

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Abortion Facilities Licensing Standards (LAC 48:I.4401 and 4431)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.4401 and §4431 as authorized by R.S. 36:254 and R.S. 40:2175.1 et seq. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 97 of the 2016 Regular Session of the Louisiana Legislature increased the time period required for certain pre-operative services. Act 563 of the 2016 Regular Session of the Louisiana Legislature provided that at least 72 hours before the abortion, the pregnant woman seeking an abortion shall be given a copy of certain printed information, including resources, programs and services for pregnant women who have a diagnosis of fetal genetic abnormality, and given printed information about resources, programs and services for infants and children born with disabilities, as well as other related matters. Act 593 of the 2016 Regular Session of the Louisiana Legislature provided for the disposal, by interment or cremation, of fetal remains and designates procedures for giving patients options for arrangements. Act 376 of the 2019 Regular Session of the Louisiana Legislature amended the definition of abortion.

The Department of Health, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing outpatient abortion facilities in order to comply with the provisions of Acts 97, 563 and 593 (*Louisiana Register*, Volume 42, Number 12). The department subsequently determined that it was necessary to amend the provisions of the December 3, 2016 Emergency Rule governing the length of retention of the certification of minors and the disposition of fetal remains (*Louisiana Register*, Volume 47, Number 3).

This proposed Rule is being promulgated in order to continue the provisions of the December 3, 2016 and March 20, 2021 Emergency Rules in compliance with Acts 97, 563 and 593 and to amend the general provisions for abortion facilities in order to update definitions and comply with the requirements of Act 376.

Title 48

PUBLIC HEALTH GENERAL

Part I. General Administration

Subpart 3. Licensing and Certification

Chapter 44. Abortion Facilities

Subchapter A. General Provisions

§4401. Definitions

Abortion or Induced Abortion ~~any surgical procedure performed, after pregnancy has been medically verified, with the intent to cause the termination~~ act of using or prescribing any

instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable pregnancy, ~~other than for~~ of a woman with knowledge that the ~~purpose~~ termination by those means will, with reasonable likelihood, cause the death of the unborn child. Such use, prescription, or means is not an abortion if done with the intent to:

1. ~~producing a live birth~~ save the life or preserve the health of an unborn child;
2. ~~removing~~ remove a dead unborn child or induce delivery of the uterine contents in case of a positive diagnosis, certified in writing in the woman's medical record along with the results of an ~~ectopic~~ obstetric ultrasound test, that the pregnancy has ended or is in the unavoidable and untreatable process of ending due to spontaneous miscarriage, also known in medical terminology as spontaneous abortion, missed abortion, inevitable abortion, incomplete abortion, or septic abortion; or
3. ~~removing a dead fetus caused by a spontaneous abortion~~ remove an ectopic pregnancy.

Certified Registered Nurse Anesthetist (CRNA)—a licensed health care practitioner who is acting within the scope of

practice of his/her respective licensing board(s) and/or
certifications.

~~CRNA—a certified registered nurse anesthetist licensed by
the Louisiana State Board of Nursing who is under the
supervision of the physician performing the abortion or an
anesthesiologist who is immediately available if needed as
defined in the medical staff bylaws and in accordance with
applicable licensing boards. A CRNA is an advanced practice
registered nurse educated in the field of nurse anesthesia and
certified according to the requirements of a nationally
recognized certifying body such as the Council on Certification
of Nurse Anesthetists or the Council on Recertification of Nurse
Anesthetists, as approved by the board and who is authorized to
select and administer anesthetics or ancillary services to
patients under their care.~~Repealed.

Genetic Abnormality—any defect, disease, or disorder that
is inherited genetically. The term includes, without limitation,
any physical disfigurement, scoliosis, dwarfism, Down syndrome,
albinism, amelia, and any other type of physical, mental, or
intellectual disability, abnormality, or disease

Physician Assistant (PA)~~—an individual who is currently approved by, licensed by, and in good standing with the Louisiana State Board of Medical Examiners to perform medical services under the supervision of a physician or group of physicians who are~~a licensed ~~by and registered with the Louisiana State Board of Medical Examiners to supervise a physician assistant and~~health care practitioner who is acting within the scope of ~~all applicable state laws and the individual's professional license~~practice of his/her respective licensing board(s) and/or certifications.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:685 (April 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 48:

Subchapter C. Pre-Operative, Intra-Operative, and Post-Operative Procedures

§4431. Screening and Pre-Operative Services

A. – E.1. ...

2. Requirements. ~~At least 24 hours prior to the pregnant woman having any part of an abortion performed or induced, and prior to the administration of any anesthesia or~~

