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Via EMAIL

Re: HFS Comments/Proposed Revisions to Rules for Abortion Facilities in Arkansas pursuant to Ark. Code Ann. § 20-8-201 *et seq.*

Ms. Jane Gaskill
Section Counsel, Health Facilities Services
Arkansas Dept. of Health
5800 W. Tenth St., Suite 400
Little Rock, Arkansas 72204
Email: Jane.Gaskill@arkansas.gov

Dear Ms. Gaskill:

The ACLU, ACLU of Arkansas, and the undersigned counsel represent Little Rock Family Planning Services, Inc. ("LRFPS"). In response to the notice of public hearing scheduled for September 3, 2020 and the invitation to submit comments on the proposed changes to the Rules for Abortion Facilities in Arkansas (hereinafter the "Rules"), we submit the following comments on behalf of LRFPS with respect to the proposed new rule set forth in section 8(G) of the proposed Rules (hereinafter, "Rule 8(G)").

Rule 8(G) states:

> Manufacturer's Guidelines. Manufacturer's guidelines shall be followed for all equipment and biologicals, including medications, for use within the facility.

LRFPS objects to Rule 8(G) on the following bases: (1) Rule 8(G) exceeds the Arkansas Department of Health's ("ADH") statutory authority under Arkansas's Administrative Procedure Act ("APA"), Ark. Code Ann. § 25-15-201 *et seq.;* (2) Rule 8(G) would preclude LRFPS from providing healthcare according to best, evidence-based medical practice; (3) Rule 8(G)'s promulgation would violate the statutory prohibition against adopting any rule that is not based on "the best reasonably attainable scientific, technical, economical or other evidence and information available concerning the need for, consequences of, and alternatives to the rule," Ark. Code Ann. §25-15-204(b)(1); and (4) Rule 8(G) would create significant constitutional issues, including, but not limited to, violation of the Fourteenth Amendment's Equal Protection Clause (because similar restrictions have not been promulgated with respect to non-abortion healthcare facilities). Each of these bases are addressed in further detail below.

A. Rule 8(G) Exceeds ADH's Statutory Authority

Arkansas's APA makes clear that the rulemaking authority of state agencies flows only from acts of the Arkansas General Assembly, that such authority shall be interpreted narrowly, and that an agency rule may be held invalid if it exceeds the agency's statutory authority. *See* Ark. Code Ann. § 25-15-220(b)(1) ("The authority of a state agency to promulgate a rule *when so empowered* by an act of the General Assembly shall be *narrowly* interpreted by the state agency") (emphasis added); Ark. Code Ann. § 25-15-212(h)(2) (court may reverse or modify agency decision if the decision is, *inter alia*, "[i]n excess of the agency's statutory authority"); *see also* Ark. Code Ann. § 25-15-204 (requiring agencies, in promulgating rules, to consider, *inter alia*, "[w]hether the agency is required by statute to adopt the proposed rule"); *McLane Co. v. Davis*, 353 Ark. 539, 551, 110 S.W.3d 251, 259 (2003) (finding an Arkansas Tobacco Control Board regulation to be arbitrary, *ultra vires* and unenforceable where Board failed to explain how its actions fell within language of the underlying Act). Accordingly, an agency must "[l]imit its rulemaking to only those areas or subject matters that are absolutely necessary to fulfill its statutory duty or obligations." Ark. Code Ann. § 25-15-220(b)(2). "A proposed rule that is promulgated based upon a broad interpretation of a state agency's rulemaking power rather than a narrow interpretation of that rulemaking power may be deemed as inconsistent with state law for the purposes § 10-3-309(f)(1)." Ark. Code Ann. § 25-15-220(c).

Rule 8(G) clearly exceeds ADH's statutory authority. ADH has cited no Arkansas statute authorizing it to promulgate the rule, and a review of other laws contained in Ark. Code Ann. § 20-16-601 *et seq.*, pertaining to abortion facilities and services, reveals no provision upon which proposed Rule 8(G) may be based. To the extent ADH claims its authority to promulgate Rule 8(G) arises from Ark. Code Ann. § 20-9-302, as amended by Act 801 of 2019,[1] that Act contains no language that would provide a basis for the rule. As such, Rule 8(G) exceeds the Department's statutory authority and is *ultra vires*.

