

HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

POLICY AND STRATEGIC PLANNING BRANCH

**OFFICE OF CERTIFICATE OF NEED AND HEALTH CARE FACILITY LICENSURE
PROGRAM**

OFFICE OF VITAL STATISTICS AND REGISTRY

Rules Implementing the Autumn Joy Stillbirth Research and Dignity Act

Proposed New Rules: N.J.A.C. 8:35

Authorized By: Cathleen D. Bennett, Commissioner, Department of Health, in consultation with the State Board of Medical Examiners, the New Jersey Board of Nursing, the State Board of Psychological Examiners, and the State Board of Social Work Examiners.

Authority: N.J.S.A. 26:8-40.27 et seq., particularly 26:8-40.32.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2017-074.

Submit written comments by June 30, 2017, electronically to www.nj.gov/health/legal/ecomments.shtml or by regular mail to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

The Department of Health (Department) is proposing new N.J.A.C. 8:35 to implement the Autumn Joy Stillbirth Research and Dignity Act (Act), N.J.S.A. 26:8-40.27 et seq., P.L. 2013, c. 217. The Act requires the Department to establish protocols that are to be followed by health care facilities providing obstetrics and newborn services that would ensure the dignified and sensitive treatment of a patient and family experiencing a stillbirth, which is an unintended fetal death that occurs after 20 weeks of pregnancy or involves the unintended death of a fetus weighing 350 or more grams. The Act also requires the Department to create a mechanism for the collection of data regarding stillbirths, which, in turn, will be made available, in a de-identified format, to the public and researchers seeking to determine risk factors and causes of stillbirths.

The proposed new rules implement the Act by establishing the minimum requirements that health care facilities providing obstetrics and newborn services must follow when a stillbirth occurs, to ensure the patient and family experiencing the stillbirth are provided not only with emotional and psychological support, but also with compassionate care and dignified treatment. The proposed new rules also implement the Act by setting forth the data that facilities must collect regarding each stillbirth, including data obtained from autopsies performed on stillborn children, and the manner in which they are to report this information to the Department, so that the Department

can make the information available, in a deidentified format, to the public and researchers who are studying how to prevent and reduce the occurrences of stillbirths.

The Department consulted with the State Board of Medical Examiners, the New Jersey Board of Nursing, the State Board of Psychological Examiners, and the State Board of Social Work Examiners on the standards included in the new rules.

The Department also met with stakeholders, including the New Jersey Hospital Association and the Maternal Child Health Consortia, to discuss the proposed new rules and the policies and procedures that health care facilities already have in place for patients and families experiencing a stillbirth. From these meetings, the Department learned that many, if not all, health care facilities in this State that provide birthing and newborn care services have policies and procedures in place for the care and treatment of patients and families experiencing a stillbirth and that many developed their procedures based upon their own experiences and interactions with these families. Based upon this information, the Department crafted the proposed new rules in a manner that not only provides for the minimum standards that all facilities must follow when caring for a patient and family experiencing a stillbirth, but also provides facilities with the flexibility to enhance these minimum standards with their own best practices for caring for these grieving patients and families. Providing facilities with flexibility to bolster their stillbirth policies and procedures with their own best practices ensures the provision of optimal, dignified care, and treatment to those families experiencing such a great loss.

A summary of the proposed new rules follows.

Proposed new N.J.A.C. 8:35-1.1 would establish the scope of the chapter, which is to implement the Act as it applies to all health care facilities providing birthing services and newborn care services.

Proposed new N.J.A.C. 8:35-1.2 would provide the purpose of the chapter, which is to effectuate the intent of N.J.S.A. 26:8-40.27 et seq., by ensuring the dignified and sensitive management of each stillbirth and of the family's grieving process, as well as by facilitating the collection of data regarding stillbirths occurring in this State with the goal of providing the deidentified data to the public and researchers seeking ways to prevent and reduce the incidence of stillbirths.

Proposed new N.J.A.C. 8:35-1.3 would establish definitions of terms used in the chapter.

Proposed new N.J.A.C. 8:35-2.1 would require facilities providing birthing and newborn care services to establish a policies and procedures manual, which would contain all of the policies and procedures required at proposed N.J.A.C. 8:35-2.2 through 2.7.