~~medication in preparation for the abortion on the pregnant woman, the physician who is to perform the abortion or a qualified person who is the physician's agent shall comply with all of the following requirements:~~

a. ~~perform an obstetric ultrasound on~~ Except as provided in Subparagraph b below, at least 72 hours prior to the pregnant woman, ~~offer~~ having any part of an abortion performed or induced, and prior to ~~simultaneously display the screen which depicts the active ultrasound images so that~~ administration of any anesthesia or medication in preparation for the abortion on the pregnant woman ~~may view them and make audible,~~ the fetal heartbeat, if present, in physician who is to perform the abortion or a ~~quality consistent~~ qualified person who is the physician's agent shall comply with ~~current medical practice.~~ ~~Nothing in this Section shall be construed to prevent~~ all of ~~the pregnant woman from not listening to the sounds detected by the fetal heart monitor, or from not viewing the images displayed on the ultrasound screen;~~ following requirements:

i. perform an obstetric ultrasound on the pregnant woman, offer to simultaneously display the screen which depicts the active ultrasound images so that the pregnant woman may view them and make audible the fetal heartbeat, if present, in a quality consistent with current medical practice. Nothing in this Section shall be construed to prevent the pregnant woman

from not listening to the sounds detected by the fetal heart monitor, or from not viewing the images displayed on the ultrasound screen;

ii. provide a simultaneous and objectively accurate oral explanation of what the ultrasound is depicting, in a manner understandable to a layperson, which shall include the presence and location of the unborn child within the uterus and the number of unborn children depicted, the dimensions of the unborn child, and the presence of cardiac activity if present and viewable, along with the opportunity for the pregnant woman to ask questions;

iii. offer the pregnant woman the option of requesting an ultrasound photograph or print of her unborn child of a quality consistent with current standard medical practice that accurately portrays, to the extent feasible, the body of the unborn child including limbs, if present and viewable;

iv. from a form that shall be produced and made available by the department, staff will orally read the statement on the form to the pregnant woman in the ultrasound examination room prior to beginning the ultrasound examination, and obtain from the pregnant woman a copy of a completed, signed, and dated form; and

v. retain copies of the election form and certification prescribed above. The certification shall be

placed in the medical file of the woman and shall be kept by the outpatient abortion facility for a period of not less than seven years. If the woman is a minor, the certification shall be placed in the medical file of the minor and kept for at least seven years or for five years after the minor reaches the age of majority, whichever is greater. The woman's medical files shall be kept confidential as provided by law.

b. ~~provide a simultaneous and objectively accurate oral explanation of what~~If the ultrasound pregnant woman certifies in writing that she currently lives 150 miles or more from the nearest licensed outpatient abortion facility that is depicting, in a manner understandable~~willing and able to a layperson, which~~perform the abortion at the particular woman's stage of pregnancy, then the physician who is to perform the abortion or a qualified person who is the physician's agent shall~~include~~comply with all of the~~presence and location requirements of §4431.E.2.a at least 24 hours prior to the woman having any part of the unborn child within the uterus and the number of unborn children depicted, the dimensions of the unborn child, and the presence of cardiac activity if present and viewable, along with the opportunity for the pregnant woman to ask questions;~~an abortion performed or induced.

e. ~~offer the pregnant woman the option of requesting an ultrasound photograph or print of her unborn child~~

~~of a quality consistent with current standard medical practice that accurately portrays, to the extent feasible, the body of the unborn child including limbs, if present and viewable;~~

~~_____ d. _____ from a form that shall be produced and made available by the department, staff will orally read the statement on the form to the pregnant woman in the ultrasound examination room prior to beginning the ultrasound examination, and obtain from the pregnant woman a copy of a completed, signed, and dated form;~~

~~_____ e. _____ retain copies of the election form and certification prescribed above. The certification shall be placed in the medical file of the woman and shall be kept by the outpatient abortion facility for a period of not less than seven years. If the woman is a minor, the certification shall be placed in the medical file of the minor and kept for at least ten years from the time the minor reaches the age of majority. The woman's medical files shall be kept confidential as provided by law.~~
c. - e. Repealed.

E.3. F. ...

