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The Department of Health and Hospitals, Bureau of Health Services Financing repealed and replaced the provisions governing the licensing standards for abortion facilities in order to incorporate the changes imposed by legislation, and further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

a. Except as provided in Subparagraph b below, at least 72 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:

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. 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.

c. - e. Repealed.

E.3. - G.1. ...

a. Except as provided in Subparagraph b below, at least 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. 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. Except as provided in Subparagraph b below, at least 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 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. 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. - NOTE. Repealed.

b. At least 72 hours before the abortion, the pregnant woman or minor female considering an abortion shall be 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. At least 72 hours before the abortion, the pregnant woman seeking an abortion 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 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 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

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Robert Andrepont
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Return Address: P.O. Box 91030
Baton Rouge, LA

Rule Title: Abortion Facilities Licensing Standards

Date Rule Takes Effect: December 3, 2016

SUMMARY

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. The following summary statements, based on the attached worksheets, will be published in the Louisiana Register with the proposed agency rule.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (SUMMARY)

It is anticipated that the implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 16-17. It is anticipated that $1,512(SGF) will be expended in FY 16-17 for the state's administrative expense for the promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will not affect federal revenue collections since the licensing fees, in the same amounts, will continue to be collected.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

This proposed Rule continues the provisions of the December 3, 2016 Emergency Rule which amended the provisions governing the licensing standards for outpatient abortion facilities in order to comply with the provisions of Acts 97, 563 and 593 of the 2016 Regular Session of the Louisiana Legislature which increased the time period for pre-operative services, mandated the distribution of printed information about services for pregnant women, and established provisions for the disposal of fetal remains. It is anticipated that the implementation of this proposed rule may result in nominal economic costs to abortion facility providers for FY 16-17, FY 17-18 and FY 18-19 with regard to staffing requirements, but may be beneficial by providing clear and concise licensing standards.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Cecile Castello
Signature of Agency Head or Designee

Evan Brasseaux, Staff Director
Legislative Fiscal Officer or Designee

Cecile Castello,
Health Standards Section Director
Typed name and Title of Agency Head or Designee

6/8/17
Date of Signature

Shathan Todd
LDH/BHSF Budget Head

06/08/17
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

This proposed Rule continues the provisions of the December 3, 2016 Emergency Rule which amended the provisions governing the licensing standards for outpatient abortion facilities in order to comply with the provisions of Acts 97, 563 and 593 of the 2016 Regular Session of the Louisiana Legislature.

B. Summarize the circumstances that require this action. If the action is required by federal regulations, attach a copy of the applicable regulation.

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.

C. Compliance with Act 11 of the 1986 First Extraordinary Session.

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

No. It is anticipated that the implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 16-17. It is anticipated that $1,512 will be expended in FY 16-17 for the state's administrative expense for the promulgation of this proposed rule and the final rule.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) ____ If yes, attach documentation.
(b) ____ If no, provide justification as to why this rule change should be published at this time.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COST OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase or (decrease) in cost to implement the proposed action?

COST	FY 16-17	FY 17-18	FY 18-19
PERSONAL SERVICES			
OPERATING EXPENSES	$1,512	$0	$0
PROFESSIONAL SERVICES			
OTHER CHARGES			
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	**$1,512**	**$0**	**$0**

2. Provide a narrative explanation of the costs or savings shown in "A.1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

In FY 16-17, $1,512 will be spent for the state's administrative expense for promulgation of this proposed rule and the final rule.

3. Sources of funding for implementing the proposed rule or rule change.

Source	FY 16-17	FY 17-18	FY 18-19
STATE GENERAL FUND	$1,512	$0	$0
SELF-GENERATED			
FEDERAL FUND	$0	$0	$0
OTHER (Specify)			
Total	**$1,512**	**$0**	**$0**

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

Yes, sufficient funds are available to implement this rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THIS PROPOSED ACTION.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustment in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

This proposed rule has no known impact on local governmental units.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

2. Indicate the sources of funding of the local governmental unit that will be affected by these costs or savings.

   There is no known impact on the sources of local governmental unit funding.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase or (decrease) in revenues can be expected from the proposed action?

REVENUE INCREASE/DECREASE	**FY 16-17**	**FY 17-18**	**FY 18-19**
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS			
LOCAL FUNDS			
Total			

Specify the particular fund being impacted

B. Provide a narrative explanation of each increase or decrease in revenue shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effects on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.)

   This proposed Rule continues the provisions of the December 3, 2016 Emergency Rule which amended the provisions governing the licensing standards for outpatient abortion facilities in order to comply with the provisions of Acts 97, 563 and 593 of the 2016 Regular Session of the Louisiana Legislature which increased the time period for pre-operative services, mandated the distribution of printed information about services for pregnant women, and established provisions for the disposal of fetal remains.

B. Also, provide an estimate of any revenue impact resulting from this rule or rule change to these groups.

   It is anticipated that the implementation of this proposed rule may result in nominal economic costs to abortion facility providers for FY 16-17, FY 17-18 and FY 18-19 with regard to staffing requirements, but may be beneficial by providing clear and concise licensing standards.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

This rule has no known effect on competition and employment.