice Act (225 ILCS 60/54.5 (West 2007

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<sup>4</sup>The FDA also requires that qualified physicians read and understand the prescribing information for mifepristone, provide each patient with a Medication Guide and Patient Agreement and, after giving the patient the opportunity to read and discuss both documents, obtain her signature on the Patient Agreement. The physician must sign the Patient Agreement, record the package serial number in the patient's record, and report any ongoing pregnancy, hospitalization, transfusion, or other serious events to the drug sponsor (the Population Council) or its designate. FDA Memorandum at 6. Under the FDA approval, mifepristone is supplied only to physicians who sign and return a Prescriber's Agreement, and distribution is subject to the distributor's requirements for storage, dosage tracking, damaged product returns, and other matters. *See* U.S. Food and Drug Administration, Center for Drug Evaluation and Research, MIFEPREX® (mifepristone) Tablets, 200 mg, Label, at 14.

Supp.)) expressly allows physicians to delegate care and treatment responsibilities to physician assistants (PAs) and to collaborate with advanced practice nurses (APNs). *See also* 225 ILCS 85/4(f), (g) (West 2007 Supp.). Under this section, licensed Illinois physicians may delegate care and treatment responsibilities to PAs through guidelines that are in accord with the Physician Assistant Practice Act of 1987 (Physician Assistant Practice Act) (225 ILCS 95/1 *et seq.* (West 2006)), and physicians in active clinical practice may collaborate with APNs under the provisions of the Nurse Practice Act (225 ILCS 65/50-1 *et seq.* (West 2007 Supp.)).

#### **Physician Assistants**

The Physician Assistant Practice Act generally authorizes a licensed PA to perform procedures within the specialty of the supervising physician and with the supervising physician exercising the level of direction, supervision, and control over the PA necessary to assure that patients receive quality medical care. 225 ILCS 95/4 (West 2007 Supp.). A supervising physician may delegate tasks or duties to a PA that are: (1) consistent with the PA's education, training, and experience; (2) specific to the practice setting; and (3) implemented and reviewed under guidelines that the physician or the physician/physician assistant team establish. 225 ILCS 95/4 (West 2007 Supp.). Section 7.5 of the Physician Assistant Practice Act (225 ILCS 95/7.5 (West 2006)) authorizes a supervising physician to delegate authority to a PA that includes dispensing (and even prescribing) specified controlled substances as delegated in the required written guidelines. Specifically, the law allows a PA to dispense or prescribe drugs or medical supplies within the scope of practice of the supervising physician. 68 Ill. Adm. Code

§1350.55, as amended by 33 Ill. Reg. 1484, 1491 (effective January 8, 2009). The law also requires that the supervising physician periodically review the medication orders issued by a PA. 225 ILCS 95/7.5 (West 2006).

Additionally, under the Physician Assistant Practice Act, the supervising physician need not be on-site with the PA. 225 ILCS 95/4 (West 2007 Supp.). Specifically, the statutory requirement for supervision of a PA "shall not be construed to necessarily require the personal presence of the supervising physician at all times at the place where services are rendered, as long as there is communication available for consultation" by telecommunications. 225 ILCS 95/4 (West 2007 Supp.).

#### **Advanced Practice Nurses**

The Nurse Practice Act provides for licensure of nurses in three categories: licensed practical nurses, registered professional nurses, and advanced practice nurses. An APN is a registered professional nurse who has met the specified qualifications for and is licensed as: a certified nurse midwife; a certified nurse practitioner; a certified registered nurse anesthetist; or a clinical nurse specialist. 225 ILCS 65/50-10, 65-20 (West 2007 Supp.). Physicians collaborate with APNs to deliver health care services "in accordance with \* \* \* the advanced practice nurse's training, education, and experience[.]" 225 ILCS 65/65-35(b) (West 2007 Supp.). For a physician and an APN to collaborate, both the Medical Practice Act and the Nurse Practice Act require a written collaborative agreement for all APNs engaged in clinical practice. 225 ILCS 60/54.5 (West 2007 Supp.); 225 ILCS 65/65-35 (West 2007 Supp.). The collaborative

agreement must describe the working relationship of the APN with the collaborating physician and authorize categories of care, treatment, or procedures to be performed by the APN. 225 ILCS 65/65-35 (West 2007 Supp.).

