#### **DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION**

**SUBJECT:** Abortion Facilities in Arkansas – Fetal Tissue Disposal

**<u>DESCRIPTION</u>**: This clarifies that abortion facilities are not responsible for fetal remains expelled away from their facilities.

<u>PUBLIC COMMENT</u>: The Department had a public hearing on November 13, 2017, and the public comment period expired on that date. The Department received two written comments:

Bettina Brownstein, an attorney representing Little Rock Family Planning Services, stated the following in an October 23, 2017, letter regarding the proposed revisions to the Rules and Regulations for Abortion Facilities in Arkansas promulgated pursuant to Act 535 of 2015 and Act 603 of 2017:

The enforcement of Act 603 was preliminarily enjoined by order of the Eastern District of Arkansas on February 28, 2017. The Court found that Act 603 was likely to be found unconstitutionally vague. This order has been appealed. However, only until such time and only if the February 28, 2017, order is reversed would Act 603 go into effect. Of course, the enforcement of any ADH rules and regulations implementing Act 603 is contingent on the federal court's decision, and no rule or regulation can go into effect absent a court order upholding its constitutionality.

Bettina Brownstein, as cooperating attorney for the ACLU of Arkansas, Susan Talcott Camp and Ruth Harlow, of the American Civil Liberties Union Foundation, and Hillary Schneller, from the Center for Reproductive Rights, all serving as attorneys for Little Rock Planning Services, sent a November 13, 2017, letter submitting comments in response to the Notice of Public Hearing. The comments to the 2017 proposed rules for abortion facilities regarding tissue disposal stated the following:

These proposed changes, as summarized in the Notice, alter a definition, "add[] requirements for proper disposition of dead fetuses and fetal remains, and specif[y] circumstances under which the requirements are inapplicable." The Notice acknowledges that it relies on Act 603 of 2017 (referred to herein as the "Tissue Disposal Mandate") as purposed authority for these changes.

Our comments raise three objections in opposition to the noticed rulemaking. First, no public hearing, public comment process, or other regulatory action, should be occurring at this time, because the Tissue Disposal Mandate has been enjoined. The Department of Health's proposed rule and solicitation of input only cause confusion for abortion facilities, their physicians and their patients, at a time when the law and rules that pre-date the Tissue Disposal Mandate continue to govern. Second, even if the Department could proceed with a rules change, the proposal—like the Tissue Disposal Mandate on which it is based—would impose unconstitutional burdens on women, is inconsistent with other legal obligations of abortion facilities, and is unworkable. Third, to the extent that the Department may wish to clarify the application of any of its rules to medication abortions, versus surgical abortions, it must do so separate and apart from any reliance on the enjoined Tissue Disposal Mandate. The currently-proposed Subsection 6(O)(1), which attempts to differentiate medical from surgical procedures and waive tissue disposal requirements from medication abortions, shares the same flaws as the larger proposed Section 6(O).

## 1. <u>State Action to Enforce the Tissue Disposal Mandate is Barred By a Preliminary Injunction</u>

As you know, the United States District Court for the Eastern district of Arkansas in *Hopkins v. Jegley*, Case No. 4:17-cv-00404-KGB, has found Dr. Hopkins likely to succeed in striking down the Tissue Disposal Mandate as unconstitutional. That Court found that the Mandate likely imposes an unconstitutional undue burden on Arkansas abortion patients and is impermissibly vague. The Court entered a preliminary injunction enjoining enforcement of any of the Tissue Disposal Mandate's requirements on July 28, 2017. The Court ordered the direct defendant in the litigation, including the Prosecuting Attorney for Pulaski County and all members of the Arkansas State Medical Board, "to notify immediately all state officials responsible for enforcing [the Tissue Disposal Mandate] about the existence and requirements of the preliminary injunction," which remains in force today and prohibits enforcement of the Mandate. An appeal has been filed, and it will likely be years before the *Hopkins v. Jegley* litigation is finally resolved.

In light of the preliminary injunction, the Tissue Disposal Mandate, including as it sought to amend Ark. Code Ann. §§20-17-801 and -802, currently has no regulatory force or effect. The prior version of Sections 801 and 802 continue to govern the operation of abortion facilities and you Department's oversight of them. In particular, the pre-existing Subsections 801(a)(1)(A), 801(a)(3), and 802 (a), as provided in Act 535 of 2015, specify that physicians and facilities disposing of tissue after an abortion "shall ensure that the fetal remains and all parts are disposed of in a fashion similar to that in which other [human] tissue is disposed and in a respectful and proper manner," including by directly releasing the human tissue for incineration, cremation or other specified methods of tissue disposal.