Proposed new N.J.A.C. 8:35-2.2 would require facilities to develop and implement policies and procedures that address the assignment of responsibilities to one primary physician when a stillbirth occurs in a facility and requires the facilities to assign specific duties to the physician, including the coordination of facility staff in the care of the patient, the preparation of the patient for viewing the stillborn child, and discussing the importance of an autopsy with the patient.

Proposed new N.J.A.C. 8:35-2.3 would require facilities to develop and implement policies and procedures for the training of all employees who provide direct

care to a patient who has delivered a stillborn child, as well as provide specific topics which must be covered in the training.

Proposed new N.J.A.C. 8:35-2.4 would require facilities to create a bereavement checklist to assist the facilities with collecting information from the patients and families of a stillborn, which will assist the facilities with providing support and comfort to the patients and families throughout the grieving process, and to maintain the required information as part of the patient's medical record.

Proposed new N.J.A.C. 8:35-2.5 would require facilities to develop and distribute a stillbirth informational pamphlet to patients and their families, which would provide support information, such as what to expect when delivering a stillborn child, as well as contact information for support groups.

Proposed new N.J.A.C. 8:35-2.6 would require a facility to develop policies and procedures to ensure that the emotional and psychosocial needs of the patient are addressed, which would include the provision of one-on-one nursing care and assistance in completing any required forms.

Proposed new N.J.A.C. 8:35-2.7(a) would require facilities to develop and implement policies and procedures for the preparation of a memory box of keepsakes from the stillborn child for the patient. Proposed new N.J.A.C. 8:35-2.7(b) would require facilities to maintain the memory box for a period of one year, if the patient elects not to accept the box upon discharge, and to establish policies and procedures for contacting the patient prior to the disposal of the box after the one-year period elapses.

Proposed new N.J.A.C. 8:35-3.1 would set forth the type of data that facilities must collect on stillborn children and the manner in which facilities must submit this data to the Department.

Proposed new N.J.A.C. 8:35-3.2 would require facilities to address the importance of an autopsy, or an alternative evaluation, of the stillborn child with the patient and to create consent and declination patient forms for autopsies and alternative evaluations. Additionally, N.J.A.C. 8:35-3.2(c) requires the performance of stillborn autopsies to comply with the American College of Obstetricians and Gynecologists' (ACOG) Management of Stillbirth, ACOG Practice Bulletin, No. 102, American College of Obstetricians and Gynecologists, 2009; 113:748-61, which is incorporated into the rule, as supplemented and amended, and which sets forth general guidelines for autopsies.

Proposed new N.J.A.C. 8:35-4.1 would require facilities to allow Department staff access to the facility and facility records to conduct compliance and enforcement surveys, as well as set penalties for violation of this chapter.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Department anticipates that the proposed new rules would have a beneficial social impact. The proposed new rules would specify the minimum requirements that health care facilities providing obstetrics and newborn services must follow when a stillbirth occurs, to ensure the patient and family experiencing the stillbirth are provided

with dignified care, as well as emotional and psychological support. The proposed new rules would also create a mechanism for the Department's collection of stillbirth data from the facilities, so that it can make the data available, in a deidentified format, to the public and researchers studying risk factors and causes of stillbirths to prevent and reduce the occurrences of stillbirths.

The Department recognizes the social impact of stillbirths upon patients and their families. Specifically, a family of a stillborn child may experience feelings of loss, guilt, anger, grief, and severe mental anguish. The proposed new rules acknowledge these feelings and provide a significant positive social impact to those suffering this tremendous loss by requiring hospitals to develop and implement policies and procedures that provide for the dignified and compassionate care of a patient experiencing a stillbirth and that facilitate a family's bereavement process by providing them with necessary information, such as referrals for grief counseling services. Additionally, the rules require health care facilities to provide stillbirth data to the Department, which will be made available, in a deidentified format, to the public and researchers who are searching for ways to prevent the occurrence of stillbirth. Thus, the proposed new rules would also have a positive social impact by assisting researchers with their studies on the prevention and causes of stillbirths, which will, in turn, help prevent future families from experiencing this same grief.

Based upon the above, the Department expects that the general public would react favorably to the proposed new rules.

Economic Impact

The Department foresees minimal to no financial consequences as a result of the proposed new rules. The Department expects that the proposed new rules would not have an economic impact on the public because they would not impose any additional direct costs on the State budget. Additionally, the proposed new rules would not have an economic impact on patients as there are no fees or other financial obligations for health care facilities to impose upon their patients for the provision of the sensitive and supportive care that will be required under these new rules.