G. Information and Informed Consent

1. Oral and Written Information Provided by Physician or Referring Physician

a. ~~At~~ Except as provided in Paragraph b below,
at least ~~24~~ 72 hours before the abortion the physician who is to

perform the abortion or the referring physician shall provide informed consent to the pregnant woman seeking an abortion, pursuant to all laws, rules and regulations regarding informed consent. The informed consent shall be communicated both orally and in-person, and in writing, and shall be provided in a private room. Documentation of all such informed consent provided shall be maintained in the patient's medical record.

b. ~~Documentation. The documentation~~ If the woman certifies in writing that she currently lives 150 miles or more from the nearest licensed outpatient abortion facility that is willing and able to perform the abortion at the particular woman's stage of pregnancy, then the physician who is to perform the abortion or the referring physician shall comply with all such informed consent provided shall be maintained in of the patient's medical record requirements of §4431.G.1 at least 24 hours prior to the abortion.

1.c. - 2.a. ...

3. Oral Information Provided by Physician, Referring Physician, or Qualified Person

a. ~~At~~ Except as provided in Subparagraph b below, at least ~~24~~ 72 hours before a scheduled abortion the physician who is to perform the abortion, the referring physician, or a qualified person shall inform the pregnant woman seeking an abortion, orally and in-person that:

i. - iv. ...

b. If the woman certifies in writing that she currently lives 150 miles or more from the nearest licensed outpatient abortion facility that is willing and able to perform the abortion at the particular woman's stage of pregnancy, then the physician who is to perform the abortion the referring physician, or a qualified person shall comply with all of the requirements of §4431.G.3 at least 24 hours prior to the abortion.

4. Provision of Printed Materials

a. At least ~~24~~72 hours before the abortion, the pregnant woman seeking an abortion shall be given a copy of the printed materials, pursuant to any applicable state laws, rules, and regulations, by the physician who is to perform the abortion, the referring physician, or a qualified person~~7~~
~~including but not limited to the following~~. These printed materials shall include any printed materials necessary for a voluntary and informed consent, pursuant to R.S. 40:1061.17. However, if the pregnant woman certifies in writing that she currently lives 150 miles or more from the nearest licensed outpatient abortion facility that is willing and able to perform the abortion at the particular woman's stage of pregnancy, she shall be given a copy of the printed materials at least 24 hours prior to an elective abortion procedure by the physician who is

to perform the abortion or a qualified person as defined in R.S. 40:1061.17(B)(4)(c).

i. ~~as a condition for consent to undergoing an elective abortion and, as such to be deemed voluntary and informed, the woman or minor female considering abortion shall be given a copy of the DHH Point of Rescue pamphlet by the physician who is to perform the abortion or a qualified person, except in the case of medical emergency as defined by applicable state laws.~~

~~NOTE: The provisions of this Section requiring a physician or qualified person to provide required printed materials to a woman considering an abortion shall become effective 30 days after the department publishes a notice of the availability of such materials.~~1.

- NOTE Repealed.

b. ~~If~~ At least 72 hours before the abortion, the pregnant woman or minor female ~~seeking~~ considering an abortion ~~is unable to read the materials, the material~~ shall be ~~read to her~~ given a copy of the department's Point of Rescue pamphlet and any other materials described in R.S. 40:1061.16 by the physician who is to perform the abortion or a qualified person as defined in R.S. 40:1061.17(B)(4)(c), except in the case of medical emergency defined by applicable state laws. However, if the pregnant woman or minor female considering an abortion certifies in writing that she currently lives 150 miles or more from the nearest licensed outpatient abortion facility

that is willing and able to perform the abortion at the particular woman's stage of pregnancy, she shall be given a copy of these printed materials at least 72 hours prior to an elective abortion procedure by the physician who is to perform the abortion or a qualified person as defined in R.S. 40:1061.17(B)(4)(c), except in the case of medical emergency defined by applicable state laws.

i. The physician or qualified person shall provide to the woman, or minor female seeking an abortion, such printed materials individually and in a private room for the purpose of ensuring that she has an adequate opportunity to ask questions and discuss her individual circumstances.

ii. The physician or qualified person shall obtain the signature of the woman or minor female seeking an abortion on a form certifying that the printed materials were given to the woman or minor female.

iii. In the case of a minor female considering an abortion, if a parent accompanies the minor female to the appointment, the physician or qualified person shall provide to the parent copies of the same materials given to the female.

iv. The signed certification form shall be kept within the medical record of the woman or minor female for a period of at least seven years.

c. ~~If~~ At least 72 hours before the abortion,
the pregnant woman seeking an abortion ~~asks questions concerning~~
~~any of~~ shall be given a copy of a printed informational document
including resources, programs and services for pregnant women
who have a diagnosis of fetal genetic abnormality and resources,
programs and services for infants and children born with
disabilities. However, if the pregnant woman certifies in
writing that she currently lives 150 miles or more from the
nearest licensed outpatient abortion facility that is willing
and able to perform the ~~information or materials, answers~~
abortion at the particular woman's stage of pregnancy, she shall
be ~~provided to her in her own language~~ given a copy of these
printed materials at least 24 hours prior to an elective
abortion procedure by the physician who is to perform abortion
or a qualified person as defined in R.S. 40:1061.17(B)(4)(c).

d. If the pregnant woman seeking an abortion is
unable to read the materials, the materials shall be read to
her. If the pregnant woman seeking an abortion asks questions
concerning any of the information or materials, answers shall be
provided to her in her own language.

