

APA-1
4/18

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-7-5

Rule Title Fetal, Infant and Maternal Mortality Review

New Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? No

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? n/a

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

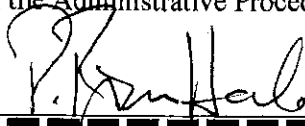
Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of Certifying Officer



Date

6/20/18

REC'D & FILED
JUN 20 2018

LEGISLATIVE SVC AGENCY

FORM APA2
10/17

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-7-5, Fetal, Infant, and Maternal Mortality Review

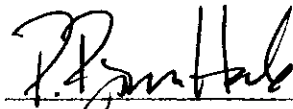
INTENDED ACTION: To Repeal and Replace the current rules

SUBSTANCE OF PROPOSED ACTION: This will allow the Department to conduct maternal mortality review as well as fetal and infant mortality review.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on July 31, 2018, at 9:00 a.m., at the RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on Friday, August 3, 2018. All comments and requests for copies of the proposed repeal and replace should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Amy R. Stratton, State Perinatal Program Director, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 206-6403.



P. Brian Hale, Agency Secretary

ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE

BUREAU OF FAMILY HEALTH SERVICES

CHAPTER 420-7-5
FETAL, INFANT, AND MATERNAL MORTALITY REVIEW

TABLE OF CONTENTS

420-7-5-.01 Purpose
420-7-5-.02 Definitions
420-7-5-.03 Review of Fetal and Infant Records/Case Reviews
420-7-5-.04 Review of Maternal Records/Committee Reviews
420-7-5-.05 Confidentiality of Information
420-7-5-.06 Interviews

420-7-5-.01 **Purpose.**

(1) The purpose of these rules is to provide administrative procedures for fetal, infant, and maternal death reviews, and maternal and family interviews, or both.

(2) The program brings together key members of the community to review cases of fetal, infant, and maternal deaths in order to identify the factors associated with those deaths, to determine if those deaths represent system issues that require change, to develop recommendations for change, and to assist in the implementation of change.

(3) The program's goal is to enhance the health and well-being of women, infants, and families by improving the community resources and service delivery systems available to them. The programs are operated under the auspices of the Alabama Department of Public Health (ADPH), Bureau of Family Health Services, State Perinatal Program.

Author: Thomas Miller, M.D.; Grace H.A. Thomas, M.D., F.A.C.O.G.

Statutory Authority: Code of Ala. 1975, §§ 22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009. Repeal and Replace Filed: June 20, 2018; effective _____.

420-7-5-.02 **Definitions.**

(1) ALABAMA PERINATAL QUALITY COLLABORATIVE (APQC). A collaborative network of teams working to improve the quality of care for mothers and

babies by identifying health care processes that need to be improved by using evidence-based, best practice methods to improve services and systems.

(2) **CASE REVIEW TEAM (CRT).** A multi-disciplinary and multi-agency committee that reviews Fetal and Infant Mortality Review (FIMR) cases and analyzes information collected from medical data abstractions and maternal or family interviews, or both, in such a way as to summarize findings, to create recommendations, to improve community resources, and service delivery systems. CRTs and Regional Perinatal Advisory Committees (RPACs) are frequently composed of many of the same members.

(3) **COMMUNITY ACTION TEAM (CAT).** CATs are composed of RPAC members and others, as appropriate.

(4) **FIMR ABTRACTOR.** An ADPH nurse who reviews and abstracts relevant information from records on related fetal and infant deaths.

(5) **FIMR COORDINATOR.** An ADPH nurse who collects, reviews, and abstracts relevant information, and records related to fetal and infant deaths, coordinates CRT and CAT meetings, and schedules and conducts maternal and family interviews, or both.

(6) **FIMR PROGRAM.** A community-based case review program that focuses on fetal and infant mortality.

(7) **FETAL DEATH.** Death prior to the complete expulsion or extraction from the mother of a product of human conception, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that, after the expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

(8) **INFANT DEATH.** A death at any time from birth up to, but not including, 1 year of age (364 days, 23 hours, and 59 minutes from the moment of birth).

(9) **LIVE BIRTH.** The complete expulsion or extraction from the mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes, or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

(10) **MATERNAL DEATH.** The death of any woman during pregnancy, childbirth, post-partum period, and up to 365 days from the end of pregnancy.