As for the facilities that would be required to comply with the new rules, they may experience a minor economic impact because the proposed new rules would require them to train their direct care staff on providing dignified support and care to the patients and families experiencing stillbirths.

The proposed new rules would also permit the Department to conduct compliance surveys, respond to complaints, and impose penalties upon a facility that is out-of-compliance with the requirements.

From the foregoing, the Department does not believe that the adoption of the proposed new rules would create a financial burden upon the Department, the health care facilities, or patients.

Federal Standards Statement

As the Department is proposing this rulemaking under the authority of the Act, and no Federal standards are involved, a Federal standards analysis is not required.

Jobs Impact

The Department does not anticipate that the proposed new rules would result in an increase or decrease in the number of jobs available in the State.

Agriculture Industry Impact

The proposed new rules would not have an impact on the agriculture industry.

Regulatory Flexibility Analysis

The vast majority of in-State births take place in licensed general hospitals, none of which are a “small business” within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Birth centers would be considered small businesses, but as the Department is imposing these requirements pursuant to the statutory requirements set forth in the Act, which apply to all health care facilities providing obstetrics and newborn services, the Department does not have the discretion to propose lesser standards for birth centers. Moreover, no lesser requirements or exceptions can be provided based upon business size in the interest of public health and quality of care. The reporting, recordkeeping, and compliance requirements are set forth in the Summary above.

Housing Affordability Impact Analysis

The proposed new rules would have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the proposed new rules would evoke a change in the average costs associated with housing because the new rules only pertain to the Act.

Smart Growth Development Impact Analysis

The proposed new rules would have an insignificant impact on smart growth and there is an extreme unlikelihood that the proposed new rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the new rules only pertain to the Act.

Full text of the proposed new rules follows:

CHAPTER 35

RULES IMPLEMENTING THE AUTUMN JOY STILLBIRTH RESEARCH AND DIGNITY

ACT

SUBCHAPTER 1. SCOPE AND PURPOSE

8:35-1.1 Scope

The rules in this chapter apply to all health care facilities providing birthing services and newborn care services.

8:35-1.2 Purpose

The purpose of this chapter is to effectuate the intent of N.J.S.A. 26:8-40.27 et seq., which is to ensure the dignified and sensitive management of each stillbirth and of the family's grieving process, as well as to facilitate the collection of data regarding stillbirths occurring in this State with the goal of providing the data, in a de-identified format, to the public and researchers studying ways to prevent and reduce the incidence of stillbirths.

8:35-1.3 Definitions

The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Alternative evaluation” means the postmortem examination of a stillborn child that is an alternative to a complete autopsy and includes a placental examination, external examination, selected biopsies, X-rays, MRI, and ultrasound, as determined

appropriate by the pathologist performing the evaluation and the consenting parents of the stillborn child.

“American College of Obstetricians and Gynecologists” means the American College of Obstetricians and Gynecologists located at 409 12th Street SW, Washington, DC 20024-2188, mailing address: PO Box 70620, Washington, DC 20024-9998, telephone (800) 673-8444 or (202) 638-5577, website www.acog.org.

“Autopsy” means the postmortem examination of a stillborn child that includes the weight of the stillborn child and placenta, head circumference, length of the stillborn child, foot length if stillbirth occurred before 23 weeks of gestation, and notation of any dysmorphic feature; photograph of the whole body, frontal and profile of face, extremities and palms, close-up of any specific abnormalities; examination of the placenta and umbilical cord; and gross and microscopic examination of membranes and umbilical cord, as determined appropriate by the pathologist performing the autopsy and the consenting parents of the stillborn child.

“Bereavement checklist” means a checklist containing information that is to be collected from the family after a stillbirth has occurred, as set forth in N.J.A.C. 8:35-2.4, and is used by the facility to assist the patient and the family with bereavement.

“Certificate of birth resulting in stillbirth” means a birth certificate issued for a stillborn child, pursuant to N.J.S.A. 26:8-37 and N.J.A.C. 8:2-1.3(a).

"Department" means the New Jersey Department of Health.

“Direct care staff” means facility staff who provide services to a patient that require interaction between the staff member and the patient. Examples include, but are not limited to, physicians, physicians’ assistants, professional nurses, midwives,

psychologists, and social workers who provide services by communicating directly with the patient.

