

## NOTICE OF INTENT

### Department of Health Bureau of Health Services Financing

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

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 48:I.4431 in the Medical Assistance Program 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.

The Department of Health and Hospitals, Bureau of Health Services Financing repealed and replaced the provisions governing the licensing standards for abortion facilities in order to incorporate the changes imposed by legislation, and further revise and clarify those provisions (*Louisiana Register*, Volume 41, Number 4).

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 provides 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 provides for the disposal, by interment or cremation, of fetal remains and designates procedures for giving patients options for arrangements. The department promulgated an Emergency Rule which amended the provisions governing outpatient abortion clinics in order to comply with the provisions of Acts 97, 563 and 593 (*Louisiana Register*, Volume 42, Number 12). This proposed Rule is being promulgated in order to continue the provisions of the December 3, 2016 Emergency Rule.

## **Title 48**

### **PUBLIC HEALTH GENERAL**

#### **Part I. General Administration**

#### **Subpart 3. Licensing and Certification**

#### **Chapter 44. Abortion Facilities**

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

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 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.

b. ~~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;~~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, then the physician who is to perform the abortion or a qualified person who is the physician's agent shall comply with all of the requirements of §4431.E.2.a at least 24 hours prior to the woman having any part of 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. - G.1. ...

a. ~~At~~ Except as provided in Subparagraph 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 of all such informed consent provided shall be maintained in the patient's medical record.~~ 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 of the requirements of §4431.G.1 at least 24 hours prior to the abortion.

1.c. - 3. ...

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. ...

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.~~

i. - 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 the information or materials, answers shall be provided~~  
~~to her in her own language~~ 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 abortion at the  
particular woman's stage of pregnancy, she shall be given a copy  
of these 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).

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. ...

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, and shall indicate on the form whether she wants to make arrangements for the disposition of fetal remains or whether she wants the

facility to make arrangements for the disposition and/or disposal of fetal remains.

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.

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 43:

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.

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.

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.

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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. 49:965.2 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.

Interested persons may submit written comments to Cecile Castello, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821 or by email to MedicaidPolicy@la.gov. Ms. Castello is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, July 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E. Gee MD, MPH

Secretary