- (11) **MATERNAL MORTALITY FAMILY INTERVIEW.** A voluntary interview conducted by the Maternal Mortality Review (MMR) Coordinator with the deceased mother's family.
- (12) **MATERNAL MORTALITY REVIEW COMMITTEE (MMRC).** A multi-disciplinary and multi-agency committee appointed by the State Health Officer to provide advice and information to ADPH and the State Health Officer on reducing maternal morbidity and mortality. Additionally, the MMRC will serve as a forum in which providers and consumers of maternal care will meet and address issues of maternal morbidity and mortality, leading to a more effective and efficient statewide maternal care system.
- (13) **MMR COORDINATOR.** An ADPH nurse who reviews and records relevant information related to maternal deaths, and coordinates the MMRC.
- (14) **MMR PROGRAM.** A state-based case review program that focuses on maternal mortality.
- (15) **MATERNAL OR FAMILY INTERVIEW.** A voluntary interview of the mother or family or both, of a deceased fetus or infant conducted by the FIMR Coordinator.
- (16) **RECORDS.** Information from vital records, records obtained from hospitals, healthcare facilities, physician's offices, funeral directors, hospital bereavement staff or counselors, medical examiners or coroners, the state forensics lab, law enforcement, emergency medical transport services teams, social service providers, and community health workers, and other medical records deemed necessary for these reviews.
- (17) **RPAC.** A multi-disciplinary and multi-agency committee appointed by the State Health Officer to provide advice and information to the State Perinatal Advisory Committee (SPAC) and the State Health Officer on regional perinatal concerns. Additionally, the RPAC will serve as a forum in which providers and consumers of perinatal care will meet and address issues of concern, leading to a more effective and efficient regional perinatal care system.
- (18) **SPAC.** A multi-disciplinary and multi-agency committee appointed by the State Health Officer to advise ADPH in the planning, organization, and evaluation of the State Perinatal Program.

Author: Thomas Miller, M.D.; Grace H.A. Thomas, M.D., F.A.C.O.G.

Statutory Authority: Code of Ala. 1975, §§ 22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009. Repeal and Replace Filed: June 20, 2018; effective _____.

420-7-5-.03 **Review of Fetal and Infant Records/Case Reviews.**

- (1) All fetal deaths of 20 weeks gestation or greater and all infant deaths, except those which fall within the purview of the Child Death Review Teams, shall be reviewed by the FIMR Program. (Code of Ala. 1975, §26-16-90)
- (2) The FIMR Program shall be based upon the guidelines of the American Congress of Obstetricians and Gynecologists National FIMR Program.
- (3) The FIMR Abstractor(s) or FIMR Coordinator(s) shall extract information from medical and related records onto standardized forms. Case summaries are then prepared on a standardized form with no identifying information. The FIMR Abstractor(s) or FIMR Coordinator(s) will not copy or remove from the facility any records made available to them for review.
- (4) The FIMR Abstractor(s) or FIMR Coordinator(s) shall extract pertinent information of significant social, economic, cultural, safety, and health factors associated with fetal or infant deaths on standardized forms, remove identifying information, and prepare case summaries to present to the FIMR CRTs for discussion.
- (5) The FIMR CRT reviews case summaries prepared by the FIMR Coordinators and these reports are provided to the SPAC regarding its findings and makes recommendations based on those findings.
- (6) The CRT's findings and recommendations shall be reported to the SPAC for approval and possible statewide implementation. Based upon the CRT's direction, the CATs shall participate in the implementation of community-based interventions and policies, as practical, in order to improve existing services and systems.
- (7) The CRTs shall review the case summary information and make recommendations based on the findings. All members attending the FIMR CRT meetings shall sign a formal pledge of confidentiality before the review process begins. At the conclusion of the meetings, all copies of FIMR case summaries shall be collected by the FIMR Coordinators and destroyed.

Author: Thomas Miller, M.D.; Grace H.A. Thomas, M.D., F.A.C.O.G.

Statutory Authority: Code of Ala. 1975, §§ 22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009. Repeal and Replace Filed: June 20, 2018; effective _____.

420-7-5-.04 **Review of Maternal Records/Committee Reviews.**

- (1) All maternal deaths shall be reviewed by the MMR Program.
- (2) The MMR Program shall be based upon the guidelines of the Centers for Disease Control and Prevention.

(3) The MMR Coordinator shall extract information from medical and related records onto standardized forms. Case summaries are then prepared on a standardized form with no identifying information. The MMR Coordinator will not copy or remove from the facility any records made available to them for review.

(4) The MMR Coordinator shall extract pertinent information of significant social, economic, cultural, safety, and health factors associated with maternal deaths on standardized forms, remove identifying information, and prepare case summaries to present to the MMRC for discussion.

(5) The MMRC reviews case summaries prepared by the MMR Coordinator and these reports are provided to the APQC regarding its findings and makes recommendations based on those findings.