“Electronic Fetal Death Record Number” means the unique numerical identifier assigned to each fetal death registered in the Department’s Office of Vital Statistics and Registry’s vital information platform.

“Facility” means a hospital licensed pursuant to N.J.A.C. 8:43G that provides obstetric services or a birth center licensed pursuant to N.J.A.C. 8:43A that provides birthing and newborn care services.

“Fetal death certificate” means the death certificate prepared for a stillborn child, as required by N.J.S.A. 26:6-11 and 26:8-37.a, and submitted to the Department’s Office of Vital Statistics and Registry through its vital information platform.

“Fetal death evaluation protocol” means the process that a facility shall follow for collecting and reporting data to the Department that is relevant to each stillbirth, as set forth in N.J.S.A. 26:8-40.29 and in accordance with the requirements of N.J.A.C. 8:35-3.1 and 3.2.

“Memory box” means a box containing keepsakes from a stillbirth, which may include a record of the stillborn child’s weight and measurements, keepsake “Certificate of Life” that may include the child’s name and birth date, as well as family members and other vital information, handprints or footprints either with an ink pad or plaster if available, items used in the child’s care, such as tape measure, identification bracelets, clothing and toiletries, lock of hair, when possible, and with the permission of the patient, photographs.

“Midwife” means an individual who is licensed by the New Jersey State Board of Medical Examiners to practice midwifery in the State of New Jersey, in accordance with N.J.S.A. 45:10-1 et seq.

“One-on-one nursing care” means nursing services that are provided to a patient by one professional nurse assigned to that patient for the duration of each nursing shift. The assigned professional nurse may also have additional duties and responsibilities during his or her shift.

“Patient” means a woman who has given birth to a stillborn child.

“Physician” means an individual who is licensed by the New Jersey State Board of Medical Examiners to practice medicine in the State of New Jersey, in accordance with N.J.S.A. 45:9-1 et seq.

“Physician assistant” means an individual who is licensed by the New Jersey State Board of Medical Examiners to practice as a physician assistant, in accordance with N.J.S.A. 45:9-27.10 et seq.

“Professional nurse” means an individual who is licensed by the New Jersey State Board of Nursing to practice professional nursing, in accordance with N.J.S.A. 45:11-26 et seq.

“Psychologist” means an individual who is licensed by the State Board of Psychological Examiners to provide professional psychological services, in accordance with N.J.S.A. 45:14B-1 et seq.

“Social worker” means an individual who is certified or licensed by the State Board of Social Work Examiners to practice social work, in accordance with N.J.S.A. 45:15BB-1 et seq.

“Stillbirth” or “stillborn child” means an unintended fetal death that:

1. Occurs after 20 weeks of pregnancy; or
2. Involves a fetus weighing 350 or more grams.

“Stillbirth informational pamphlet” means a pamphlet containing information and available resources for parents and family members suffering a stillbirth, in accordance with the requirements of N.J.A.C. 8:35-2.5.

SUBCHAPTER 2. POLICIES AND PROCEDURES

8:35-2.1 Policies and procedures

(a) A facility shall develop, implement, and review, at least annually, a stillbirth policies and procedures manual.

(b) Each review of the manual shall be documented, and the manual shall be available in the facility and provided to representatives of the Department upon request.

(c) The manual shall include, at a minimum:

1. The policies and procedures for physician responsibilities required under N.J.A.C. 8:35-2.2;

2. The policies and procedures for direct care staff training required under N.J.A.C. 8:35-2.3;

3. The bereavement checklist required under N.J.A.C. 8:35-2.4;

4. The stillbirth informational pamphlet required under N.J.A.C. 8:35-2.5;

5. The policies and procedures for patient support required under N.J.A.C. 8:35-2.6; and

6. The policies and procedures for the memory box required under N.J.A.C. 8:35-2.7.

8:35-2.2 Physician responsibilities

(a) A facility shall establish and implement policies and procedures for the assignment of responsibilities to one primary physician when a stillbirth occurs.

These responsibilities shall include, at a minimum:

1. Coordinating staff assisting with labor, delivery, and postmortem procedures;
2. Communicating a description of the condition of the stillborn child to the patient and family in order to prepare them for viewing the stillborn child, if they so choose;
3. Addressing the issue of an autopsy with the patient and other parent, as set forth at N.J.A.C. 8:35-3.2; and
4. Advising the patient that a midwife or other health care professional that provided her with care during the pregnancy may be present during any discussions with the physician.