It was only with the Tissue Disposal mandate enacted in 2017 that Arkansas attempted to require that tissue from an abortion be "disposed of in accordance with the provisions of Ark. Code Ann. §20-17-102[,]" the Final Disposition Rights Act ("FDRA"). The Department's proposed new Part O in Section 6 of the Rules and Regulations for Abortion Facilities attempts to impose such a requirement of ensuring compliance with the FDRA, but doing so now, by regulation, is contrary to the currently-governing version of Sections 801 and 802. Those statutes govern how facilities and physicians who provide abortions are to dispose of embryonic and fetal tissue (with patients having 48 hours in some instances to direct otherwise), and apply the general standards quoted in the previous paragraph. The FDRA, by contrast, describes an elaborate system of determining control over one's own eventual remains or over the dead bodies of next of kin, and is directed at funeral homes and crematoria, not health care providers.

Of course, a regulation cannot amend a statute by rulemaking, nor can a regulation specify requirements that are contrary to statute. *See Yamaha Motor Corp., U.S.A. v. Richard's Honda Yamaha*, 344 Ark. 44, 56, 38 S.W.3d 356, 363 (2001) ("an administrative regulation cannot be contrary to statute"); *State ex rel. Atty. Gen. v. Burnett*, 200 Ark. 655, 140 S.W.2d 673, 675 (1940) (striking as void a rule that attempted to amend the governing statute). The proposed new Section 6(O) should be withdrawn and considered no further, because there is no statutory authority for it. It contradicts the currently governing law in Section 801 and 802.

# 2. <u>Proposed Section 6(O) Is Not Only Contrary to Current Governing Law, But Suffers from the Same Defects as the Enjoined Mandate</u>

As exhaustively shown in the *Hopkins v. Jegley* litigation, it is impossible for abortion physicians or facilities, in the context of that care, to ensure compliance with the FDRA and its rules for control over disposition of dead bodies. *See* 2017 WL 3220445 at \*56-\*68. For example, a woman's decision about whether to proceed with an abortion or continue her pregnancy is constitutionally protected as her own yet the FDRA introduces additional decision-makers into her abortion care, such as her sexual partner, or, if she and her sexual partner are minors, both her own parents and his parents. Attempting to comply with the FDRA would cause abortion facilities and their staffs not only to intrude upon their patient's autonomy, but also to breach physician-patient confidentiality. The FDRA, as another example, also includes cost-sharing and dispute-resolution mechanisms over which a physician or facility has no control, and that they cannot police to ensure compliance. Moreover, the FDRA was enacted to govern much different circumstances, and is repeatedly vague or inapposite as applied to physicians and health care facilities. As the District Court found, it fails to explain to either providers or enforcement authorities what exactly is required or forbidden. 2017 WL 3220445 at \*67.

Proposed Section 6(O) has all the same failings, because it states only that, "Each facility shall ensure that each dead fetus or fetal remains are disposed of in accordance with the provisions of Ark. Code Ann. §20-17-102" – the FDRA – but adds no clarity or explanation as to how that might conceivably occur. The proposed regulation is therefore itself unconstitutionally vague, and threatens to impose the same undue burdens as the Tissue Disposal Mandate if it were ever allowed to become final and effective. The Department should, instead, withdraw the proposed regulation.

To the extent that the Department wishes to clarify the regulatory definition of "dead fetus" in Part F of Section 3 ("Definitions"), to become a definition of both "dead fetus and fetal remains," the Department has the statutory authority to do that under the currently governing versions of Sections 801 and 802, which came from Act 535 of 2015. Act 535 is also references in the Notice of Public Hearing for November 13, 2017. Such amendment of that definition, however, which tracks Section 801(b)(2)(A) and reflects the use of the phrase "fetal remains" elsewhere in Sections 801 and 802, will not affect how tissue disposal currently occurs.

## 3. <u>Subsection (1) Also Rests on Flawed Authority; It Confuses Further with "Human Remains"</u>

Subsection 6(O)(1) attempts to carve out medication abortions from the over-arching requirement of Section 6(O), and thus is attempting to limit the Departments' regulation and oversight of tissue disposal. But that sub-part is part of a larger regulatory section that conflicts with the Constitution and is without current statutory authority. See supra Points 1 & 2. In addition, the Department does not have sole regulatory and enforcement authority with regard to the requirements of the Tissue Disposal Mandate, should they ever take effect. Thus, the Department cannot, without a court's intervention or the participation of all other enforcement authorities, unilaterally adopt a limiting construction of the Mandate.