B. Rule 8(G) Is Contrary to Best, Evidence-Based Medical Practice

As the U.S. Food and Drug Administration ("FDA") has recognized, "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment."[2] Following from this, it is longstanding and well-accepted practice for medical professionals to exercise their best clinical judgment to lawfully use a drug or medical device in a manner that departs from the

[1] *See* ADP's Indexed Summary of Changes – Abortion Facility Rules (090419) at 9, https://www.healthy.arkansas.gov/images/uploads/pdf/Abortion_Summary_(no_green)_09042019.pdf (listing Act 801 of 2019 as providing the basis for "8(D)(1) change to statutory language" while "also not[ing]: follow manufacturer's guidelines – 8(G), p. 8-3").

[2] *See* U.S. Food and Drug Administration, Guidance for Institutional Review Boards and Clinical Investigators: "Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices. 1998 Update. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices.

manufacturer's guidelines or is "off-label" where such use is supported by scientific and medical evidence and is in the best interests of the patient.[3] Indeed, numerous professional medical associations, including the American Medical Association ("AMA"), have confirmed their "strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion."[4]

There are instances where medical professionals providing medical care to pregnant patients may need to use drugs or medical devices in a manner that departs from the manufacturer's guidelines or the label in order to provide the best possible evidence-based medical care to the patient. For example, for appropriate candidates with ectopic pregnancy, off-label use of methotrexate, a cancer-treating drug, is considered the standard and preferred method of treatment. Indeed, the American College of Obstetricians and Gynecologists ("ACOG") has recommended the off-label use of methotrexate for certain women with ectopic pregnancies.[5] Similarly, the ability to use a

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[3] *See, e.g.*, *id.*; *see also* American Medical Association, Policy, Patient Access to Treatments Prescribed by Their Physicians H-120.988, (hereinafter "AMA Policy Statement") https://policysearch.ama-assn.org/policyfinder/detail/off-label?uri=%2FAMADoc%2FHOD.xml-0-201.xml; American Academy of Orthopaedic Surgeons, Position Statement, Physician Directed Use of Medical Products, (hereinafter AAOS Position Statement) https://aaos.org/contentassets/1cd7f41417ec4dd4b5c4c48532183b96/1177-physician-directed-use-of-medical-products.pdf (acknowledging common practice and noting that "government has long recognized that physicians may prescribe or administer any legally marketed product for an off-label use within the practice of medicine"); Fitzgerald AS, O'Malley PG. Staying on track when prescribing off-label. *Am Fam Physician.* 2014; 89(1):4-5 ("off-label use is common, accounting for approximately 10-20% of prescriptions").

[4] AMA Policy Statement; *see also* Physician-Directed Applications, A Position Statement of the Alliance of Specialty Medicine, March 2017, https://www.aans.org/-/media/Files/AANS/Advocacy/PDFS/Position-Statements/ASM-Physician-Directed-Applications-Position-Statement-Update-March-2017.ashx?la=en&hash=FA4DCBBF9AA2B888342CC3D30902D57D8B8167F0 ("Physician-directed applications, also known as 'off-label' uses [of medical products], are an integral component of . . . medical practice, particularly for specialty physicians. . . . It is not uncommon for some off-label uses of medical products to become standard of care in the practice of medicine"); AAOS Position Statement ("The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons may prescribe or administer any legally marketed product for an off-label use within the authorized practice of medicine in the exercise of appropriate medical judgment for the best interest of the patient."); Committee on Drugs, American Academy of Pediatrics, *Uses of Drugs Not Described in the Package Insert (Off-Label Uses)*, Pediatrics 110, no. 1: 181-83 (2002), http://pediatrics.aappublications.org/content/110/1/181 (endorsing off-label prescribing of drugs "based on sound scientific evidence, expert medical judgment, or published literature" and when "done . . . in the best interest of the patient).