8:35-2.3 Training for direct care staff

(a) A facility shall establish and implement policies and procedures for the training of all direct care staff who may provide care to a patient who has experienced a stillbirth. The training policies and procedures shall address, at a minimum:

1. Effective communication skills to ensure that information regarding the stillbirth is delivered to the patient and family in a sensitive manner, including the appropriate and sensitive delivery of the following information:

i. What to expect when delivering a stillborn child;

ii. The availability of grief counseling;

iii. The opportunity to develop a plan of care that meets the patient and family's social, religious, and cultural needs; and

iv. The importance of an autopsy and thorough evaluation of a stillborn child to facilitate research into the potential causes of stillbirths;

2. Bereavement education regarding the grieving process associated with stillbirths; and

3. Cultural, spiritual, and religious awareness and education regarding stillbirths.

(b) The facility shall document the training provided to each direct care staff member in the staff member's personnel file.

1. The direct care staff shall receive training upon hire and on an annual basis thereafter, or more frequently as necessary.

8:35-2.4 Requirements for bereavement checklist

(a) A facility shall develop and implement a bereavement checklist to assist the facility with obtaining information from the patient and family of a stillborn child that is needed for the facility to aid the patient and family with the grieving process.

1. The checklist shall be available to all direct care staff members and shall include at least the following information:

- i. The stillborn child's name, if the child was named by the parent(s);
- ii. The date and time of birth;
- iii. The date the Fetal Death Certificate was prepared;
- iv. The gender of the stillborn child;
- v. The gestational age of the stillborn child;
- vi. The number of living children the parents of the stillborn child have;
- vii. The contents of the memory box;
- viii. Whether the parents requested a blessing or baptism and, if so, what ceremony was performed and by whom;
- ix. Whether the parents suffered a previous loss of a stillborn child;
- x. The name and address of the patient's primary support person;
- xi. Whether the parents requested a certificate of birth resulting in stillbirth;
- xii. Whether the patient would like to include other family members, including siblings of the stillborn and visitors of their choosing, in postmortem activities; and

xiii. Confirmation that the stillbirth information pamphlet required under N.J.A.C. 8:35-2.5 was provided to the family.

(b) A copy of the completed bereavement checklist shall be maintained as part of the patient's medical record.

8:35-2.5 Stillbirth informational pamphlet

(a) A facility shall develop a stillbirth informational pamphlet for distribution to the patient and family that contains materials that will assist with the bereavement process and disposition of the remains of a stillborn child. The stillbirth information pamphlet shall address, but is not limited to:

1. What to expect when delivering a stillborn child;
2. The availability of a blessing or baptism, including contact information for available clergy;
3. The opportunity for the patient and family to meet with the facility chaplain or other individual from the family's religious community;
4. Funeral and cremation options, including contact information for local funeral directors;
5. The opportunity to have the patient and family spend time with and hold the stillborn child without time restrictions;
6. The availability of and contact information for community support groups and grief counselors; and
7. How to obtain a certificate of birth resulting in stillbirth, if the parents so desire.

8:35-2.6 Patient and family support

(a) A facility shall establish and implement policies and procedures for supporting the patient and family before, during, and after a stillbirth. The policies and procedures shall address, at a minimum:

1. Guidelines to assess a family's awareness and knowledge regarding the stillbirth process;

2. The provision of one-on-one nursing care for the duration of the patient's stay at the facility;

3. Protocols to ensure coordinated visits to the patient and family by facility staff trained to:

i. Address the psychosocial needs of a family experiencing a stillbirth;

ii. Provide guidance in the bereavement process; and

iii. Assist with completing any forms required in connection with the stillbirth, including the form to consent to an autopsy or alternative evaluation of the stillborn child; and

4. The provision of psychological and emotional support by direct care staff to the patient and family following a stillbirth, which support shall include, at a minimum:

i. Referring to the stillborn child by name (for a named child), if appropriate; and

ii. Offering the family the opportunity to:

(1) Cut or assist in cutting the umbilical cord;

(2) Obtain a blessing, baptism, or other appropriate religious observance to accommodate the family's spiritual needs;

(3) Meet with the facility chaplain or other individual from the family's religious community; and

(4) Prepare a memory box as required by N.J.A.C. 8:35-2.7.

iii. Providing the patient and family with the opportunity to receive and hold the stillborn child in private without time restrictions.