An APN's scope of practice expressly includes (but is not limited to) "[p]rescriptive authority[.]" 225 ILCS 65/65-30 (West 2007 Supp.); *see also* 225 ILCS 85/4(g) (West 2007 Supp.). A collaborating physician may delegate this authority pursuant to a written collaborative agreement. This authority includes "prescription of, selection of, orders for, administration of, storage of, acceptance of samples of, and dispensing over the counter medications, legend drugs, medical gases, and [specified] controlled substances \* \* \*, and other preparations[.]" 225 ILCS 65/65-40 (West 2007 Supp.). As with PAs, APNs may dispense or prescribe drugs or medical supplies within the scope of practice of the supervising physician. 68 Ill. Adm. Code §1305.40, as amended by 30 Ill. Reg. 4657, 4670 (effective March 1, 2006). The law also requires that the supervising physician periodically review the medication orders issued by an APN. 68 Ill. Adm. Code §1305.40(f), as amended by 30 Ill. Reg. 4657, 4671 (effective March 1, 2006).

Just as the Physician Assistant Practice Act allows the physician to supervise a PA from another location, the Nurse Practice Act provides that the collaborative relationship "shall not be construed to require the personal presence of a physician \* \* \* at all times at the place where services are rendered." Instead, the statute requires that methods of communication be

available for the APN to consult with the collaborating physician in person or by telecommunications in accordance with the guidelines established in the collaborative agreement. 225 ILCS 65/65-35 (West 2007 Supp.); 225 ILCS 60/54.5 (West 2007 Supp.).

### The Abortion Law

Subsection 2(4) of the Abortion Law (720 ILCS 510/2(4) (West 2006)) defines the term "abortion" as:

the use of any instrument, medicine, drug or any other substance or device to terminate the pregnancy of a woman known to be pregnant with an intention other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus.

The use of mifepristone, a "medicine" or "drug," to terminate a pregnancy falls within the definition of "abortion" contained in subsection 2(4).

Section 3.1 of the Abortion Law (720 ILCS 510/3.1 (West 2006)) provides, in relevant part:

No abortion shall be performed except by a physician after either (a) he determines that, in his best clinical judgment, the abortion is necessary, or (b) he receives a written statement or oral communication by another physician, hereinafter called the "referring physician", certifying that in the referring physician's best clinical judgment the abortion is necessary.<sup>5</sup>

The determinative question is whether section 3.1 prohibits APCs from dispensing mifepristone.

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<sup>5</sup>The General Assembly enacted the Abortion Law in 1975 and added section 3.1 in 1979. *See* Public Act 79-1126, effective November 20, 1975; Public Act 81-1078, effective January 1, 1980. The General Assembly last amended section 3.1 in 1984 (*see* Public Act 83-1128, effective June 30, 1984), before enacting the Medical Practice Act, the Physician Assistant Practice Act, and the Nurse Practice Act.

### ANALYSIS

As discussed above, the FDA has placed restrictions on the availability of mifepristone. Although mifepristone must be provided "by or under the supervision of a physician[.]" the FDA also recognized that state laws may allow physicians to delegate medical tasks to qualified non-physician healthcare professionals, and therefore expressly permitted precisely this delegation consistent with state law.

Illinois law allows the carefully supervised physician delegation of certain medical care. The Medical Practice Act, the Physician Assistant Practice Act, and the Nurse Practice Act together create a cohesive scheme authorizing physicians to delegate medical care to APCs. Illinois APCs may dispense, administer, or even prescribe most classes of prescription drugs upon the delegation of a "supervising" or "collaborating" physician. 225 ILCS 95/4 (West 2007 Supp.); 225 ILCS 65/65-35 (West 2007 Supp.). Accordingly, whether APCs may dispense mifepristone turns on whether section 3.1 of the Abortion Law supercedes the express delegation set forth in these later-enacted statutes, which control the practice of medicine in Illinois.