[5] ACOG, Tubal Ectopic Pregnancy, Practice Bulletin No. 193, March 2018, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/03/tubal-ectopic-pregnancy.

Foley catheter, a device most often used to drain the bladder, is sometimes crucial for treating uterine bleeding. While use of a Foley catheter for this purpose may depart from the manufacturer's guidelines, it is widely accepted by the medical profession as the most appropriate and evidence-based care in certain cases when uterine bleeding occurs.[6] [7]

LRFPS's use of equipment and medications is always in accordance with best medical practice based on the best available medical, scientific, and technical evidence. However, there may certain instances, including some of those identified above, where LRFPS needs to use drugs and/or medical devices in a manner not contemplated by the label or manufacturer's guidelines in order to provide the safest and most effective evidence-based medical care to its patients. Rule 8(G) would interfere with LRFPS's ability to this care, in contravention of best medical evidence and practice.

C. **Rule 8(G) Violates the Rule-Making Requirements Set Forth by Ark. Code Ann. §25-15-204**

Ark. Code Ann. §25-15-204(b)(1) requires ADH to base any new rule on the "best reasonably attainable scientific and technical information available concerning the need for, consequences of, and alternatives to the rule." As shown above, the best scientific and technical information militates against a restriction such as Rule 8(G), since medical practitioners must be able to exercise their best medical judgment to use a drug or device in an off-label manner when that judgment is supported by the best medical evidence. Therefore, the "consequences" of imposing such a restriction would be severe: medical professionals would be precluded from exercising their clinical judgment to provide the safest, most appropriate, and most effective medical care, in furtherance of the best interests of their patients. Accordingly, proposed Rule 8(G) simply cannot be said to be based on the "best reasonably attainable scientific and technical information" and, as such, contravenes the requirements set forth in Ark. Code Ann. §25-15-204(b)(1).[8]

D. **Rule 8(G) Violates the Equal Protection Clause of the Fourteenth Amendment**

The Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution prohibits states from denying to any person within their jurisdiction the equal protection of the laws. An

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[6] *See, e.g.*, Timor-Tritsch I. E., Cali G., Monteagudo A., et al. Foley balloon catheter to prevent or manage bleeding during treatment for cervical and Cesarean scar pregnancy. *Ultrasound in Obstetrics and Gynecology*. 2015;46(1):118–123. doi: 10.1002/uog.14708.

[7] Off-label use of medications by physicians when appropriate was explicitly affirmed by ADH Secretary Dr. Jose Romero in testimony at a joint meeting of the Arkansas House and Senate Insurance and Commerce committees and the Arkansas Health Insurance Marketplace Oversight Subcommittee. https://www.arkansasonline.com/news/2020/sep/01/drug-barred-in-covid-cases-legislators-told/?news-arkansas.

[8] An agency is also required to consider a number of other factors in promulgating rules. *See* Ark. Code Ann. § 25-15-204 (listing factors). There is no indication that ADH considered those factors in proposing Rule 8(G).

examination of the laws and ADH's rules and regulations pertaining to other healthcare facilities reveals that ADH has subjected no other healthcare facility to a restriction like Rule 8(G), that would operate to preclude medical professionals from exercising their best medical judgment in using drugs and medical equipment in a manner that comports with well-established, evidence-based medical practice. As such, a rule like 8(G), which singles out abortion facilities and providers for differential and unfair treatment, violates the Equal Protection Clause.

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On behalf of LRFPS, we appreciate the opportunity to comment on the proposed rules and request that the proposed Rule 8(G) be withdrawn. If we can provide additional information, please do not hesitate to contact us. We ask to be kept apprised of any further action concerning Rule 8(G) as LRFPS is prepared to provide additional information and comment prior to final action by the Board.

Cordially

Bettina E. Brownstein

Bettina E. Brownstein
Brooke Augusta Ware

On Behalf of the ACLU of Arkansas Foundation, Inc.

Meagan Burrows
ACLU Reproductive Freedom Project