NOTE: The provisions of this Section requiring a physician
or qualified person to provide required printed materials
to a woman considering an abortion shall become effective
30 days after the department publishes a notice of the
availability of such materials.

5. Certification and Reporting

a. Prior to the abortion, the outpatient abortion facility shall ensure the pregnant woman seeking an abortion has certified, in writing on a form provided by the department that the information and materials required were provided at least ~~24~~72 hours prior to the abortion, or at least 24 hours prior to the abortion in the case of a woman who has given prior certification in writing that she currently lives 150 miles or more from the nearest licensed outpatient abortion facility that is willing and able to perform the abortion at the particular woman's stage of pregnancy. This form shall be maintained in the woman's medical record.

b. ...

c. The pregnant woman seeking an abortion is not required to pay any amount for the abortion procedures until the ~~24~~72-hour period has expired, or until expiration of the 24-hour period applicable in the case of a woman who has given prior certification in writing that she currently lives 150 miles or more from the nearest licensed outpatient abortion facility that is willing and able to perform the abortion at the particular woman's stage of pregnancy.

6. - 7.b. ...

8. Disposition of Fetal Remains

a. Each physician who performs or induces an abortion which does not result in a live birth shall ensure that the remains of the fetus are disposed of by interment or cremation, in accordance with the provisions of R.S. 8:651 et seq. and the provisions of LAC 51:XXVI.102 of the Sanitary Code.

b. Prior to an abortion, the physician shall orally and in writing inform the pregnant woman seeking an abortion in the licensed abortion facility that the pregnant woman has the following options:

i. the option to make arrangements for the disposition and/or disposal of fetal remains by interment or cremation, in accordance with the provisions of R.S. 8:651 et seq.; or

ii. the option to have the outpatient abortion facility/physician make the arrangements for the disposition and/or disposal of fetal remains by interment or cremation, in accordance with the provisions of R.S. 8:651 et seq.

c. The pregnant woman shall sign a consent form attesting that she has been informed of these options; if the pregnant woman wants to make arrangements for the disposition of fetal remains, she will indicate so on the form; if no such indication is made on the form by the pregnant woman, the outpatient abortion facility/physician shall make the

arrangements for the disposition and/or disposal of fetal remains by interment or cremation, in accordance with the provisions of R.S. 8:651 et seq.

d. the requirements of §4431.G.8 regarding dispositions of fetal remains, shall not apply to abortions induced by the administration of medications when the evacuation of any human remains occurs at a later time and not in the presence of the inducing physician or at the facility in which the physician administered the inducing medications.

NOTE: The department acknowledges that federal litigation is pending on the issue of disposal of aborted fetal remains and is presently subject to a non-enforcement agreement as of the date that these regulations are published. Regulated entities shall refer to the status of the litigation regarding enforceability of these regulations in June Medical Services LLC, et al versus Phillips, et al, Case No._16-444, United States District Court, Middle District, and any matter consolidated with such matter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:700 (April 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 48:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability or autonomy as described in R.S. 49:972 by ensuring that outpatient abortion facilities protect the health and safety of the patients receiving services.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

Small Business Statement

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule may have an adverse impact on small businesses, as described in R.S. 49:978.1 et seq., if the requirements of these licensing changes increases the financial burden on providers. With the resources available to the department, a regulatory flexibility analysis has been prepared in order to consider methods to minimize the

potential adverse impact on small businesses. The department has determined that there is no less intrusive or less costly alternative methods of achieving the intended purpose since the changes result from legislative mandates.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule may have an impact on the staffing level requirements or qualifications required to provide the same level of service and may result in nominal direct or indirect cost to the provider to provide the same level of service. These provisions may also negatively impact the provider's ability to provide the same level of service as described in HCR 170.

Public Comments

Interested persons may submit written comments to Tasheka Dukes, RN, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821. Ms. Dukes is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on April 29, 2022.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary

ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on April 11, 2022. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on, April 28, 2022 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after April 11, 2022. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips

Secretary