The primary objective of statutory construction is to ascertain and give effect to the intent of the General Assembly, and the most reliable indicator of this intent is the plain and ordinary meaning of the statutory language. *People v. Perry*, 224 Ill. 2d 312, 323 (2007). In construing a statute, it is presumed that the General Assembly did not intend absurdity, inconvenience, or injustice. *Alvarez v. Pappas*, 229 Ill. 2d 217, 228 (2008). Statutes relating to the same subject must be compared and construed consistently, giving effect to all of the provisions of each if possible. *Cinkus v. Village of Stickney Municipal Officers Electoral Board*,



228 Ill. 2d 200, 218 (2008). Further, "when two statutes appear to be in conflict, the one that was enacted later should prevail as a later legislative expression of intent." *Jahn v. Troy Fire Protection District*, 255 Ill. App. 3d 933, 941 (1994), *aff'd*, 163 Ill. 2d 275 (1994).

While it specifies that only physicians may perform abortions, section 3.1 of the Abortion Law places no express limits on the manner in which they do so. Thus, section 3.1 allows physicians to perform abortions in a manner consistent with their medical practice generally. Here in Illinois, three statutes, the Medical Practice Act, the Physician Assistant Practice Act, and the Nurse Practice Act, all enacted after the Abortion Law, guide the practice of medicine. These statutes manifest the General Assembly's clear intent to expand the lawful scope of medical practice to include physicians' delegation of authority to APCs. Under these statutes, it is my opinion that a physician may delegate the task of dispensing mifepristone and other drugs to an APC acting under the physician's supervision.

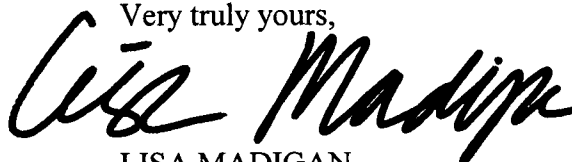
Under the laws governing the practice of medicine in Illinois, physicians work in concert with APCs to provide appropriate patient care. Interpreting section 3.1 to prohibit APC assistance would lead to the illogical conclusion that a physician must perform every aspect of patient care, a result clearly at odds with established canons of statutory construction and irreconcilable with Illinois law. Section 3.1, which makes no attempt to restrict the way in which physicians conduct their practice, is properly interpreted to allow physicians to provide care with the assistance of APCs, as physicians do in the normal course. State law specifically authorizes APCs to assist physicians by dispensing medication under physician supervision, and section 3.1 does nothing to restrict this practice.

Were there any doubt that this is the proper reading of Illinois law, section 3.1 is a criminal statute and "[c]riminal or penal statutes are to be strictly construed in favor of an accused and nothing should be taken by intendment or implication beyond the obvious or literal meaning of the statute." *People v. Woodard*, 175 Ill. 2d 435, 444 (1997). Reading section 3.1 to bar APCs from dispensing mifepristone would stretch that section well beyond its "obvious or literal meaning" to criminalize conduct that is otherwise expressly permitted under the Medical Practice Act, the Physician Assistant Practice Act, and the Nurse Practice Act. Section 3.1 may not be read to criminalize the lawful practice of medicine in Illinois.

#### CONCLUSION

The FDA allows APCs to dispense mifepristone under the supervision of a qualified physician when state law permits this practice. In Illinois, several statutes, all enacted after the Illinois Abortion Law of 1975, expressly authorize physicians to delegate certain medical care (including the dispensing of medication) to APCs. Section 3.1 of the Abortion Law requires that abortions be performed by physicians. However, nothing in that section prevents physicians from undertaking this or any other medical care with the assistance of an APC as allowed under Illinois law. Thus, it is my opinion that section 3.1 does not prohibit APCs from dispensing mifepristone in accordance with the Medical Practice Act, the Physician Assistant Practice Act, and the Nurse Practice Act.

Very truly yours,

A handwritten signature in black ink, appearing to read "Lisa Madigan". The signature is fluid and cursive, with the first name "Lisa" written in a larger, more prominent script than the last name "Madigan".

LISA MADIGAN  
ATTORNEY GENERAL