(1) During this time, the patient may bathe and clothe the stillborn child using clothing and supplies of their own or those provided by the facility.

8:35-2.7 Memory box

(a) A facility shall develop and implement policies and procedures to ensure that a memory box is prepared for a patient who experiences a stillbirth and provided to the patient upon discharge.

(b) In the event the patient elects not to accept the memory box upon discharge, the facility shall retain the memory box for a minimum of one year from the date of the patient's discharge. Prior to disposing of the box upon the expiration of the one-year-retention period, the facility shall:

1. Attempt to contact the patient by telephone within 30 days of the end of the one-year-retention period to determine whether the patient wishes to receive the memory box.

i. If the patient is reached by telephone, then her acceptance or declination of the memory box shall be recorded in her medical record.

2. Contact the patient by certified mail, if contact is not made by telephone, advising her that she has 30 days from the date of the letter to inform the facility as to whether she wishes to obtain the memory box and that failure to advise the facility of her wishes during this time period may result in the disposal of the box.

(c) All contacts and attempts to contact the patient required under (b) above shall be documented in the patient's medical record prior to the facility disposing of the memory box.

SUBCHAPTER 3. FETAL DEATH DATA COLLECTION AND AUTOPSY

8:35-3.1 Fetal death data collection

(a) A facility shall use the fetal death certificate as its fetal death evaluation protocol for the collection and reporting of the stillbirth data set forth in N.J.S.A. 26:8-40.29.a.

(b) For the fetal death evaluation protocol for autopsies and alternative evaluations, a facility shall electronically submit the reports compiled from these postmortem examinations to the Department.

1. A facility shall submit each written report compiled from an autopsy and alternative evaluation to the Department at stillbirthregistry@doh.nj.gov within 30 days of receipt of the report.

2. The written reports must contain the unique Electronic Fetal Death Record Number assigned to the Fetal Death Certificate.

3. The facility shall redact all personally identifying information from the autopsy and alternative evaluation reports submitted to the Department.

8:35-3.2 Autopsy and alternative evaluation

(a) The facility shall provide postmortem services for stillborn children in accordance with N.J.A.C. 8:43G-25.

(b) The primary physician shall address the following with the patient:

1. The availability of a complete autopsy or an alternative evaluation of the child and what each postmortem examination entails;

2. The importance of an autopsy for the family;

3. The significance autopsy findings may have on the patient's future pregnancies; and

4. The significance that data from an autopsy may have on other families through research.

(c) If the parents of a stillborn child consent to an autopsy, the autopsy shall meet the standards established by the American College of Obstetricians and Gynecologists or its successor in accordance with the Management of Stillbirth, ACOG Practice Bulletin, No. 102, American College of Obstetricians and Gynecologists, 2009; 113:748-61, incorporated herein by reference, as supplemented and amended.

1. The results of the autopsy shall be documented in the patient's medical record.

(d) If the parents of a stillborn child do not consent to an autopsy, they shall be offered an alternative evaluation and, if they consent to such an evaluation, the evaluation shall meet the standards established by the American College of Obstetricians and Gynecologists or its successor in accordance with the Management of Stillbirth, ACOG Practice Bulletin, No. 102, American College of Obstetricians and Gynecologists, 2009; 113:748-61.

1. The results of the alternative evaluation shall be documented in the patient's medical record.

(e) The facility shall develop a declination form for the patient to sign when she declines an autopsy and alternative evaluation.

1. A copy of the executed declination form shall be filed with the patient's medical record.

(f) The facility shall develop a consent form for both autopsies and alternative evaluations, which must be signed by the patient prior to the performance of the postmortem examination.

1. The forms must set forth the details of the autopsy or alternative evaluation that will be performed on the stillborn child.

2. The consent forms must contain a notice that all reports generated as a result of the postmortem procedures will be reported to the Department, in a de-identified format, and will be made available to the public and researchers.

SUBCHAPTER 4. ENFORCEMENT

8:35-4.1 Enforcement

(a) Authorized Department staff may conduct compliance and enforcement survey visits at a facility at any time. Such visits may include, but shall not be limited to, the review of all facility documents and patient records, as well as conferences with patients, responsible parties of patients, and facility staff.

(b) Penalties for violations of this chapter shall be assessed pursuant to N.J.S.A. 26:8-69.