(6) The MMRC shall review the case summary information and make recommendations based on the findings. All members attending the MMRC meetings shall sign a formal pledge of confidentiality before the review process begins. At the conclusion of the meetings, all copies of the MMRC case summaries shall be collected by the MMR Coordinator and destroyed.

(7) The MMRC findings and recommendations shall be reported to the APQC for approval and possible statewide implementation. Based upon the MMRC's direction, the APQC and the Alabama Section-American Congress of Obstetricians and Gynecologists shall participate in the implementation of interventions and policies as practical in order to improve existing services and systems.

Author: Thomas Miller, M.D.; Grace H.A. Thomas, M.D., F.A.C.O.G.

Statutory Authority: Code of Ala. 1975, §§ 22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009. Repeal and Replace Filed: June 20, 2018; effective _____.

420-7-5-.05 **Confidentiality of Information.**

(1) All information, interviews, reports, statements, or memoranda reviewed by or furnished to the FIMR and MMR Programs shall be privileged and confidential. Any discussions, findings, conclusions, or recommendations resulting from the review of records by the FIMR and MMR Programs, shall be privileged and confidential. All information, interviews, reports, statements, or memoranda reviewed by or furnished to the FIMR and MMR Programs shall be used only in the exercise of proper functions and duties of the programs, and shall not be public record and shall not be admissible in court for any purpose and shall not be subject to discovery in any civil action.

(2) All information and records acquired or developed by the FIMR and MMR Programs shall be secured with restricted access. When no longer of use, said information and records shall be destroyed.

(3) Statistical information and data may be released by the FIMR and MMR Programs as long as no identifying information is provided.

Author: Thomas Miller, M.D.; Grace H.A. Thomas, M.D., F.A.C.O.G.

Statutory Authority: Code of Ala. 1975, §§ 22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009. Repeal and Replace Filed: June 20, 2018; effective _____.

420-7-5-.06 **Interviews.**

(1) As part of the FIMR Program, the mother, family, or both of a deceased fetus or infant shall be contacted and asked to participate in a voluntary interview. The purposes of the interview are to learn about the mother's experiences before and during pregnancy, to learn about events during the infant's life and around the time of death, to assess the family's needs and provide appropriate referral, and to facilitate bereavement and suggest appropriate interventions.

(2) As part of the MMR Program, the family of a deceased mother may be contacted and asked to participate in a voluntary interview. The purposes of the interview are to learn about the experiences before and during pregnancy, to learn about events during the mother's life and around her time of death, to assess the family's needs and provide appropriate referrals, and to facilitate bereavement and suggest appropriate interventions.

Author: Thomas Miller, M.D.; Grace H.A. Thomas, M.D., F.A.C.O.G.

Statutory Authority: Code of Ala. 1975, §§ 22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009. Repeal and Replace Filed: June 20, 2018; effective _____.

ALABAMA STATE BOARD OF HEALTH
 ALABAMA DEPARTMENT OF PUBLIC HEALTH
 BUREAU OF FAMILY HEALTH SERVICES
 ADMINISTRATIVE CODE

CHAPTER 420-7-5
 FETAL INFANT MORTALITY REVIEW

TABLE OF CONTENTS

420-7-5-.01	Purpose
420-7-5-.02	Definitions
420-7-5-.03	Review Of Records
420-7-5-.04	Confidentiality Of Information
420-7-5-.05	Case Reviews/Interviews

420-7-5-.01 Purpose.

(1) The purpose of these rules is to provide administrative procedures for fetal and infant death reviews and maternal/family interviews.

(2) The program brings together key members of the community to review cases of fetal and infant deaths in order to identify the factors associated with those deaths, to determine if those deaths represent system issues that require change, to develop recommendations for change and to assist in the implementation of change.

(3) The program's goal is to enhance the health and well-being of women, infants and families by improving the community resources and service delivery systems available to them. The program is operated under the auspices of the Alabama Department of Public Health (ADPH), Bureau of Family Health Services, State Perinatal Program.

Author: Thomas Miller, M.D.

Statutory Authority: Code of Ala. 1975, §§22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009.

420-7-5-.02 Definitions.

(1) FETAL DEATH. Death prior to the complete expulsion or extraction from the mother of a product of human conception, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after the expulsion or extraction the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

(2) LIVE BIRTH. The complete expulsion or extraction from the mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes, or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

(3) INFANT DEATH. A death at any time from birth up to, but not including, 1 year of age (364 days 23 hours and 59 minutes from the moment of birth).