The subsection also adds to the confusion created by the proposed regulations, because it references "human remains" when the definition in the proposed regulatory changes uses the terms "dead fetus or fetal remains[.]" That definition encompasses either embryonic or fetal tissue, and under the current versions of the statutory Sections 801 and 802, such tissue also is included in the definition of "human tissue." Subsection 6(O)(1)'s reference to "human remains," however, does not track any aspect of the currently-governing statutes that relate to tissue disposal after an abortion, and instead is a phrase used at time in the FDRA to reference an individual's body after death. Even this exclusion from Section 6(O)'s requirements, in light of its confusing content and lack of any proper statutory authority, cannot stand alone and should be abandoned.

If the Department sought to draft a new regulation specifying that its oversight of abortion facilities' proper disposition of embryonic and fetal tissue does not extend to tissue expelled or evacuated after a patient leaves the facility, as is the case in medication abortion, the Department could do so under the current governing statutes. The limitations in Section 801, for example, do not apply unless a physician or facility has acquired possession of the tissue, which would not occur when tissue passes outside the facility. Section 802's requirement is simply that "tissue be disposed of in a fashion similar to that in which other tissue is disposed," and that would encompass tissue, for example, passed through miscarriage at home and disposed there; the "same fashion" of disposal is permitted for tissue from a medication abortion. Thus, the objective of Subsection 6(O)(1) can be accomplished, but not pursuant to that subsection as proposed.

**RESPONSE:** The Department has no plans to enforce the controverted provisions until the matter is resolved.

The rule was filed under the emergency provisions of the Administrative Procedure Act on November 14, 2017, and will expire on March 14, 2018.

The proposed effective date for the final rule is March 15, 2018.

**FINANCIAL IMPACT**: There is no financial impact.

**LEGAL AUTHORIZATION:** The Department of Health has the authority to make any and all necessary and reasonable rules and regulations of a general nature for the protection of the public health and safety. *See* Ark. Code Ann. §20-7-109(a)(1)(A).

The purpose of this proposed rule is to implement changes resulting from Act 603 of 2017, sponsored by Representative Kim Hammer, which requires "all dead fetuses be disposed of in accordance with the Arkansas Final Disposition Rights Act."

In addition to adding the requirements of Act 603, the Department states that the purpose is to clarify that abortion facilities are not responsible for the disposition of dead fetuses and fetal tissue when the evacuation occurs outside the presence of the inducing physician or away from the facility in which the physician administered the inducing medications. This proposed rule change also amends the current rules to include the legal definition of "dead fetus or fetal tissue" as defined by Ark. Code Ann. §20-17-801(b)(2)(A).

## QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY	Department of Heal	th		Jerpanikalisi 1
DIVISION	Center for Health P	rotection/Health	Facilities S	Section
DIVISION DIRECTOR	Renee Mallory			
CONTACT PERSON	Robert Brech			
ADDRESS	4815 West Markhan	n, St., Slot 31, L	ittle Rock,	AR
PHONE NO. 501-661-22 NAME OF PRESENTER A MEETING		501-661-2357	E- MAIL t Brech	robert.brech@arkansas.gov
PRESENTER E-MAIL ro	bert brech@arkansas	· ·	t Dicen	
		RUCTIONS		
this Rule" below.  D. Submit two (2) copies of two (2) copies of the propona K. Day Administrative Arkansas Leg Bureau of Leg One Capitol I	indexing your rules, this questionnaire a posed rule and requivis we Rules Review Secutislative Council gislative Research Mall, 5 <sup>th</sup> Floor	please give the paid financial impared documents.	proposed oact stater	citation after "Short Title of
Little Rock, A				
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2. What is the subject of the pule?		sition of fetal tiss	sue	05.031 amili 06.0009 -27.46-1
. Is this rule required to com	ply with a federal sta	tute, rule, or regu	ılation?	Yes 🗌 No 🖂
If yes, please provide the fe	ederal rule, regulation	, and/or statute c	itation.	tanta ari
Was this rule filed under the Procedure Act? If yes, what is the effective rule?			7	Yes No 🗌
When does the emergency expire?	rule 3-14-20	018		

	Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?  Yes  No
5.	Is this a new rule? Yes No No If yes, please provide a brief summary explaining the regulation.
	Does this repeal an existing rule? Yes No No If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.
rul	Is this an amendment to an existing le?  Yes No No Structure No Structure and a summary of the substantive changes. Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."
6.	Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Act 603 of 2017
7. res	What is the purpose of this proposed rule? Why is it necessary? To clarify that abortion facilities are not eponsible for fetal remains expelled away from their facilities.
8.	Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). <a href="http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulations.aspx">http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulations.aspx</a>
9.	Will a public hearing be held on this proposed rule? Yes No I  If yes, please complete the following:  Date: 11/13/2017  Time: 10:00  Suite 801, 5800 West Tenth Street,
	Place: <u>Little Rock, Arkansas</u> When does the public comment period expire for permanent promulgation? (Must provide a date.)  //13/2017
	What is the proposed effective date of this proposed rule? (Must provide a date.) 15/17
12.	Do you expect this rule to be controversial? Yes No No If yes, please  The Department is not aware of any significant controversy at this time regarding this rule.