(4) STATE PERINATAL ADVISORY COUNCIL (SPAC). A multi-disciplinary and multi-agency council appointed by the State Health Officer to advise the Alabama Department of Public Health in the planning, organization, and evaluation of the State Perinatal Program.

(5) REGIONAL PERINATAL ADVISORY COUNCIL (RPAC). A multi-disciplinary and multi-agency council appointed by the State Health Officer to provide advice and information to the State Perinatal Advisory Council and the State Health Officer on regional perinatal concerns. Additionally, the RPAC will serve as a forum in which providers and consumers of perinatal care will meet and address issues of concern, leading to a more effective and efficient regional perinatal care system.

(6) CASE REVIEW TEAM (CRT). Regional CRTs are composed of RPAC members.

(7) COMMUNITY ACTION TEAM (CAT). Regional CATs are composed of RPAC members and others, as appropriate.

REPEAL

(8) FETAL INFANT MORTALITY REVIEW PROGRAM (FIMR). FIMR is a community-based case review program that focuses on fetal and infant mortality.

(9) FIMR COORDINATOR. An ADPH nurse who reviews relevant information, and records related to fetal and infant deaths, and coordinates case review meetings.

(10) RECORDS. Information from vital records, social services records, hospitals, healthcare facilities, physician's offices, funeral directors, hospital medical records staff, hospital bereavement staff or counselors, medical examiners or coroners, emergency medical transport services teams, social service providers, and community health workers and other medical records deemed necessary for these reviews.

(11) MATERNAL/FAMILY INTERVIEW. Interview(s) conducted by the FIMR Coordinator to learn about the mother's experiences before and during pregnancy; to learn about events during the infant's life and around its time of death; to assess the family's needs and provide appropriate referrals; and to facilitate bereavement and suggest appropriate interventions.

Author: Thomas Miller, M.D.

Statutory Authority: Code of Ala. 1975, §§22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009.

420-7-5-.03 Review Of Records.

(1) All fetal deaths of 20 weeks gestation or greater and all infant deaths except those which fall within the purview of the Child Death Review Teams (§26-16-90, Code of Ala. 1975) shall be reviewed by FIMR.

(2) The FIMR program shall be based upon the guidelines of the American College of Obstetricians and Gynecologists National Fetal Infant Mortality Review Program.

(3) FIMR staff shall be provided access to all records defined in these rules.

(4) The coordinator shall extract pertinent information of significant social, economic, cultural, safety and health factors associated with fetal or infant death on

standardized forms; remove identifying information and prepare case summaries to present to the CRT for discussion.

(5) The CRT reviews case summaries and provides reports to the State Perinatal Advisory Council regarding its findings and makes recommendations based on those findings.

Author: Thomas Miller, M.D.

Statutory Authority: Code of Ala. 1975, §§22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009.

420-7-5-.04 Confidentiality Of Information.

(1) All information, interviews, reports, statements, or memoranda reviewed by or furnished to FIMR staff and any discussions, findings, conclusions, or recommendations resulting from the review of records by FIMR staff and CRTs are declared to be privileged and confidential. All information, interviews, reports, statements, or memoranda reviewed by or furnished to FIMR shall be used only in the exercise of proper functions and duties of the FIMR program, and shall not be public records and shall not be admissible in court for any purpose and shall not be subject to discovery in any civil action.

(2) All information and records acquired or developed by FIMR shall be secured and have restricted access and shall be destroyed when no longer of use.

(4) Statistical information and data may be released by FIMR as long as no identifying information is provided.

Author: Thomas Miller, M.D.

Statutory Authority: Code of Ala. 1975, §§22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009.

420-7-5-.05 Case Review/Interviews.

(1) As part of the case review, the family of a deceased fetus or infant shall be contacted and asked to participate in a voluntary interview.

(2) FIMR staff shall extract information from medical and related records onto standardized forms without entering any

REPEAL

identifying information. Case summaries are then prepared on a standardized form. The FIMR staff will not copy or remove from the facility any records made available to them for review.

(3) The CRT shall review the case summary information and make recommendations based on the findings. All members attending the CRT meetings shall sign a formal pledge of confidentiality before the review process begins. At the conclusion, of the meetings, all CRT copies of the case summaries shall be collected by the FIMR coordinator and destroyed.

(4) The CRT's findings and recommendations shall be reported to SPAC for approval and possible statewide implementation. Based upon CRT direction, the CATs shall participate in the implementation of community-based interventions and policies as practical in order to improve existing services and systems.

Author: Thomas Miller, M.D.

Statutory Authority: Code of Ala. 1975, §§22-9A-21, 22-2-2(6).

History: New Rule: Filed December 17, 2008; effective January 21, 2009.