13. Please give the name Please provide their p	s of persons, groups, or organi position (for or against) if know	izations that you expect to cown.	mment on these rules?

#### FINANCIAL IMPACT STATEMENT

#### PLEASE ANSWER ALL QUESTIONS COMPLETELY

DE	PART	MENT	Department of	Health			8
DIV	ISIO	N	Center for Hea	alth Protection/Health	Facilities Section	i i,	
PEI	RSON	COMPLE	TING THIS ST	FATEMENT Rober	rt Brech	7.00	
TEI	LEPH	ONE NO.	501-661-2297	FAX NO. 501-661-2	2357 EMAIL: rober	t.brech@arl	kansas.gov_
To Sta	comp temer	ly with Ark. at and file tw	Code Ann. § 25 o copies with the	5-15-204(e), please co ne questionnaire and p	omplete the following proposed rules.	Financial Ir	npact
SH	ORT	TITLE OF	THIS RULE	Abortion Facilities	in Arkansas		
1.	Does	this propos	ed, amended, or	repealed rule have a	financial impact?	Yes [	No 🖂
2.	econ	omic, or oth	er evidence and	onably obtainable scie information available lternatives to the rule?	concerning the	Yes 🖂	No 🗌
3.	In co	nsideration gency to be	of the alternative the least costly i	es to this rule, was thi rule considered?	s rule determined by	Yes 🖂	No 🗌
	Ifan	agency is pr	oposing a more	costly rule, please sta	ate the following:		
	(a)	How the ad	ditional benefits	s of the more costly ru	ale justify its additions	al cost;	
	(b)	The reason N/A	for adoption of	the more costly rule;			
	(c)		e more costly ru e explain; and;	nle is based on the inte	erests of public health	, safety, or v	welfare, and
	(d)	Whether th explain.	e reason is with	in the scope of the ago	ency's statutory autho	ority; and if s	so, please
4.	If the	purpose of t	his rule is to imp	olement a federal rule o	r regulation, please star	te the follow	ing:
	(a)	What is the	cost to implem	ent the federal rule or	regulation?		
	Cui	rrent Fiscal	Year		Next Fiscal Year		
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	Total
(b) What is the additional cost of	the state rule?
Current Fiscal Year	Next Fiscal Year
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Revenue	General Revenue
Federal   Funds	Federal Funds
Cash Funds	Cash Funds
C	Special Revenue
Other (Identify)	Other (Identify)
Total	Total
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What is the total estimated cost by the proposed, amended, or repealed explain how they are affected.  Current Fiscal Year	fiscal year to any private individual, entity and business subject d rule? Identify the entity(ies) subject to the proposed rule and  Next Fiscal Year
\$ 0	\$ 0
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implement this rule? Is this the co	y fiscal year to state, county, and municipal government to ost of the program or grant? Please explain how the government
implement this rule? Is this the coaffected.  Current Fiscal Year	y fiscal year to state, county, and municipal government to ost of the program or grant? Please explain how the government  Next Fiscal Year  \$ 0
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implement this rule? Is this the coaffected.  Current Fiscal Year  O  With respect to the agency's answ or obligation of at least one hundre private entity, private business, statwo (2) or more of those entities could be agency is required by a time of filing the financial impact.	Next Fiscal Year  Next Fiscal Year  Deers to Questions #5 and #6 above, is there a new or increased coed thousand dollars (\$100,000) per year to a private individual, at government, county government, municipal government, or to ombined?  Yes No  Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the statement. The written findings shall be filed simultaneously t and shall include, without limitation, the following:

(3) a description of the factual evidence that:

(a) justifies the agency's need for the proposed rule; and

- (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:

(a) the rule is achieving the statutory objectives;

(b) the benefits of the rule continue to justify its costs; and

(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

## PROPOSED REVISIONS TO THE RULES AND REGULATIONS FOR ABORTION FACILITIES IN ARKANSAS

#### NOVEMBER 2017 EMERGENCY RULE

Act 603 of 2017 passed in the recent legislative session. The Act requires that all dead fetuses be disposed of in accordance with the Arkansas Final Disposition Rights Act and was to become effective on July 31, 2017. The Act is unclear if abortion facilities would be responsible for the disposition of dead fetuses and fetal tissue when the evacuation occurs outside the presence of the inducing physician or away from the facility in which the physician administered the inducing medications. This amendment makes it clear that the facility would not be responsible when that occurs.